Contents

Reviews

The Effect of Information and Communication Technology and Social Networking Site Use on Older People's Well-Being in Relation to Loneliness: Review of Experimental Studies (e23588)
Georgia Casanova, Daniele Zaccaria, Elena Rolandi, Antonio Guaita ................................................................. 7

Compliance With Mobile Ecological Momentary Assessment of Self-Reported Health-Related Behaviors and Psychological Constructs in Adults: Systematic Review and Meta-analysis (e17023)
Marie Williams, Hayley Lewthwaite, François Fraysse, Alexandra Gajewksa, Jordan Ignatavicius, Katia Ferrar. ................................................................. 22

Acceptance and Use of Home-Based Electronic Symptom Self-Reporting Systems in Patients With Cancer: Systematic Review (e24638)
Younmin Cho, Haiting Zhang, Marcelline Harris, Yang Gong, Ellen Smith, Yun Jiang ................................................................. 41

eHealth Applications to Support Independent Living of Older Persons: Scoping Review of Costs and Benefits Identified in Economic Evaluations (e24363)
Sandra Süß, Hilco van Elten, Marjan Askari, Anne Weggelaar-Jansen, Robbert Huijsman ................................................................. 410

Digital Health Solutions to Control the COVID-19 Pandemic in Countries With High Disease Prevalence: Literature Review (e19473)
Sharareh R Niakan Kalhori, Kambiz Bahadjinbeigi, Kolsoum Delidar, Marsa Gholamzadeh, Sadriej Havasmael-Gohari, Seyed Ayyoubzadeh ................................................................. 6

Evidence Synthesis of Digital Interventions to Mitigate the Negative Impact of the COVID-19 Pandemic on Public Mental Health: Rapid Meta-review (e23365)
Christian Rauschenberg, Anita Schick, Dusan Hirjak, Andreas Seidler, Isabell Paetzold, Christian Apelbacher, Steffi Riedel-Heller, Ulrich Reininghaus ................................................................. 682

Viewpoints

Guidelines for Conducting Virtual Cognitive Interviews During a Pandemic (e25173)
James Shepperd, Gabrielle Pogge, Jean Hunleth, Sienna Ruiz, Erika Waters ................................................................. 53

Effort-Optimized Intervention Model: Framework for Building and Analyzing Digital Interventions That Require Minimal Effort for Health-Related Gains (e24905)
Amit Baumel, Frederick Muench ................................................................. 424
What Every Reader Should Know About Studies Using Electronic Health Record Data but May Be Afraid to Ask (e22219)

Adoption of COVID-19 Contact Tracing Apps: A Balance Between Privacy and Effectiveness (e25726)
Emily Seto, Priyanka Challa, Patrick Ware.

Clinical Trial Data Sharing for COVID-19–Related Research (e26718)
Louis Dron, Alison Dillman, Michael Zoratti, Jonas Haggstrom, Edward Mills, Jay Park.

Artificial Intelligence–Aided Precision Medicine for COVID-19: Strategic Areas of Research and Development (e22453)
Enrico Santus, Nicola Marino, Davide Cirillo, Emmanuele Chersoni, Arnau Montagud, Antonella Santuccione Chadha, Alfonso Valencia, Kevin Hughes, Charlotte Lindvall.

Original Papers

A Novel Mobile App (Heali) for Disease Treatment in Participants With Irritable Bowel Syndrome: Randomized Controlled Pilot Trial (e24134)
Aaron Rafferty, Rick Hall, Carol Johnston.

Development of a Web-Based Mindfulness Program for People With Multiple Sclerosis: Qualitative Co-Design Study (e19309)
Amy-Lee Sesel, Louise Sharpe, Heidi Beadnell, Michael Barnett, Marianna Szabo, Sharon Naismith.

Evaluating a Hybrid Web-Based Training Program for Panic Disorder and Agoraphobia: Randomized Controlled Trial (e20829)
Lara Ebenfeld, Dirk Lehr, David Ebert, Stefan Kleine Stegemann, Heleen Riper, Burkhardt Funk, Matthias Berking.

Association of Spontaneous and Induced Self-Affirmation With Smoking Cessation in Users of a Mobile App: Randomized Controlled Trial (e18433)
Elizabeth Seaman, Cendrine Robinson, David Crane, Jennifer Taber, Rebecca Ferrer, Peter Harris, William Klein.

Designing the Optimal Digital Health Intervention for Patients’ Use Before and After Elective Orthopedic Surgery: Qualitative Study (e25885)
Anna Robinson, Robert Slight, Andrew Husband, Sarah Slight.

Online Mindfulness-Based Cognitive Behavioral Therapy Intervention for Youth With Major Depressive Disorders: Randomized Controlled Trial (e24380)

Electronic Health Risk Behavior Screening With Integrated Feedback Among Adolescents in Primary Care: Randomized Controlled Trial (e24135)
Laura Richardson, Elizabeth Parker, Chuan Zhou, Julie Kientz, Elizabeth Ozer, Carolyn McCarty.

Risk Factors and Leadership in a Digitalized Working World and Their Effects on Employees’ Stress and Resources: Web-Based Questionnaire Study (e24906)
Anita Bregenzer, Paulino Jimenez.
An Interactive Web-Based Sexual Health Literacy Program for Safe Sex Practice for Female Chinese University Students: Multicenter Randomized Controlled Trial (e22564)
Janet Wong, Wen Zhang, Yongda Wu, Edmond Choi, Herman Lo, Wendy Wong, Jasmine Chio, Hau Tam, Fei Ngai, Marie Tarrant, Man Wang, Hextan Ngan, Daniel Fong. .................................................. 165

Health Care Students' Knowledge of and Attitudes, Beliefs, and Practices Toward the French COVID-19 App: Cross-sectional Questionnaire Study (e26399)
Ilaria Montagni, Nicolas Roussel, Rodolphe Thiébaut, Christophe Tzourio. ................................................................. 181

Investigating Associations Between Screen Time and Symptomatology in Individuals With Serious Mental Illness: Longitudinal Observational Study (e23144)
Philip Henson, Elena Rodriguez-Villa, John Torous. ........................................... 195

Cost-effectiveness of a Telemonitoring Program for Patients With Heart Failure During the COVID-19 Pandemic in Hong Kong: Model Development and Data Analysis (e26516)
Xinchang Jiang, Jiaqi Yao, Joyce You. ......................................................... 203

Opportunities and Challenges for Digital Social Prescribing in Mental Health: Questionnaire Study (e17438)
Shivani Patel, Gerry Craigen, Mariana Pinto da Costa, Becky Inkster. ................................................................. 215

Informatics Methodology Used in the Web-Based Portal of the NASCITA Cohort Study: Development and Implementation Study (e23087)
Michele Zanetti, Antonio Clavenna, Chiara Pandolfini, Claudia Pansieri, Maria Calati, Massimo Cartabia, Daniela Miglio, Maurizio Bonati. 228

Effects of Information Architecture on the Effectiveness and User Experience of Web-Based Patient Education in Middle-Aged and Older Adults: Online Randomized Experiment (e15846)
Tessa Dekkers, Marijke Melles, Stephan Vehmeijer, Huib de Ridder. ................................................................. 239

User-Centered Development of a Web Platform Supporting Community-Based Health Care Organizations for Older Persons in Need of Support: Qualitative Focus Group Study (e24006)
Verena Biehl, Heidrun Becker, Alenka Ogrin, Alenka Reissner, Johannes Burger, Andrea Glaesssel. 261

A Clinical Communication Tool (Loop) for Team-Based Care in Pediatric and Adult Care Settings: Hybrid Mixed Methods Implementation Study (e25505)
Amna Husain, Eyal Cohen, Raluca Dubrowski, Trevor Jamieson, Allison Kurahashi, Bhadra Lokuge, Adam Rapoport, Stephanie Saunders, Elaine Stasulis, Jennifer Stinson, Saranjah Subramaniam, Pete Wegier, Melanie Barwick. ................................................................. 276

Adaptation of Extended Reality Smart Glasses for Core Nursing Skill Training Among Undergraduate Nursing Students: Usability and Feasibility Study (e24313)
Sun Kim, Youngho Lee, Hyoseok Yoon, Jongmyung Choi. ................................................................. 303

Assessment of Diagnostic Competences With Standardized Patients Versus Virtual Patients: Experimental Study in the Context of History Taking (e21196)
Maximilian Fink, Victoria Reitmeier, Matthias Stadler, Matthias Siebeck, Frank Fischer, Martin Fischer. ................................................................. 315

Linguistic Analysis of Online Communication About a Novel Persecutory Belief System (Gangstalking): Mixed Methods Study (e25722)
Andrew Lustig, Gavin Brooke, Daniel Hunt. ................................................................. 330

Toward a Multivariate Prediction Model of Pharmacological Treatment for Women With Gestational Diabetes Mellitus: Algorithm Development and Validation (e21435)
Carmelo Velardo, David Clifton, Steven Hamblin, Rabia Khan, Lionel Tarassenko, Lucy Mackillop. ................................................................. 340
The Perceived Impact and Usability of a Care Management and Coordination System in Delivering Services to Vulnerable Populations: Mixed Methods Study (e24122)
Rubina Rizvi, Courtney VanHouten, Tiffani Bright, Mollie McKillop, Shira Alevy, David Brotman, Megan Sands-Lincoln, Jane Snowdon, Barbie Robinson, Carolyn Staats, Gretchen Jackson, William Kassler. 354

e-Mental Health Program Usage Patterns in Randomized Controlled Trials and in the General Public to Inform External Validity Considerations: Sample Groupings Using Cluster Analyses (e18348)
Samineh Sanatkar, Peter Baldwin, Kit Huckvale, Helen Christensen, Samuel Harvey. 364

Commencement of and Retention in Web-Based Interventions and Response to Prompts and Reminders: Longitudinal Observational Study Based on Two Randomized Controlled Trials (e24590)
Athanasios Andriopoulos, Erik Olsson, Ylva Hägg Sylven, Jonas Sjöström, Birgitta Johansson, Louise von Essen, Helena Grönqvist. 372

Classification of the Use of Online Health Information Channels and Variation in Motivations for Channel Selection: Cross-sectional Survey (e24945)
Di Zhang, Zhen Shi, Hongchao Hu, Gang Han. 384

Contribution of Free-Text Comments to the Burden of Documentation: Assessment and Analysis of Vital Sign Comments in Flowsheets (e22806)
Zhijun Yin, Yongtai Liu, Allison McCoy, Bradley Malin, Patricia Sengstack. 397

The Reliability of Remote Patient-Reported Outcome Measures via Mobile Apps to Replace Outpatient Visits After Rotator Cuff Repair Surgery: Repetitive Test-Retest Comparison Study for 1-Year Follow-up (e20989)
Taek Hong, Myung Kim, Dong Ryu, Jun Park, Gi Bae, Yoon Jeon. 437

Preferences for Artificial Intelligence Clinicians Before and During the COVID-19 Pandemic: Discrete Choice Experiment and Propensity Score Matching Study (e26997)
Taoran Liu, Winghei Tsang, Yifei Xie, Kang Tian, Fengqiu Huang, Yanhui Chen, Oiyng Lau, Guanrui Feng, Jianhao Du, Bojia Chu, Tingyu Shi, Junjie Zhao, Yiming Cai, Xueyan Hu, Babatunde Akinwumi, Jian Huang, Casper Zhang, Wai-Kit Ming. 449

Artificial Intelligence Techniques That May Be Applied to Primary Care Data to Facilitate Earlier Diagnosis of Cancer: Systematic Review (e23483)

Future Medical Artificial Intelligence Application Requirements and Expectations of Physicians in German University Hospitals: Web-Based Survey (e26646)
Oliver Maassen, Sebastian Fritsch, Julia Palm, Saskia Deflge, Julian Kunze, Gernot Marx, Morris Riedel, Andreas Schuppert, Johannes Bickenbach. 492

Natural Language Processing and Machine Learning for Identifying Incident Stroke From Electronic Health Records: Algorithm Development and Validation (e22951)
Yiqing Zhao, Sunyang Fu, Suzette Bielinski, Paul Decker, Alanna Chamberlain, Veronique Roger, Hongfang Liu, Nicholas Larson. 510

Machine Learning for Mental Health in Social Media: Bibliometric Study (e24870)
Jina Kim, Daeho Lee, Eunil Park. 520

Exploring Usage of COVID Coach, a Public Mental Health App Designed for the COVID-19 Pandemic: Evaluation of Analytics Data (e26559)
Beth Jaworski, Katherine Taylor, Kelly Ramsey, Adrienne Heinz, Sarah Steinmetz, Ian Pagano, Giovanni Moraja, Jason Owen. 552
Barriers to the Large-Scale Adoption of a COVID-19 Contact Tracing App in Germany: Survey Study (e23362)
Annelies Blom, Alexander Wenz, Carina Cornesse, Tobias Rettig, Marina Fikel, Sabine Friedel, Katja Möhring, Elias Naumann, Maximilian Reifenscheid, Ulrich Krieger. 565

Minimizing the Impact of the COVID-19 Epidemic on Oncology Clinical Trials: Retrospective Study of Beijing Cancer Hospital (e26799)
Zhiying Fu, Min Jiang, Kun Wang, Jian Li. 576

Understanding Concerns, Sentiments, and Disparities Among Population Groups During the COVID-19 Pandemic Via Twitter Data Mining: Large-scale Cross-sectional Study (e26482)
Chunyan Zhang, Songhua Xu, Zongfang Li, Shunxu Hu. 593

Comparing Public Perceptions and Preventive Behaviors During the Early Phase of the COVID-19 Pandemic in Hong Kong and the United Kingdom: Cross-sectional Survey Study (e23231)
Leigh Bowman, Kin Kwok, Rozlyn Redd, Yuan yuan Yi, Helen Ward, Wan Wei, Christina Atchison, Samuel Wong. 609

A Comprehensive Overview of the COVID-19 Literature: Machine Learning–Based Bibliometric Analysis (e23703)
Alaa Abd-Alrazaq, Jens Schneider, Borbala Mifsud, Tanvir Alam, Mowafa Househ, Mounir Hamdi, Zubair Shah. 623

Virtual Health Care for Community Management of Patients With COVID-19 in Australia: Observational Cohort Study (e21064)
Owen Hutchings, Cassandra Dearing, Dianna Jagers, Miranda Shaw, Freya Raffan, Aaron Jones, Richard Taggart, Tim Sinclair, Teresa Anderson, Angus Ritchie. 642

Behavioral Intention to Receive a COVID-19 Vaccination Among Chinese Factory Workers: Cross-sectional Online Survey (e24673)
Ke Zhang, Yuan Fang, He Cao, Hongbiao Chen, Tian Hu, Yaqi Chen, Xiaofeng Zhou, Zixin Wang. 653

Factors Affecting Public Adoption of COVID-19 Prevention and Treatment Information During an Infodemic: Cross-sectional Survey Study (e23097)
Yangyang Han, Binshan Jiang, Rui Guo. 696

Antecedents of Individuals’ Concerns Regarding Hospital Hygiene and Surgery Postponement During the COVID-19 Pandemic: Cross-sectional, Web-Based Survey Study (e24804)
Thomas Ostermann, Julia Gampe, Jan Röder, Theda Radtke. 714

Examining Tweet Content and Engagement of Canadian Public Health Agencies and Decision Makers During COVID-19: Mixed Methods Analysis (e24883)
Catherine Slavik, Charlotte Buttle, Shelby Sturrock, J Darlington, Niko Yiannakoulias. 726

Effectiveness of Interactive Tools in Online Health Care Communities: Social Exchange Theory Perspective (e21892)
Dixuan Ren, Baolong Ma. 749

A Self-Assessment Web-Based App to Assess Trends of the COVID-19 Pandemic in France: Observational Study (e26182)
Fabrice Denis, Arnaud Fontanet, Yann-Mael Le Douarin, Florian Le Goff, Stephan Jeanneau, François-Xavier Leschure. 757

Benchmarking Triage Capability of Symptom Checkers Against That of Medical Laypersons: Survey Study (e24475)
Malte Schmieding, Rudolf Mørgel, Maike Schmieding, Markus Feufel, Felix Balzer. 780
Letter to the Editor

Practical Considerations and Successful Implementation of Vital Signs Monitoring. Comment on “Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial” (e14042)

Caoimhe Walsh, David Zargaran, Nikhil Patel, Amelia White, Foteini Koumpa, Ravina Tanna, Muhammad Ashraf. .......................... 546

Corrigenda and Addendas

Correction: Using the Patient Portal Sexual Health Instrument in Surveys and Patient Questionnaires Among Sexual Minority Men in the United States: Cross-sectional Psychometric Validation Study (e28358)
Kevon-Mark Jackman, Jeremy Kane, Hadi Kharrazi, Renee Johnson, Carl Latkin. ................................................................. 549

Correction: Measurement of Digital Literacy Among Older Adults: Systematic Review (e28211)
Sarah Oh, Kyung-A Kim, Minsu Kim, Jaeuk Oh, Sang Chu, JiYeon Choi. ................................................................. 551
The Effect of Information and Communication Technology and Social Networking Site Use on Older People’s Well-Being in Relation to Loneliness: Review of Experimental Studies

Georgia Casanova1, MSc; Daniele Zaccaria2, PhD; Elena Rolandi3, MSc; Antonio Guaita1, MD

1Centre for Socio-Economic Research on Ageing, National Institute of Health & Science on Ageing, Istituto di Ricovero e Cura a Carattere Scientifico, Ancona, Italy
2Centre of Competence on Ageing, Department of Business Economics, Health and Social Care, University of Applied Sciences and Arts of Southern Switzerland, Manno, Switzerland
3Golgi Cenci Foundation, Abbiategrasso, Italy

Corresponding Author:
Georgia Casanova, MSc
Centre for Socio-Economic Research on Ageing
National Institute of Health & Science on Ageing
Istituto di Ricovero e Cura a Carattere Scientifico
Via Santa Margherita 5
Ancona
Italy
Phone: 39 347 0836007
Email: g.casanova@inrca.it

Abstract

Background: In the last decades, the relationship between social networking sites (SNSs) and older people’s loneliness is gaining specific relevance. Studies in this field are often based on qualitative methods to study in-depth self-perceived issues, including loneliness and well-being, or quantitative surveys to report the links between information and communication technologies (ICTs) and older people’s well-being or loneliness. However, these nonexperimental methods are unable to deeply analyze the causal relationship. Moreover, the research on older people’s SNS use is still scant, especially regarding its impact on health and well-being. In recent years, the existing review studies have separately focused their attention on loneliness and social isolation of older people or on the use of ICTs and SNSs in elderly populations without addressing the relationship between the former and the latter. This thorough qualitative review provides an analysis of research performed using an experimental or quasi-experimental design that investigates the causal effect of ICT and SNS use on elderly people’s well-being related to loneliness.

Objective: The aims of this review are to contrast and compare research designs (sampling and recruitment, evaluation tools, interventions) and the findings of these studies and highlight their limitations.

Methods: Using an approach that integrates the methodological framework for scoping studies and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for systematic reviews, we identified 11 articles that met our inclusion criteria. A thematic and content analysis was performed based on the ex post categorization of the data on the selected studies, and the data were summarized in tables.

Results: The analysis of the selected articles showed that: (1) ICT use is positively but weakly related to the different measures of older people’s well-being and loneliness, (2) overall, the studies under review lack a sound experimental design, (3) the main limitations of these studies lie in the lack of rigor in the sampling method and in the recruitment strategy.

Conclusions: The analysis of the reviewed studies confirms the existence of a beneficial effect of ICT use on the well-being of older people in terms of reduced loneliness. However, the causal relationship is often found to be weak. This review highlights the need to study these issues further with adequate methodological rigor.

(J Med Internet Res 2021;23(3):e23588) doi:10.2196/23588

KEYWORDS
review; aging; loneliness; older people’s well-being; ICTs; social network sites
Introduction

The percentage of people aged 65 years and older in the world will rise to 24% in 2030 [1]. Literature underlines how loneliness is one of the main risk factors that have negative effects on seniors’ health [2]. Loneliness is usually defined as an undesirable subjective experience related to unfulfilled intimate and social needs [3]. In Europe, between 10% and 20% of elderly people in Western and Northern Europe and 30% to 55% in Eastern Europe declared feeling lonely [4]. Many interventions have been adopted to reduce loneliness and increase the well-being of elders. Among them, information and communication technologies (ICTs) have been used to help older adults cope with loneliness [5]. The use of ICTs has grown significantly since the 2000s [6]. ICTs are those technologies that can be used to interlink information technology devices such as PCs with communication technologies such as telephones and their telecommunication networks. Michiels and Van Crowder [7] reported almost 20 years ago how ICTs are an expanding assembly of technologies. In the last decades, PCs, laptops, smartphones, tablets with email, and the internet are examples of ICTs able to connect people and support their social life [8]. These types of ICTs, intended to alleviate loneliness and social isolation among older people, are considered significant in expanding and sustaining social contact and improving emotional well-being [9] and are the focus of this review. Recently, experts’ attention has also been drawn to the role of technologies aimed at promoting social relationships, such as social networking sites (SNSs) [10]. Boyd et al [11] defined the SNSs as web-based services that allow individuals to (1) construct a public or semipublic profile within a bounded system, (2) articulate a list of other users with whom they share a connection, and (3) view and traverse their list of connections and those made by others within the system. At the moment, Facebook, Instagram, LinkedIn, and Twitter are the most popular SNSs. In particular, Facebook seems to be the most used by older people [12]. The relationship between SNSs and loneliness in older people is gaining specific relevance. However, research on older people’s SNS use is still scant, especially regarding their impact on health and well-being. Eggermont and colleagues [13] report that older people consider SNSs useful tools to contrast loneliness, one that should integrate (but not replace) face-to-face contacts. Gibson et al [14] have found that older adults are concerned about privacy issues. Some studies also examine older people’s characteristics that favor SNS adoption. For example, Liu et al [15] report that, in the United States, elderly users of SNSs are more likely to be younger, female, and widowed. Studies in this field are often based on qualitative methods, because they allow studying in-depth self-perceived issues, including loneliness and well-being, but to a lesser extent the causal relationship between them [16]. Among quantitative studies, the survey analysis is most used to report the links between ICTs and older people’s well-being [17] or loneliness [18]. Despite the increased attention gained by these studies, the survey—often applied to cross-sectional analysis—does not allow the detection of a causal relationship. In 2013, Nef et al [12] underlined a shortage of experimental research on the relationship between ICT use and older adult well-being, considered more adequate to analyze the causal relationship between phenomena [19].

In recent years, review studies have focused on loneliness and social isolation of older people [20,21] or on the use of ICTs and SNSs in elderly populations without tackling the relationship between the former issue and the latter [12,22]. One of the few literature reviews focused on the relationship between ICT use and loneliness in older people underlines how this research field involves different theoretical frames from various scientific fields [22]. The existing quantitative experimental studies on these issues have significant limitations that may hamper the relevance of the research findings, such as small and not representative samples [23].

The purpose of this review is to contribute to the literature debate on the effect of SNS use on older people’s well-being with specific attention on loneliness, focusing on experimental and quasi-experimental studies. The main aims are to examine and compare the selected studies, analyzing their protocols (sampling, evaluation tools, and treatments) and their findings to identify strengths and limitations and support the development of further similar studies. According to the aims, we present a thorough qualitative review of experimental studies in this field.

Methods

Review Procedures

To ensure a high quality of reporting, this study used the 5 stages for reviews proposed by Arksey and O’Malley [24]: (1) identification of research questions; (2) identification of relevant studies; (3) selection of studies; (4) charting the data; and (5) collating, summarizing, and reporting the results. Taking into account the low spread of the analyzed studies, we decided to improve the method path by the integration of stages 2 and 3 with the 4 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) stages: identification, screening, eligibility, and inclusion [25]. Figure 1 shows the complete method implemented in this review. The combination of these methods ensures the review will stay linear and focused, as proposed by Arksey and O’Malley [24], and limits losing useful papers on the topic thanks to PRISMA approach.
Identification of Research Questions and Selection Process

In the first stage, we identified 3 research questions: (1) What are the main methodological characteristics of the study designs? (2) What causal evidence exists on the relationships between ICTs, SNSs, and well-being in older people, particularly as regards loneliness? (3) What are the main studies’ declared limitations?

In March 2020 for stages 2 and 3, we performed a comprehensive literature search in the main search engines used in health and social sciences: Scopus, PubMed, Web of Science, and Sociological Abstracts. The search was based on a set of keywords (“older people,” “elderly,” “loneliness,” “well-being,” “information and communication technologies,” “social networks,” and “Facebook”) clustered in the search process to enhance the relationship between web-based communication technologies, isolation, and loneliness conditions of older people, as detailed in Figure 1. Facebook has been included in the set of keywords because, as specified in the introduction, this SNS is most used by older people. The search was conducted in English. We found 204 records, without duplicates, published from 2002 to 2019, that met the following eligibility criteria: (1) study uses experimental or quasi-experimental design; (2) study is based on pre-post controlled trials; (3) loneliness and/or well-being are outcomes; and (4) the target population is people aged over 60 years, considered the threshold for the aging process [26]. Two independent researchers (GC, DZ) screened the identified studies for their relevance based on title and abstract, and 185 studies were excluded: records not pertinent (n=69); qualitative studies (n=67); loneliness and well-being were not considered as the outcome (n=23); methodological papers (n=6); literature reviews (n=13); and target population includes people under 60 years (n=7). A total of 19 articles met the inclusion criteria.

Data Extraction, Data Synthesis, and Analysis

In stage 4, we organized the materials to be analyzed. First, we ordered the collected papers by date from the oldest to the newest [27-37]. Moreover, we identified the review’s framework and related categories to provide our analysis (detailed in Table 1). Two macro areas of analysis have been identified: main characteristics of the protocols and main contents of the studies. For both of them, we identified a set of specific categories of analysis, one or more related main questions, and the items to collect. In stage 5, two researchers (GC, DZ) independently extracted the items based on the identified categories. To collect similar information on all studies, we performed a thematic and content analysis [38] based on the ex-post categorization of variables (eg, specific items) [39] to (1) detect the presence of variables in each selected study, (2) identify different modalities of selected variables (eg, tools used or different choices on sampling process), and (3) make them easy to read based on classification and summarization of specific contents. Last, to answer our research questions, the first author completed the data analysis using standardized self-made forms corresponding to Tables 2-4.
Table 1. Frameworks of analysis: general items, main questions, and detected items by analysis macro areas.

<table>
<thead>
<tr>
<th>Categories and general items</th>
<th>Main questions</th>
<th>Detected items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keywords</td>
<td>• What are the items of study declared by authors?</td>
<td>• List of keywords</td>
</tr>
<tr>
<td>Methods</td>
<td>• Is the study experimental?</td>
<td>• Presence of randomized trial study</td>
</tr>
<tr>
<td>Sample</td>
<td>• What is the dimension of the sample?</td>
<td>• Number of participants in assessments</td>
</tr>
<tr>
<td>Population</td>
<td>• What are the age characteristics of population?</td>
<td>• Range of age group</td>
</tr>
<tr>
<td></td>
<td>• Mean age</td>
<td></td>
</tr>
<tr>
<td>Selection criteria</td>
<td>• What are the applied selection criteria?</td>
<td>• Place of living</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Previous experience with ICT(^a) use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Healthy conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Level of social engagement</td>
</tr>
<tr>
<td>Recruitment</td>
<td>• What is the recruitment strategy?</td>
<td>• Place of recruitment</td>
</tr>
<tr>
<td>Control group</td>
<td>• How many control groups are included in the protocol?</td>
<td>• Presence of control group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Typologies of control groups</td>
</tr>
<tr>
<td>Assessments</td>
<td>• How many assessments are included?</td>
<td>• Number and timing of follow-up evaluations</td>
</tr>
<tr>
<td>Intervention</td>
<td>• How long is the intervention?</td>
<td>• Number of intervention weeks or years</td>
</tr>
<tr>
<td></td>
<td>• What activities are performed in the intervention?</td>
<td>• Presence of training course and training size</td>
</tr>
<tr>
<td><strong>Contents of studies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study issues</td>
<td>• Is the study focused on SNS(^b) use?</td>
<td>• Presence of SNS focus</td>
</tr>
<tr>
<td>Outcomes</td>
<td>• What are the outcomes included in the study?</td>
<td>• List of outcomes</td>
</tr>
<tr>
<td></td>
<td>• Is loneliness one of them?</td>
<td>• Presence of loneliness as an outcome</td>
</tr>
<tr>
<td>Evaluation tools</td>
<td>• What are the evaluation tools used in the study?</td>
<td>• Presence of validated scales</td>
</tr>
<tr>
<td></td>
<td>• Which validated scales have been used?</td>
<td>• Presence of self-made instruments</td>
</tr>
<tr>
<td>Main results</td>
<td>• What are the main results of study?</td>
<td>• Summarize the results</td>
</tr>
<tr>
<td>Declared limitations</td>
<td>• What are the main limitations of study?</td>
<td>• Summarize the limitation</td>
</tr>
</tbody>
</table>

\(^a\)ICT: information and communication technology.

\(^b\)SNS: social networking site.
Table 2. Keywords and protocol characteristics.

<table>
<thead>
<tr>
<th>Author name and year</th>
<th>Keywords</th>
<th>Randomized trial</th>
<th>Sample size, baseline (f/u(^b))</th>
<th>Age range (mean)</th>
<th>Recruitment in care home</th>
<th>Control group</th>
<th>&gt;1 f/u</th>
<th>Length of training (intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White et al (2002) [27]</td>
<td>Older people; social isolation; internet; psychosocial impact</td>
<td>(\neq)</td>
<td>100 (84)</td>
<td>59-83 (71.5)</td>
<td>*</td>
<td>P(^c)</td>
<td>no</td>
<td>9 h (20 w)</td>
</tr>
<tr>
<td>Fokkema &amp; Knipscheer (2007) [28]</td>
<td>N/A(^d)</td>
<td>no</td>
<td>21 (12)</td>
<td>66+ (N/A)</td>
<td>no</td>
<td>V(^e)</td>
<td>*</td>
<td>10 h (3 yrs)</td>
</tr>
<tr>
<td>Shapira et al (2007) [29]</td>
<td>Internet; senior well-being; personal sense of empowerment; Israel</td>
<td>no</td>
<td>46 (39)</td>
<td>70-93 (81.2)</td>
<td>*</td>
<td>A(^f)</td>
<td>no</td>
<td>20 h (15 w)</td>
</tr>
<tr>
<td>Siegers et al (2008) [30]</td>
<td>Computer use; internet; well-being</td>
<td>*</td>
<td>236 (211)</td>
<td>64-75 (N/A)</td>
<td>no</td>
<td>P,P(^g)</td>
<td>*</td>
<td>4 h (54 w)</td>
</tr>
<tr>
<td>Woodward et al (2010) [31]</td>
<td>Gerontology; information and communication technologies; older adults; computer training; social support; mental health</td>
<td>*</td>
<td>83 (83)</td>
<td>60-89 (71.8)</td>
<td>no</td>
<td>P(^h)</td>
<td>*</td>
<td>24 h (24 w)</td>
</tr>
<tr>
<td>Blažun et al (2012) [32]</td>
<td>Older people; loneliness; computer training course; socialization; health; well-being</td>
<td>no</td>
<td>58 (45)</td>
<td>58-93 (72.9)</td>
<td>*</td>
<td>no</td>
<td>no</td>
<td>4 h (3 w)</td>
</tr>
<tr>
<td>Cotten et al (2012) [33]</td>
<td>Computers; internet; loneliness; social isolation; older adults; independent living; assistant living facilities</td>
<td>*</td>
<td>205 (205)</td>
<td>N/A (82.7)</td>
<td>*</td>
<td>A,P(^i)</td>
<td>*</td>
<td>N/A (8 w)</td>
</tr>
<tr>
<td>Myhre et al (2017) [34]</td>
<td>Executive functions; social interaction; social media; technology; training; working memory</td>
<td>*</td>
<td>43 (41)</td>
<td>75-86 (81.7 / 75.7?)</td>
<td>*</td>
<td>A,P(^j)</td>
<td>no</td>
<td>6 h (8 w)</td>
</tr>
<tr>
<td>Larsson et al (2016) [35]</td>
<td>Loneliness; social activities; social contact</td>
<td>*</td>
<td>30 (30)</td>
<td>61-89 (71.2)</td>
<td>no</td>
<td>P(^k)</td>
<td>*</td>
<td>N/A</td>
</tr>
<tr>
<td>Quinn (2018) [36]</td>
<td>Older adults; executive functions; social media training; experiment</td>
<td>*</td>
<td>34</td>
<td>N/A (76.5)</td>
<td>no</td>
<td>P(^l)</td>
<td>*</td>
<td>8 h (4 w)</td>
</tr>
<tr>
<td>Morton et al (2018) [37]</td>
<td>Computers; internet; social connections; cognitive capacity; well-being</td>
<td>*</td>
<td>97 (76)</td>
<td>60-95 (80.7)</td>
<td>* not exclusive</td>
<td>P,D(^m)</td>
<td>no</td>
<td>18 h (12 w)</td>
</tr>
</tbody>
</table>

\(^a\)f/u: follow-up.  
\(^b\): yes, not available, or not declared in paper.  
\(^c\)P: passive control group or waiting list.  
\(^d\)N/A: not applicable.  
\(^e\)V: virtual control group by online survey.  
\(^f\)A: active control group.  
\(^g\)D: double intervention with different place of living and two control groups.
Table 3. Contents of studies: focus on social networking sites, outcomes, and tools.

<table>
<thead>
<tr>
<th>Author name and year</th>
<th>Focus on SNS&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Loneliness</th>
<th>Beneficial effects</th>
<th>Other outcomes</th>
<th>Specific questionnaire</th>
<th>Validated scales</th>
</tr>
</thead>
<tbody>
<tr>
<td>White et al (2002) [27]</td>
<td>no</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>Psychological and social well-being</td>
<td>no</td>
<td>UCLA Loneliness Scale, UCLAS&lt;sup&gt;c&lt;/sup&gt;, CES-Depression&lt;sup&gt;d&lt;/sup&gt;, PCLS&lt;sup&gt;e&lt;/sup&gt;, CAS&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>Fokkema and Knipscheer (2007) [28]</td>
<td>no</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Distinction between social loneliness and emotional loneliness</td>
<td>no&lt;sup&gt;b&lt;/sup&gt;</td>
<td>SJGLS-6&lt;sup&gt;g&lt;/sup&gt;</td>
</tr>
<tr>
<td>Shapira et al (2007) [29]</td>
<td>no</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Psychological well-being</td>
<td>no</td>
<td>UCLAS, DPFS&lt;sup&gt;h&lt;/sup&gt;, DACL&lt;sup&gt;i&lt;/sup&gt;, SAS&lt;sup&gt;j&lt;/sup&gt;, PCS&lt;sup&gt;k&lt;/sup&gt;, LSS&lt;sup&gt;l&lt;/sup&gt;</td>
</tr>
<tr>
<td>Siegers et al (2008) [30]</td>
<td>no</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>Physical, social, and emotional well-being</td>
<td>no</td>
<td>SJGLS-6, SF-36&lt;sup&gt;m&lt;/sup&gt;, SCL-90&lt;sup&gt;n&lt;/sup&gt;, IADL scale&lt;sup&gt;o&lt;/sup&gt;, EPQ-R&lt;sup&gt;p&lt;/sup&gt;, ECS&lt;sup&gt;q&lt;/sup&gt;</td>
</tr>
<tr>
<td>Woodward et al (2010) [31]</td>
<td>no</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>Mental health</td>
<td>*</td>
<td>Antonucci’s HMT&lt;sup&gt;r&lt;/sup&gt;, Gagnè-MNSS&lt;sup&gt;s&lt;/sup&gt;, CSE-16&lt;sup&gt;t&lt;/sup&gt;</td>
</tr>
<tr>
<td>Blazun et al (2012) [32]</td>
<td>no</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>*</td>
<td>no</td>
</tr>
<tr>
<td>Cotten et al (2012) [33]</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>weakly</td>
<td>Social well-being</td>
<td>*</td>
<td>RTL-34&lt;sup&gt;u&lt;/sup&gt;</td>
</tr>
<tr>
<td>Myhre et al (2017) [34]</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>Cognitive functions</td>
<td>no</td>
<td>UCLA Loneliness Scale, LSNS-18&lt;sup&gt;v&lt;/sup&gt;, SPS-10&lt;sup&gt;w&lt;/sup&gt;, RAVLT&lt;sup&gt;x&lt;/sup&gt;, ReyCFT&lt;sup&gt;z&lt;/sup&gt;, DSST&lt;sup&gt;aa&lt;/sup&gt;, DFRTT&lt;sup&gt;bb&lt;/sup&gt;, COWAT&lt;sup&gt;cc&lt;/sup&gt;, Miyake EFs&lt;sup&gt;dd&lt;/sup&gt;</td>
</tr>
<tr>
<td>Larsson et al (2016) [35]</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>UCLA Loneliness Scale, ESF&lt;sup&gt;ee&lt;/sup&gt;, VAS&lt;sup&gt;ff&lt;/sup&gt;</td>
</tr>
<tr>
<td>Quinn (2018) [36]</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>no</td>
<td>Cognitive functions</td>
<td>no</td>
<td>MMSE&lt;sup&gt;gg&lt;/sup&gt;, COAST&lt;sup&gt;hh&lt;/sup&gt;, SDMT&lt;sup&gt;ii&lt;/sup&gt;, WAIS&lt;sup&gt;jj&lt;/sup&gt;</td>
</tr>
<tr>
<td>Morton et al (2018) [37]</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>*&lt;sup&gt;b&lt;/sup&gt;</td>
<td>no</td>
<td>Computer attitude; sense of self-worth (competence, autonomy, and personal identity); cognitive and mental health</td>
<td>no</td>
<td>UCLA Loneliness Scale, SNAI&lt;sup&gt;kk&lt;/sup&gt;, ACRE-R&lt;sup&gt;ll&lt;/sup&gt;, CES-D Depression&lt;sup&gt;mm&lt;/sup&gt;, GAI-SE&lt;sup&gt;nn&lt;/sup&gt;, GHQ-12&lt;sup&gt;oo&lt;/sup&gt;, SWL&lt;sup&gt;pp&lt;/sup&gt;, SWLS&lt;sup&gt;qq&lt;/sup&gt;, CAS</td>
</tr>
</tbody>
</table>

<sup>a</sup>SNS: social networking site.
<sup>b</sup>*yes or not available.
<sup>c</sup>UCLAS: Revised UCLA Loneliness Scale.
<sup>d</sup>CES-Depression: CES-Depression Scale.
<sup>e</sup>PCLS: Perceived Control Life Situation.
<sup>f</sup>CAS: Computer Attitude Scale.
<sup>g</sup>SJGLS-6: 6-Item De Jong Gierveld Loneliness Scales.
<sup>h</sup>DPFS: Difficulties in Physical Functioning Scale.
<sup>i</sup>DACL: Depressive Adjective Checklist.
<sup>j</sup>SAS: Self-Anchoring Scale.
<sup>k</sup>PCS: Perceived Control scale.
<sup>l</sup>LSS: Life Satisfaction Scale.
<sup>m</sup>SF-36: 36-item Short Form Health Survey.
<sup>n</sup>SCL-90: 90-item Symptom Check List.
<sup>o</sup>IADL scale: Specific Questionnaire to Measure Daily Activities.
<sup>p</sup>EPQ-R: Subscales of the Eysenck Personality Questionnaire.
<sup>q</sup>ECS: External Control Scale.
<sup>r</sup>Antonucci’s HMT: Antonucci’s Hierarchical Mapping Technique.
<sup>s</sup>Gagnè-MNSS: Gagnè Motivation and Need Satisfaction Scale.
<sup>t</sup>CSE-16: Computer Self-Efficacy 16-item Scales.
<sup>u</sup>RTLS-34: Rasch Type Loneliness Scale 34-item.
<sup>v</sup>LSNS-18: Lubben Social Network Scale 18-item version.
SPS-10: Social Provision Scale.

RAVLT: Rey Auditory Verbal Learning test.

ReyCFT: Rey Complex Figure Test.

DSST: Digit Symbol Substitution Test.

DFRTT: Deary-Liewald Reaction Time Test.

TMT: Trail Making Test.

COWAT: Controlled Oral Word Association Test and Category Fluency Test.

Miyake EFsT: Miyake Executive Function Test.


VAS: visual analog scale.

MMSE: Mini-Mental State Examination.

COAST: California Older Adults Stroop Test.

SDMT: Symbol Digit Modalities Test.

WAIS: Wechsler Digit Span Forward and Backward subtest.

SNAI: Social Networking Activity Index.

ACE-R: Addenbrooke’s Cognitive Examination–Revised.

CES-D Depression: CES-D Depression Scale.

GAI-SF: Geriatric Anxiety Inventory Short Form.

GHQ-12: General Health Questionnaire.

SWL: 5-Item Satisfaction With Life Scale.

SWLS: The Satisfaction With Life Scale.
<table>
<thead>
<tr>
<th>Author name and year</th>
<th>Results</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| White et al (2002) [27] | • Successful intervention. Improvement of PC use by all participants  
• No significant correlation between self-reported health, activity limitations, and internet use | • Short follow-up time to evaluate intervention effect in terms of loneliness  
• Need for more intensive intervention  
• Use of self-reported condition of PC use for selection criteria |
| Fokkema and Knipscheer (2007) [28] | • Feeling of loneliness significantly decreased in both follow-ups (2 and 3 years after baseline)  
• Greatest reduction took place in the first step (T0 to T1)  
• Difference of reduction of loneliness between intervention group and control group is significant  
• Emotional loneliness reduction is significant, unlike the results on social loneliness  
• Qualitative findings confirm results that the internet helps to maintain contact with family or friends and it is a meaningful way to pass time | • Social contacts of participants increased due to classes and tutoring included in the intervention. These could influence effects of loneliness  
• Experiment was only performed once, and results should then be checked by repeat study  
• Suboptimal matching of intervention and control groups created a problem with identifying the intervention as the reason for the reduction of loneliness |
| Shapira et al (2007) [29] | • Positive effects on loneliness, less depression, more satisfaction with life, and more control and pleasure with their current quality of life | • Short and simple intervention to analyze a complex phenomenon  
• Language barrier in PC use  
• Lack of analysis of secondary effects (eg, social environment and activism) |
| Siegers et al (2008) [30] | • No significant differences (including for loneliness) were observed between groups and between times of follow-ups | • Lack of analysis of changes in lifestyles  
• Self-report measures of aspects of well-being  
• Exposure time bias: 1 year too short to make structural changes but too long to measure small daily changes in attitude |
| Woodward et al (2010) [31] | • No significant effect on loneliness and depressive symptoms between groups and between times  
• Experimental group reported a significantly higher quality of life compared with control group  
• No significant effect on social support outcome  
• Significantly greater computer self-efficacy and use of ICTs for both groups | • Randomization on people who agreed to participate made a self-selected sample not corresponding to a real population |
| Blažun et al (2012) [32] | • Loneliness reduction was statistically significant, detected in pre-post analysis related to gender (female), living alone, living in town  
• Improvement in independence of people living alone in town and their perception of safety | • Different trials in country cases  
• Data collection bias; questionnaire translation |
| Cotten et al (2012) [33] | • Weak and negative correlation between going online and loneliness  
• Moderate correlation between internet outcome variables and quality of communication  
• Mean social relation network: 11.2 members—friends and family | • Small sample  
• Lack of analysis of detailed information on participants |
| Myhre et al (2017) [34] | • Social outcome measured no significant change between pre- and posttimes | • Small sample  
• Randomization sample had been adapted by availability of individuals  
• Socialization in group should have had an effect on results |
| Larsson et al (2013) [41] | • Significant effect on satisfaction loneliness  
• Online contacts were significantly improved  
• No changes in offline contacts satisfaction | • Lack of active control groups |
| Quinn (2018) [36] | • No significant differences pre-post  
• No significant improvement on MMSEb | • Small sample  
• Lack of detailed information on participants |
Results

Protocol Characteristics: Methods

The main findings are summarized in Tables 2-4. Some methodological differences have been detected in study designs. First, 9 studies [27,29,31-37] were experimental with randomized sampling, while 2 [28,30] were quasi-experimental studies. In addition, 2 studies [27,34] were based on previous pilot studies. In the end, Larsson et al [35] used a crossover study and White et al [27] integrated the quantitative study with a short qualitative interview performed at the follow-up.

Protocol Characteristics: Population, Sample, and Inclusion Criteria

A total of 953 participants were recruited for these studies, and 860 of them took part in the postintervention assessment. Thus, around 10% of participants dropped out of the experimental studies before the follow-up. The age groups were different in each of the analyzed studies: from the largest, 58 to 93 years, in the Blažun et al [32] and Morton et al [37] studies to the smallest, 64 to 75 years [29] and 75 to 86 years [32], defined by 11 years’ range (Table 2). The participants mean age, when declared, was over 71 years, with 4 studies ([29,33,34,37] reporting a mean age over 81 years.

Furthermore, the sample sizes were very heterogeneous among studies. Taking into consideration the follow-ups, most of the studies involved fewer than 50 participants [28,29,32,34-36], while in 3 studies, the sample size was more than 75 but less than 85 [27,31,37]. Only Siegers et al [30] and Cotten et al [33] proposed samples comprising more than 200 subjects. Power analysis to support the sample size definition was conducted in only one study [30].

The studies imposed a range of inclusion criteria (20 in total, see Multimedia Appendix 1). In the summarizing phase, we identified 4 categories of criteria: (1) health conditions, (2) level of experience on PC and ICT use, (3) place of residence, and (4) social engagement. Health condition was the most used inclusion criteria: only 4 studies did not provide health condition criteria to take part in the study [28,31,33,35]. Health was frequently conceptualized as cognitive ability. This information was collected as self-reported information by participants [28,34] or caregivers [27,32]. Four studies directly measured the cognitive level using the Mini-Mental State Examination, but heterogeneous thresholds are used to identify cognitively intact individuals: in the Morton et al [37] study 19 points were sufficient to be included in the sample, Siegers et al [30] fixed the minimum score at 24 points, and Blažun et al [32] and Myhre et al [34] put it at 26 points. In most of the selected studies, low level of knowledge and use of technologies has been used as a specific inclusion criterion. Some specific differences were detected: White et al [27], Fokkema and Knipscheer [28], and Morton et al [37] generally focused only on PC use, while Quinn [36] shifted the focus to SNS use. Myhre et al [34] considered both, underlining the complexity of social interaction based on use of technologies. Conversely, Siegers et al [30] and Larsson et al [35] selected people who were already experienced in using a PC. Last, the availability of a PC at home was required by Larsson et al [35] and Myhre et al [34], while Morton et al [37] required available space and infrastructure for internet use.

The place of residence criteria were strongly related to the recruitment process. Five studies [27,29,32-34] involved people in residential homes, communities, or day centers, but only Cotten et al [33] declared that living in residential homes was one of the selection criterion. Morton et al [37] included people living at home and in residential care to build a double comparison sample: intervention and control groups living in 2 different places. The remaining 5 studies recruited exclusively older people living at home.

Social engagement criteria were adopted in 2 studies: Larsson et al [35] selected retired people who reported loneliness and social isolation experiences, while Fokkema and Knipscheer [28] combined reported loneliness experiences with willingness to take part in the study.

Protocol Characteristics: Control Groups, Follow-Up, and Interventions

All studies except for Blažun et al [32] benefited from at least one control group. The waiting list as a passive control group was a choice in 4 papers [27,31,35,36]. Fokkema and Knipscheer [28] chose to use an online survey as a virtual passive control group. Shapira et al [29] included only an active control group, with an alternative intervention to a selected part of the sample. Instead, to support the comparative control action, Myhre et al [34] and Cotten et al [33] combined active and passive control groups. Two passive control groups were used by Siegers et al [30] to compare the results between individuals not interested in attending the training course on PC use and those included...
in the waiting list despite their interest. Morton et al. [37] identified 2 intervention groups and 2 waiting lists to further detect differences due to living places (at home or residential care institution).

Five protocols were characterized by a single follow-up at the end of the intervention [27,29,32,34,37]. In 2 cases, an additional follow-up was planned at 4 months [36] or 12 [30] months after the intervention. Fokkema and Knipscheer [28] proposed 2 long-term follow-ups at 14 months and 24 months after the baseline. Cotten et al. [33] included multiple follow-ups at 3 months, 6 months, and 12 months. This choice is quite similar to what proposed by Woodward et al [31], based on 3 repeat measurements every 3 months after baseline (at 3 months, 6 months, and 9 months). In the crossover study by Larsson et al [35], participants were tested 2 times after baseline, as expected in this kind of method.

All experimental studies used training classes on PC or SNS as the main part of the intervention. In 4 studies, training did not last longer than 9 hours, and the intervention duration was often less than 8 weeks [32-34,36]. Most interventions included the provision of extra incentives to support ICT use (eg, tutoring and exercise sections [27-31,37]). Siegers et al. [30] and Fokkema an Knipscheer [28] made a choice to invest in long-term online tutoring. Both offered short training (4 hours and 10 hours) before their long intervention. Siegers et al. [30] preferred to use online tutoring, while in the study by Fokkema and Knipscheer [28] participants were supported and coached by visiting volunteers once every 2 or 3 weeks throughout the 3 years of the project. The protocol by Morton et al. [37] provided 18 hours of training in the first month of intervention, while the second and third months were devoted to online tutoring.

Contents of Studies: Focal Issues, Outcomes, and Tools Used

Papers published after 2013 considered SNS use as an independent variable, while the previous ones focused their attention on PC use, including email activity (Table 3). Loneliness was analyzed as a specific well-being outcome by all studies except Quinn [36], who focused on self-perceived SNS impact on personal social life and personal relationship network without direct reference to loneliness. In particular, loneliness was the single outcome analyzed in Larsson et al. [35] and Blažun et al. [32]. Fokkema and Knipscheer [28], taking inspiration from Weiss’s theory, distinguished between social loneliness and emotional loneliness [40] and provided a measurement of both. Other studies presented additional outcomes focused on the health and well-being of older people: cognitive functions [32,34], cognitive and mental health [31,37], psychological effects [27,29,30], and emotional well-being [30]. The study by Morton et al. [37] stressed sense of self-worth meant as autonomy, personal competence and personal identity. Social well-being (meant also as social isolation) was analyzed as participation in social activities [30] or social network ties and measured as quantity and quality of online communication [33,37].

International validated scales were the most commonly used measurement tools, but 2 studies included bespoke questionnaires created by the authors [32,33]. The 44 scales and/or tests were summarized in 5 categories: (1) aspects of social relationship life, (2) neuropsychological conditions, (3) clinical and physical well-being, (4) psychological well-being, and (5) ICT attitude and use. The complete list of validated scales with breakdown by category is provided in Multimedia Appendix 2.

Three studies [27,29,33] used the UCLA Loneliness Scale as a single perceived social measurement tool, while 2 studies combined that scale with others: Myhre et al. [34] added the Lubben Social Network Scale 18-item and the Social Provisions Scale and Larsson et al. [35] added the Evaluation of Social Interaction scale. Siegers et al. [30] and Fokkema and Knipscheer [28] used the RTLS-34 scale exclusively, Woodward et al. [31] combined the RTLS-34 with Antonucci’s Hierarchical Mapping Technique.

Clinical and physical well-being was investigated by Shapiro et al. [29] using the Difficulties in Physical Functioning Scale and by Siegers et al. [30] using the Lawton Instrumental Activities of Daily Living Scale, 90-item Symptom Checklist, and the 36-item Short Form Health Survey. Myhre et al. [34], Larsson et al. [35], and Quinn [36] included neuropsychological tests, measuring intelligence, attention, memory and executive function abilities (as detailed in Table 3). White et al. [27], Morton et al. [37], Woodward et al. [31], Shapiro et al. [29], and Siegers et al. [30] preferred to study the effects on the psychological well-being of older people using the Life Satisfaction Scale, depression level, and mastering of life phenomena. In addition, White et al. [27], Morton et al. [37], and Woodward et al. [31] choose to use the Computer Attitude Scale and the 16-item Computer Self-Efficacy Scale.

Contents of Studies: Findings and Declared Limitations

Five studies highlight the positive effect of ICT use including SNS use on the social relationships of older people (Table 4). The investigations by Shapiro et al. [29], Fokkema and Knipscheer [28], Blažun et al. [32], and Woodward et al. [31] highlight beneficial effects on loneliness and depressive symptoms, increased life satisfaction, and more control and pleasure with their current quality of life. One of them, Blažun et al. [32], showed the reduction of loneliness stratified by gender: the improvement in perceived loneliness was more common among women than men. Conversely, Siegers et al. [30], Morton et al. [37], and Myhre et al. [34] observed no statistically significant differences in pre-post evaluations, despite the data showing a decreasing trend of loneliness among participants. Even if Morton et al. [37] underlined an improvement in both intervention groups included in their study, albeit one not statistically significant, the larger upgrade was detected in people living in residential care compared with those living at home. Fokkema and Knipscheer [28] stressed how the long-term (2 and 3 years after baseline) improvement on loneliness was statistically significant, unlike what had been detected at the first follow-up. However, participants in the training course of ICTs and SNSs improved their competence and sense of self-worth through increased social activity [37], but these positive effects on online communications do not impact personal satisfaction related to offline contacts [35]. Cotten et al. [33] confirmed that the improvement of online
activities did not influence the quality of communications or the size of the personal network in the social relationship; if, generally, the network comprised 11 people, most of them were old friends and family members. This assumption was further confirmed by the findings of Fokkema and Knipscheer [28]. The reduction of emotional loneliness proved significant, unlike the results on social loneliness. Moreover, the qualitative findings underline that, for the interviewed participants, the internet was a meaningful way to pass time because it helped maintain contact with family or friends.

In addition to general results on the main declared outcomes, some papers reported the effects of treatment on secondary outcomes in terms of the success of training [27]. Morton et al [37] identified additional indirect effects on mental health outcomes of older people involved in the study. In particular, increased personal competence on ICT use was related to improvement in the sense of self-worth, strength of personal identity, and self-esteem. Similarly, Blažun et al [32] detected an enhanced independence of participants living alone in town and in their perception of safety. The study by Quinn [36] detected the lack of statistical significance of SNS use on cognitive functions in older people.

The authors highlighted how their study protocols presented limitations. In 2 cases, the intervention duration was considered too short to assess ICT effect on older people’s loneliness [27,29]. White et al [27] and Siegers et al [30] underlined how an exposure time of less than 1 year was not enough to grasp a complex phenomenon as ICT effect on loneliness, but, at the same time, it is too long to measure small daily changes in older people’s attitudes. The sample size was identified as a focal limitation in 3 experimental studies [33,34,36]: small samples (composed of 30 or 50 people) do not seem able to monitor pre-post differences in the relationships between ICT use and older people’s emotional well-being, in particular loneliness. Also, Cotten et al [33] reported a similar limitation due to small sample size, despite the involvement of more than 205 individuals. Moreover, the issue of sample size should be linked to other limitations arising from the sampling process. In particular, the above mentioned authors [33,34,36] focused attention on the lack of detailed information about participant lifestyles, and, consequently, on the inability to perform integrative stratified analysis. Siegers et al [30] and Quinn [36] agreed with Cotten et al [33] about the lack of secondary analysis on participants’ lifestyle context (eg, social environment, attitude toward active lifestyle, or participation in volunteering associations). Instead, from the point of view of Myhre et al [34] and Woodward et al [31], the main limitation of their studies concerned the adaptation of the randomization process due to the availability of the individuals to participate in the training course. Two studies [27,30] reported limitations due to the chosen measures, in particular regarding the use of self-reported scales to assess loneliness. Last, some bias was observed due to the translation of research and intervention tools from the original language to participants’ language [29,32]. Some limitations coming from the structure of the interventions were identified by Fokkema and Knipscheer [28] and Morton et al [37]. In particular, the increase of social contacts between participants in the training course and their interactions with trainers and tutors could influence the effects on loneliness, although the study designs did not allow us to disentangle the effects of training from the trainer’s visits. In the end, Morton et al [37] placed the emphasis on how the issue of the impact of online communication in older age and on the benefits coming from specialized courses would be transcended, since new generations of older people will already be ICT users.

Discussion

Principal Findings

The analysis of the findings of the reviewed studies highlights the growing interest in assessing the impact of SNSs on the social well-being of elderly people. The existence of a positive effect of ICT use on older people’s loneliness seems to be confirmed, even if it is often a weak or not statistically significant effect. Moreover, the results underline how the use of ICTs has positive effects on the individual sense of self-worth, strength of personal identity, and self-esteem. The literature emphasizes the connection between these aspects of mental and psychological well-being and loneliness [42]. These results underline, once more, the hard work needed to analyze by experimental studies complex phenomena such as loneliness.

The small number of experimental studies available in the literature on the effect of ICTs on social well-being and loneliness of older people and the limitations declared by the authors of the analyzed studies confirm this assumption. Indeed, many of these limitations concern the lack of control on the secondary variables that potentially influence the outcome, such as the effect of social contact during the training course, which is not easy to isolate [43]. In addition, the characteristics of lifestyle and level of social engagement of participants take on a specific relevance in the study designs. It is not by chance that the biggest limitation detected is small sample size, which does not ensure assessment of many of these secondary variables and, thus, a switch from specific findings to general assumptions on causal relationship. To confront the difficulty in defining the protocol, this review underlines how different methods are implemented to balance methodological accuracy and improvement of knowledge of the considered phenomenon. In addition, protocol designs were rarely supported by power analysis, pilot studies, or short qualitative studies [44].

Despite the low level of attrition in the selected studies (always below 10%), long- and medium-term studies involving older people need to take it into account carefully, because it could occur nonrandomly, thus posing challenges in the accuracy of results [45]. Furthermore, the heterogeneity of the selected population meets the debate on the definition of older people, conventionally defined as persons age 60 years. This definition is currently discussed in the literature [46]. Demographic trends and the literature underline how nowadays older age is setting in later [47]. This trend is confirmed by the sample composition: older people involved in the selected studies are generally aged 70 years or more.

In almost all of the reviewed studies, participants must have been early users of ICTs, but in some of them the availability of a PC is a fundamental participation criterion. This choice, although it alleviates the cost and management of the study, can
represent a source of bias in the sampling process. Indeed, in almost all cases the ICT use is self-reported by participants and may correspond to a different level of actual knowledge and ability in using the PC.

This review stresses the strong impact of the chosen recruitment process on the target population and sampling design. In particular, recruitment by flyers mostly involves people living at home and with a high level of autonomy, while recruitment in residential homes could find less healthy people with some functional limitations (eg, hearing or walking) [48]. These conditions could influence the social life of participants significantly. The assessment of loneliness was often not considered as a prerequisite to be involved in the study, even if it was the main outcome of several studies. Considering that loneliness is a subjective feeling, its detection at baseline allows a pre-post measurement of individual change and a comparison between individuals with different starting conditions. The sample must ensure the availability of this measurement, but often the reviewed studies underlined a bias in the sampling process: people who volunteered to participate in the study were often active people with fewer loneliness experiences. The widespread inclusion of at least one control group supports the analysis of the causal relationship between dependent (health and well-being of older people) and independent (ICT use) variables compared with daily life activities (passive control group) or a different socialization intervention (active control group). The detected trend of single follow-up underlines how these studies are often aimed at evaluating the short-term effect of an intervention. To capture long-term effects, some studies proposed further follow-ups after 6 months or 12 months or, as done by Fokkema and Knipscheer [28], after 3 years. The choice of Fokkema and Knipscheer [28] seems to be successful because it detected a changing trend in significant loneliness, underlining how loneliness trends are better detected by long-term rather than short-time evaluation. However, this choice needs a longer intervention characterized by additional tutoring activities between follow-ups to support ICT use by participants. Otherwise, as declared by Fokkema and Knipscheer [28] and Morton et al [37], a long-term intervention could facilitate the interfering effect of internal social activities on the self-perception of loneliness.

In the last 5 years, in line with the broader use of SNSs, the number of studies that have observed the socializing role of ICTs has grown. Loneliness is the primary measured outcome of individual social well-being and is often considered strongly related to other well-being aspects, such as personal life satisfaction, cognitive health conditions, and the ability to manage daily life events. The heterogeneity and number of measurement tools used confirm the theoretical and methodological debate on how complex phenomena (such as loneliness or social isolation) should be measured [49]. The variety of validated scales ensures the appropriateness of measure for quantitative studies, but it does not allow us to read the inside aspects of a personal feeling of loneliness. The choice to use multiple scales, done by many authors, pushes us to a deeper understanding of the issue [50]. Moreover, the use of validating scales ensures reliability of measurements, but each scale measures a specific aspect of loneliness phenomenon, and the variety of scales between studies reduces the comparability of results.

**Limitations**

Some limitations need to be considered in this review. First, the small amount of experimental articles in this area and their heterogeneity make it hard to produce a meta-analysis of the results and draw generalized conclusions. The decision to limit the literature search to articles published in English might have led to selection bias, although English is by far the leading language in this field of research. Second, the complex nature of the outcomes compared with the small size of the study samples limits the generalizability of the conclusions.

**Conclusions**

This review aimed to clarify how experimental studies improve the understanding of the causal relationships between older people’s ICT use and their well-being concerning loneliness. Moreover, this review highlights the analysis of protocols applied to support the design of future research in this field. In particular, we compared 11 experimental and quasi-experimental studies published from 2002 to 2019. The characteristics of the analyzed study protocols (research questions, outcomes, evaluation tools, and treatments) highlighted difficulties in design, sampling, and management of the interventions. Nevertheless, despite the declared limitations, the overall findings are positive, highlighting the need for studying these issues with adequate methodological rigor. First, care is needed to discern the causal relationship between the dependent and independent variables from the effects of other intervening variables. Second, these difficulties affect the possibility of carrying out more than one follow-up—usually at the end of the intervention—and force the recruitment of small samples. The extensive use of the passive control group is an indirect effect of these difficulties. Moreover, this review underlines how the complex nature of loneliness and, even more, its relationship with ICT use, would require a complex and complete design of evidence-based studies, characterized by multivariable schemes and large sample sizes. On the other hand, randomized controlled studies allow the identification and analysis of causal relationships. The experimental studies included in the review show some difficulties and limitations in data collection due to the exclusive use of standardized tools to analyze the loneliness issue, in which individual feeling seems better detected by qualitative than quantitative methods.

The findings coming from the reviewed studies seem to confirm a beneficial effect—albeit weak—of ICT use on the well-being of older people in terms of reduced loneliness. The weakness of these results, along with the growing interest in the relationship between ICT use and loneliness in older age, draws attention to the need for development of further evidence-based studies. Future research in this field should take account of the need for studies with multidisciplinary design. The integration of clinical, psychological, and sociological research approaches would allow us to better verify primary and secondary outcomes of ICT use for older people’s well-being, including loneliness. Moreover, quantitative protocol studies could benefit from a larger randomized sampling—better if supported by power
analysis—and by a short qualitative set of questions to improve the understanding and validity of the results.

Acknowledgments

This research was supported by Fondazione Cariplo under grant for “Bando 2017, ricerca scientifica: Ricerca sociale sull’invecchiamento: persone, luoghi e relazioni” (number 0946). This study was partially supported by Ricerca Corrente funding from the Italian Ministry of Health to Istituti di Ricovero e Cura a Carattere Scientifico—Istituto Nazionale di Ricovero e Cura degli Anziani.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Keywords and protocol characteristics.

Multimedia Appendix 2

Reference list of the international validated scales used in the reviewed studies.

References


Abbreviations

- ICT: information and communication technology
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- SNS: social networking site
- UCLA: University of California Los Angeles

©Georgia Casanova, Daniele Zaccaria, Elena Rolandi, Antonio Guaita. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 01.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.

https://www.jmir.org/2021/3/e23588

J Med Internet Res 2021 | vol. 23 | iss. 3 | e23588 | p.21

(page number not for citation purposes)
Compliance With Mobile Ecological Momentary Assessment of Self-Reported Health-Related Behaviors and Psychological Constructs in Adults: Systematic Review and Meta-analysis

Marie T Williams1*, BAppSc, PhD; Hayley Lewthwaite1,2*, BAppSc, BHlthScHons, PhD; François Fraysse3, PhD; Alexandra Gajewskia3, BClinExPhys, BAHons, Dip Ed; Jordan Ignatavicius3, BPhysio; Katia Ferrar3*, BAppSc, BHlthScHons, PhD

1Innovation, Implementation And Clinical Translation in Health, Allied Health and Human Performance, University of South Australia, Adelaide, Australia
2Department of Kinesiology and Physical Education, Faculty of Education, McGill University, Montreal, QC, Canada
3Alliance for Research in Exercise, Nutrition and Activity, Allied Health and Human Performance, University of South Australia, Adelaide, Australia

*these authors contributed equally

Abstract

Background: Mobile ecological momentary assessment (mEMA) permits real-time capture of self-reported participant behaviors and perceptual experiences. Reporting of mEMA protocols and compliance has been identified as problematic within systematic reviews of children, youth, and specific clinical populations of adults.

Objective: This study aimed to describe the use of mEMA for self-reported behaviors and psychological constructs, mEMA protocol and compliance reporting, and associations between key components of mEMA protocols and compliance in studies of nonclinical and clinical samples of adults.

Methods: In total, 9 electronic databases were searched (2006-2016) for observational studies reporting compliance to mEMA for health-related data from adults (>18 years) in nonclinical and clinical settings. Screening and data extraction were undertaken by independent reviewers, with discrepancies resolved by consensus. Narrative synthesis described participants, mEMA target, protocol, and compliance. Random effects meta-analysis explored factors associated with cohort compliance (monitoring duration, daily prompt frequency or schedule, device type, training, incentives, and burden score). Random effects analysis of variance (P≤0.05) assessed differences between nonclinical and clinical data sets.

Results: Of the 168 eligible studies, 97/105 (57.7%) reported compliance in unique data sets (nonclinical=64/105 [61%], clinical=41/105 [39%]). The most common self-reported mEMA target was affect (primary target: 31/105, 29.5% data sets; secondary target: 50/105, 47.6% data sets). The median duration of the mEMA protocol was 7 days (nonclinical=7, clinical=12). Most protocols used a single time-based (random or interval) prompt type (69/105, 65.7%); median prompt frequency was 5 per day. The median number of items per prompt was similar for nonclinical (8) and clinical data sets (10). More than half of the data sets reported mEMA training (84/105, 80%) and provision of participant incentives (66/105, 62.9%). Less than half of the data sets reported number of prompts delivered (22/105, 21%), answered (43/105, 41%), criterion for valid mEMA data (37/105, 35.2%), or response latency (38/105, 36.2%). Meta-analysis (nonclinical=41, clinical=27) estimated an overall compliance of 81.9% (95% CI 79.1-84.4), with no significant difference between nonclinical and clinical data sets or estimates before or after data exclusions. Compliance was associated with prompts per day and items per prompt for nonclinical data sets. Although widespread heterogeneity existed across analysis (I2>90%), no compelling relationship was identified between key features of mEMA protocols representing burden and mEMA compliance.
Conclusions: In this 10-year sample of studies using the mEMA of self-reported health-related behaviors and psychological constructs in adult nonclinical and clinical populations, mEMA was applied across contexts and health conditions and to collect a range of health-related data. There was inconsistent reporting of compliance and key features within protocols, which limited the ability to confidently identify components of mEMA schedules likely to have a specific impact on compliance.

(J Med Internet Res 2021;23(3):e17023) doi:10.2196/17023

KEYWORDS
mobile momentary ecological assessment; adult; compliance; systematic review; meta-analysis; mobile phone

Introduction

Background

Ecological momentary assessment (EMA) is a survey method that allows collection of data on participant behaviors, affect, and perceptual experiences in real-time (momentary) and real-life environments (ecological) [1]. In its original form, EMA required pen and paper diaries or logs to be completed on random (signal) or fixed (interval) time-based schedules or in response to a specific target behavior, psychological or social event (event-based). With the advent of handheld technologies, mobile EMA (mEMA) and increasingly mobile ecological momentary interventions (mEMIs) can be completed through automated schedules via handheld devices such as tablets and mobile phones.

As mEMA or mEMI have the potential to capture data in real time, the level of recall bias is potentially reduced. In addition, contextual (where and who the respondent is with) and antecedents to the specific target behavior or psychological construct can be obtained [1,2]. As a survey approach, mEMA or mEMI has undeniable utility, but data are dependent on participants consistently responding to the mEMA or mEMI schedule (compliance) [3]. Although electronically delivered surveys to personal mobile devices provide a means of time or date stamping and limit the possibility of hoarding, back and forward filling [4], concerns have been raised about protocol burden, missing data (especially if systematic), mindless answering, and survey habitation when lengthier questionnaires can be circumvented by a no response to initial questions [2]. EMA data with low compliance rates are unlikely to be ecologically valid; however, it is also possible to have good individual compliance with data of questionable accuracy [5,6].

In the last 5 years, there have been at least 10 systematic reviews focused on EMA and/or reporting aspects of compliance to EMA schedules in youth (<18 years [7-9]; <22 years [10]), mixed youth and adult cohorts [11-13], or specific adult populations [5,14-16]. Compliance with EMA in youth (nonclinical and clinical samples) has been reported to range between 44% and 96% [8-10] and in mixed youth and adult cohorts, between 23% and 94% [11-14]. Reports of compliance in specific adult clinical populations range from 21% to 99% (chronic pain, 21%-99% [15]; psychotic disorders, 78%-86% [16]; substance use, 75%, (95% CI 72.37-77.65) [5].

Although Stone and Shiffman [17] have highlighted the need for explicit reporting of compliance in their original reporting guidelines for EMA, recurring issues relating to the reporting of compliance include (1) missing, incomplete, or ambiguous data; (2) heterogeneity in reporting; (3) impact of data exclusions; and (4) combining traditional (paper-based) and mEMA data [5]. Participant compliance with mEMA or mEMI—in theory—is related to the total protocol burden, which is a function of monitoring duration, frequency and complexity of prompts, and familiarity with the technology. However, as Jones et al [5] note, to date, there is little compelling, systematic evidence to support an association between EMA burden and compliance rates. These issues make it difficult to determine which, if any, features of EMA protocols positively or negatively influence compliance to EMA schedules.

The purpose of this systematic review is to guide the development of an mEMA protocol, which could be used for future studies of health-related behaviors and psychological constructs (including symptoms) in adults with and without chronic disease. The primary question for this systematic review is as follows: In adult nonclinical and clinical populations, which factors are associated with increased compliance to mEMA protocols for collection of health-related behaviors and psychological constructs (including symptoms)?

Objectives

The objectives of this systematic review were to describe:
1. Health-related behaviors and psychological constructs assessed using mEMA
2. mEMA protocol and compliance reporting
3. Associations between key components of mEMA protocols and participant compliance

Methods

Search Registration

The search strategy and review protocol were registered prospectively with the International Prospective Register of Systematic Reviews (PROSPERO 2016: CRD42016051726).

Eligibility

Observational studies (cohort, cross-sectional) of mEMA in adults (>18 years of age) were eligible for inclusion in this review if these (1) reported participant compliance with mEMA; (2) were a primary study published in English between 2006 and 2016 inclusive; (3) included adults (>18 years) either apparently healthy (nonclinical population) or with health conditions (clinical population); and (4) collected mEMA data using mobile devices as a primary or secondary outcome. References were excluded if these were (1) experimental designs investigating intervention efficacy; (2) duplicate publications or secondary analysis of the same data set; or (3) conference
abstracts, protocols, commentaries (editorials or letters), or systematic or narrative reviews.

Information Sources and Search Strategy
A range of electronic databases were searched to identify eligible studies: AMED (Allied and Complementary Medicine), CINAHL, Cochrane Library and CENTRAL (Cochrane Central Register of Controlled Trials), Embase, MEDLINE (including epub ahead of print), PsycINFO, Scopus, and Web of Science. An academic librarian (Carole Gibbs, University of South Australia) assisted with the development of the search strategy regarding conceptualization, operators (operational terms), and limiters [18] with the final search undertaken during a single week. Search terms and associated MeSH (Medical Subject Heading) alternatives, which were adapted for use in all databases, related to the population (adults), assessment (mEMA), and outcomes of interest (health behaviors, perceptual experiences including symptoms, affect or mood). Key search terms included “ecological momentary assessment,” “EMA,” “mobile ecological momentary assessment,” “mEMA,” “electronic diary,” “SMS or short message service,” “prompting,” “text messaging,” “health behaviour,” “symptom,” and “adult.” Reference lists of included studies and systematic reviews identified during the search were reviewed to identify additional potentially relevant studies.

Study Selection
The titles and abstracts of studies identified from the search process were screened against a priori eligibility criteria and full-text versions imported into Covidence (Covidence systematic review software, Veriitas Health Innovation). Both screening steps were undertaken by individual members of the research team working in pairs (AG and MW, HL and FF) with each person completing the task independently, before meeting with their partner to compare results and resolve disagreements (consensus).

Data Collection
A data extraction template was prospectively developed; it was guided by the Checklist for Reporting EMA studies proposed by Liao et al [10] and pilot-tested on 5 randomly selected eligible studies. Working in pairs (AG and MW, JI and KF, HL and FF), individual members of the research team extracted all data before meeting with their partner to compare results and resolve disagreements by discussion. As this review aims to describe the features of mEMA schedules associated with increased mEMA protocol adherence, assessment of methodological bias was not planned.

Data Items
Data were extracted across 4 domains:

Publication demographics: title, authors, year of publication.

Participants: recruitment source, medical condition or diagnosis (clinical populations), sample size (enrolled, attrition or withdrawn and included in analysis), and age (mean/median, SD).

mEMA protocol: target behavior or psychological construct, mobile device type (PDA, palmtop computer, electronic diary, mobile or smartphone, tablet, other), participant training (yes/no), provision of incentives (course credit, financial, other, or none), incentive thresholds (yes/no) monitoring duration (days), prompt type (random signal, interval, event-based), frequency per day, number of questions/items per prompt type (reported or estimated from information reported in studies), strategy to deal with unanswered prompts, and time allowed for survey response. Where authors did not report the number of items per prompt type, but rather included descriptions of standardized instruments which were converted to mEMA survey items, a full version of the standardized instrument was accessed, and number of items calculated.

mEMA compliance: verbatim (or where possible calculated from reported data), participant completion (number included in analysis, data exclusions), criteria/thresholds for mEMA data, number of prompts delivered/answered per person/cohort (planned, actual, average, range), and response latency as time (mean, SD) [8,10].

Data Management
Data were tabulated to provide descriptive summaries. The mEMA surveys commonly included multiple questions reflecting behavioral or psychological constructs. Although the authors of mEMA studies did not always specify the primary outcome for these observational studies, most studies explicitly reported the key variable of interest for mEMA, which we interpreted to be the primary mEMA target. Where other data were also collected by the same mEMA survey, we denoted those as secondary mEMA targets. The primary mEMA target of studies was identified, and studies were grouped and reported according to two broad domains: (1) behavior (eg, dietary, physical activity, and smoking) and (2) psychological construct (eg, affect, cognition, and sensations/symptoms). For each domain, a narrative synthesis was used to summarize participants, mEMA protocol, and compliance data for nonclinical and clinical data sets.

With the exception of device type, where possible, we adopted the operationalization of variables common to Wen et al [9] or Jones et al [5] unless the distribution of our data resulted in very unbalanced cells or our data could provide greater resolution. Potential mEMA protocol factors related to compliance were categorized for analysis. Monitoring duration was categorized as follows: ≤7 days, >7 days to ≤14 days, or >14 days. Prompt frequency was grouped as follows: 1-3 prompts per day; 4-5 prompts per day; or ≥6 prompts per day. Minimum items per prompt were categorized as follows: ≤5, >5 to ≤9.5, >9.5 to ≤26, and >26. Device type was categorized as mobile phone, PalmPilot/PDA, or other. The reporting of training or familiarization sessions or provision of incentives were dichotomized as yes/no or labeled as not reported.

Given ongoing concerns about the burden imposed by EMA schedules and compliance, in addition to these individual factors, we explored a novel composite metric to reflect aspects previously identified as possible contributing factors (monitoring duration, frequency, type, and complexity of prompts).

Where possible, a mEMA burden score was calculated for each study by multiplying:
• the total monitoring duration in days (d; all days included in all waves)
• by the maximum frequency of time-based prompts (random and interval) per day (f)
• by the minimum number of compulsory questions/items within all prompts per day (i) and
• by a weighting reflecting the number of prompt types scheduled per day (w; eg, time-based [signal or interval] and/or event-based) with each prompt type weighted as 1 (min weight=1, max=3).

For example, the mEMA burden score for a 14-day monitoring schedule (d), where 5 random signal prompts were delivered per day (f), with each prompt requiring responses to a minimum of 12 items/questions (i; 60 items in total per day), would be 840. If event-based prompts (irrespective of the number of items within the prompt) were added to this schedule (w), the burden score would rise to 1680. Burden scores were calculated and reported in quartiles: 0 to 283.5, 284 to 810, 811 to 1806, or ≥1807.

**Meta-analysis**

Random effects restricted maximum likelihood estimator meta-analyses were undertaken using the approach reported by Jones et al [5] and Wen et al [9], with both authors advising to assist in accurate replication. All statistical analyses were conducted using JASP (Jeffreys’s Amazing Statistics Program, version 0.9.2; 2019). Studies were included in the meta-analysis if they reported all data necessary for the meta-analysis procedure and cohort compliance (%) could be extracted before data exclusions when possible. Sensitivity analysis was conducted to explore the impact of compliance rates reported before and after data exclusion. The effect sizes (ESs) were calculated by logit transforming the proportion of completed prompts (ie, compliance rates; proportion/[1−proportion]). SEs were then estimated using the following equation:

\[ \sqrt{\left(\frac{1}{np}+\frac{1}{n(1-p)}\right)} \]

Where, n is the sample size and p is the proportion.

To adjust for clustering within participants, the SE was adjusted by the effective sample size (ESS). The ESS equation is as follows:

\[ kn/(1+[k−1] \text{ICC}) \]

Where, k is the number of study prompts, n is the participant number, ICC is either the reported intraclass correlation coefficient (ICC) or the SD of reported compliance, and p is the proportion of completed prompts.

For studies that did not report SD data, sensitivity analyses were conducted by computing the SEs using the 25 and 75 percentiles of available SDs. The sensitivity analyses did not show any differences. Therefore, analysis used imputed median SD (where the original SD was not reported). To aid interpretation, inverse logit transformation was conducted to enable reporting of proportions. The I2 statistic was used to quantify heterogeneity across the ES. Pooled compliance rates were initially explored for combined nonclinical and clinical data sets and then compared between nonclinical and clinical studies.

To explore the relationships between the pooled compliance rates (nonclinical and clinical data sets) and EMA protocol factors (ie, monitoring duration, prompt frequency, device type, training, incentives, and burden score), random effects analysis of variance was conducted as part of the meta-analysis program. Moderator analyses were conducted separately for nonclinical and clinical pooled compliance.

**Results**

**Overview**

Figure 1 presents the outcome of the search strategy. Of the 282 studies reviewed as full text, 168/282 (59.6%) included mEMA; however, 42.3% (71/168) were excluded because mEMA compliance was not reported. The majority of the 97 studies retained for this review comprised studies that recruited or reported a single nonclinical group (61/97, 63%) or a clinical (31/97, 32%) group. Two studies included 2 [19] or 3 clinical groups [20]. In addition, 3 studies included clinical and nonclinical comparator groups (4 groups [21], 2 groups [22,23]). Overall, 105 data sets were included in this review (nonclinical: 64/105, 61%; clinical: 41/105, 39%). A description of all included data sets is presented in Multimedia Appendix 1 [19-114].

A total of 44,796 participants were included in the analyses (nonclinical: 42,338/44,796, 94.51%; clinical: 2431/44,796, 5.43%) with a median sample size of 62 (nonclinical: n=89; clinical: n=40; Multimedia Appendix 2). Two data sets (nonclinical) were outliers because of the sample size (n=21,947; n=11,572) [24,25]. The main sources of recruitment for nonclinical data sets were educational institutions (30/64, 47%) and community (26/64, 41%), whereas clinical data sets were predominantly recruited from medical/health services (21/41, 51%) and community (17/41, 41%). For clinical data sets, the most common health conditions were psychiatric or mental health (12/41, 29%), chronic pain and fibromyalgia (6/41, 15%), and eating disorders (5/41, 12%). Multimedia Appendix 2 presents a summary of the study characteristics grouped by primary mEMA target.
Objective 1: Health-Related Behaviors and Psychological Constructs Assessed With mEMA

Using the primary mEMA target, data sets were grouped into 2 broad domains: Behavior or Psychological construct. Within the Behavior domain, the Other category reflects single studies (7), where the primary mEMA target did not align with more common behavior targets (social interactions/activities [26,27], sexual [28], leisure [29], nonsuicidal self-injurious [30], HIV prevention [31], and oral behaviors) [32].

The most frequent primary mEMA target across all domains for nonclinical and clinical data sets was affect (31/105, 29.5% of data sets; nonclinical n=15/64, 14%, clinical n=16/41, 15%). The most common primary mEMA target in nonclinical data sets (n=64) reflected the Behavior domain (total 38/64, 59%), whereas clinical data sets (n=41) reflected the Psychological domain (total 32/41, 78%).

With the exception of 1 clinical study (fatigue) [33], the remaining data sets included mEMA items/questions beyond the primary mEMA target. The most frequent secondary targets assessed were affect (50/105, 47.6%), social environment (33/105, 31.4%), physical activity (25/105, 23.8%), cognition (24/105, 22.8%), and physical environment (20/105, 19%). Multimedia Appendix 2 presents a summary of secondary mEMA targets and participant characteristics grouped by the primary mEMA target.

Objective 2: mEMA Protocol and Compliance Reporting

Multimedia Appendix 3 presents a summary of mEMA protocols grouped by primary mEMA target. Among the included studies,
mEMA data were most commonly collected using handheld computer/PDAs (61/105, 58.1%) with mobile phones accounting for approximately one-third (37/105, 35.2%). Participant training in mEMA was reported by most studies (nonclinical: 49/64, 77%; clinical: 35/41, 85%). The provision of incentive (financial or other) was more frequent in nonclinical protocols (nonclinical: 46/64, 72%; clinical: 20/41, 49%).

Across all data sets (n=105), the median monitoring duration for mEMA protocols was 7 days (range: 1-182 days), with durations differing between nonclinical (median 7 days, range 1-49 days) and clinical protocols (median 12 days, range 1-182 days). Most studies included a single prompt type (overall data sets: 69/105, 65.7%; nonclinical: 40/64, 63%; clinical: 29/41, 71%), with random signals being the most common in nonclinical protocols (49/64, 77%) and interval in clinical protocols (25/41, 61%). Of the remaining study protocols, 23% (24/105) of studies included 2 prompt types and 11% (12/105) protocols included all 3 prompt types (random signal, interval, and event-based). The frequency of time-based prompts (signal or interval) ranged from 1 to 42 per day (median: nonclinical=5, range 1-36; clinical=4, range=1-42). The number of specific questions/items within a standard prompt varied markedly across study protocols; it ranged between 1 and 73 (median: nonclinical=10; clinical=8).

Table 1 presents a summary of reporting for compliance metrics for mEMA time-based prompts (ie, signal and fixed prompts). Participant attrition (dropout) rates were reported or could be calculated for half of the 105 data sets (nonclinical: 31/64, 48%; clinical: 22/41, 54%). Less than half of the data sets reported the number of prompts delivered (overall: 22/105, 21%; nonclinical: 14/64, 22%; clinical: 8/41, 20%) or answered (overall: 43/105, 41%; nonclinical: 29/64, 45%; clinical: 14/41, 34%). Approximately one-third of the data sets reported a criterion for valid mEMA data or reasons for data exclusions (overall: 37/105, 35%; nonclinical: 25/64, 39%; clinical: 12/41, 29%). Criteria for valid EMA data fell into 2 main groups, with the most common based on assessment completion (ie, specified threshold for number of prompts completed per day or percentage of overall compliance), followed by response latency period threshold (eg, prompt required to be answered within 30 min). Of the data sets reporting a criterion for response time (overall: 38/105, 36%; nonclinical: 16/64, 25%; clinical: 22/41, 54%), this ranged from 1.5 to 60 min (median 15 min; Multimedia Appendix 3). Other reasons for data exclusion were based on specific time of day prompts (excluding the first or last of the day), technical malfunctions, or unspecified (eg, general statements on participants’ limited or poor compliance).

Of the 105 data sets, 82/105 (78.1%) reported compliance using a single metric (cohort, average per person or other), with compliance at the cohort level most common (overall: 62/105, 59%; nonclinical: 34/64, 53%; clinical: 28/41, 68%). Compliance was less frequently reported using the single metric of average per person (overall: 20/105, 19%; nonclinical: 14/64, 22%; clinical: 6/41, 15%) or compliance for both cohort and average per person (overall: 18/105, 17%; nonclinical: 12/64, 19%; clinical: 6/41, 15%). The remaining data sets (n=5; nonclinical: n=4, clinical: n=1) reported compliance after combining event/time-based signals [34] or separate tasks [35], number of completed protocol days [36], total number of prompts (data) available [37], or proportion of completed questions/items per prompt [38]. Cohort compliance reported before data exclusions ranged from 38% to 98% (median 82%) and after data exclusions from 50% to 97% (median 81%; Table 1).
Table 1. Summary of mobile ecological momentary assessment (mEMA) compliance reporting.

<table>
<thead>
<tr>
<th>Primary mEMA&lt;sup&gt;a&lt;/sup&gt; target</th>
<th>NC&lt;sup&gt;b&lt;/sup&gt; or C&lt;sup&gt;c&lt;/sup&gt; (n)</th>
<th>Reported N=data sets (%)</th>
<th>Cohort compliance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Attrition rate</td>
<td>Total prompts delivered</td>
<td>Total prompts answered</td>
</tr>
<tr>
<td>Smoking</td>
<td>NC (12)</td>
<td>8 (66)</td>
<td>4 (33)</td>
</tr>
<tr>
<td></td>
<td>C (1)</td>
<td>1 (100)</td>
<td>1 (100)</td>
</tr>
<tr>
<td>Alcohol</td>
<td>NC (8)</td>
<td>3 (37)</td>
<td>1 (12)</td>
</tr>
<tr>
<td></td>
<td>C (0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Eating behaviors</td>
<td>NC (10)</td>
<td>6 (60)</td>
<td>2 (20)</td>
</tr>
<tr>
<td></td>
<td>C (3)</td>
<td>2 (66)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>Physical activity</td>
<td>NC (5)</td>
<td>1 (20)</td>
<td>1 (20)</td>
</tr>
<tr>
<td></td>
<td>C (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>NC (3)</td>
<td>0 (0)</td>
<td>2 (66)</td>
</tr>
<tr>
<td></td>
<td>C (4)</td>
<td>4 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Personality traits</td>
<td>NC (7)</td>
<td>4 (57)</td>
<td>1 (14)</td>
</tr>
<tr>
<td></td>
<td>C (0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Affect</td>
<td>NC (15)</td>
<td>7 (46)</td>
<td>2 (13)</td>
</tr>
<tr>
<td></td>
<td>C (16)</td>
<td>9 (56)</td>
<td>2 (12)</td>
</tr>
<tr>
<td>Cognitions</td>
<td>NC (2)</td>
<td>1 (50)</td>
<td>0 (0)</td>
</tr>
<tr>
<td></td>
<td>C (0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Symptoms</td>
<td>NC (2)</td>
<td>1 (50)</td>
<td>1 (50)</td>
</tr>
<tr>
<td></td>
<td>C (16)</td>
<td>6 (37)</td>
<td>4 (25)</td>
</tr>
<tr>
<td>Total</td>
<td>NC (64)</td>
<td>31 (48)</td>
<td>14 (22)</td>
</tr>
<tr>
<td></td>
<td>C (41)</td>
<td>22 (54)</td>
<td>8 (20)</td>
</tr>
<tr>
<td></td>
<td>t (105)</td>
<td>53</td>
<td>22</td>
</tr>
<tr>
<td>%</td>
<td>50.4</td>
<td>20.9</td>
<td>40.9</td>
</tr>
</tbody>
</table>

<sup>a</sup>mEMA: mobile ecological momentary assessment.
<sup>b</sup>NC: nonclinical.
<sup>c</sup>C: clinical.
<sup>d</sup>NA: not available as domain includes a single study.
<sup>e</sup>N/A: not applicable.

Question 3: Associations Between Key Features of mEMA Protocols and mEMA Compliance

Of the 105 data sets included in this review, 65% reported sufficient data for inclusion in the meta-analysis (n=68 data sets: 41/105 [39%] ESM nonclinical and 27/105 [26%] ESM clinical; Multimedia Appendix 1) [20,21,23,26,27,29-31,33,36,39-90]. The remaining data sets did not report cohort compliance but reported average per-person compliance [19,24,25,91-106,28,32] or other [34,35,37,38,107-110], or where cohort compliance was reported, a variable required for the meta-analysis was not [111-114].

The overall compliance rate across all 68 ESs was 81.9% (95% CI 79.1-84.4). There was sizable heterogeneity across the compliance rates ($I^2=98$). Sensitivity analysis exploring the impact of pre and postdata exclusion compliance rates showed no significant difference ($P=.67$; before exclusion: n=50, 81.6%; after exclusion: n=18, 82.8%). There was no significant difference ($P=.16$) between the pooled compliance of nonclinical studies (80.4%; 95% CI 76.1-83.9; $I^2=98.6$) and clinical studies (84.2%; 95% CI 80.1-87.4; $I^2=95.7$). Three studies included more than 1 data set and reported compliance ESs for each (data sets n=2 [23], n=3 [20], and n=4 [21]). Sensitivity analysis was undertaken to explore the impact of double counting of mEMA protocol factors within the meta-analysis, where multiple ESs were reported within single studies. When a single ES was retained for each of these studies (lowest ES of the 2 [23], median of 3 [20], ES closest to the average for 4 [21]), the
pooled 62 ESs (81.3%, 95% CI 78.2-84.2) and reported variance ($I^2=98$) were essentially the same as the full data set (68 ESs: 81.9%; 95% CI 79.1-84.4; $I^2=98$). To ensure that subgroup analysis was not affected, all analyses were conducted without duplicate ESs, and all relationships were consistent with those of the full data set.

For nonclinical studies, 2 factors (prompt frequency and items/prompt) were significantly related to mEMA compliance. For prompt frequency, the overall model was nonsignificant ($P=.07$), but the coefficient was significant ($P<.001$). Prompting 1 to 3 times per day was associated with higher compliance (87%; 95% CI 82.5-90.4) compared with studies with more than 3 prompts per day (76.9%) and 6 or more prompts per day (79.4%). The number of items per prompt was significant for both the overall model ($P=.04$) and the coefficient ($P<.001$).

For clinical data sets (n=27), no factors were significantly related to compliance. The number of items per prompt approached significance ($P=.05$). Compliance appeared to be lower in studies with 9.5-26 items per prompt (71.1%; 95% CI 62.5-78.6). Significant heterogeneity was reported for all significant findings (nonclinical and clinical), with $I^2$ values in excess of 90%, suggesting that although some variance can be explained by the significant factors, a large amount of variance remained unexplained. The burden score was not significantly related to compliance. The meta-analysis factor analysis compliance proportions are presented in Table 2.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Clinical data sets, n=27</th>
<th>Nonclinical data sets, n=41</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol factors</strong></td>
<td>Pooled compliance (95% CI) n (%)</td>
<td>Pooled compliance (95% CI) n (%)</td>
</tr>
<tr>
<td>Monitoring period, day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;7</td>
<td>12 (44) 81.6 (74.1-87.3)</td>
<td>24 (58) 77.4 (71.3-85.5)</td>
</tr>
<tr>
<td>&gt;7 to ≤14</td>
<td>4 (15) 84.4 (74.3-91.1)</td>
<td>9 (22) 82.1 (71.30-89.5)</td>
</tr>
<tr>
<td>&gt;14</td>
<td>11 (41) 86.7 (81.2-91.0)</td>
<td>8 (19) 85.3 (80.5-89.1)</td>
</tr>
<tr>
<td><strong>Device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td>5 (19) 88.6 (71.5-96.1)</td>
<td>17 (41) 78.6 (71.9-84.0)</td>
</tr>
<tr>
<td>PDA</td>
<td>18 (66) 81.9 (74.7-85.8)</td>
<td>22 (54) 80.2 (74.2-84.9)</td>
</tr>
<tr>
<td>Other</td>
<td>4 (15) 88.8 (82.4-93.1)</td>
<td>2 (5) 92.2 (86.3-95.7)</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>23 (85) 84.4 (79.7-88.4)</td>
<td>36 (88) 80.4 (76.0-84.3)</td>
</tr>
<tr>
<td>No</td>
<td>0 (0) N/A</td>
<td>0 (0) N/A</td>
</tr>
<tr>
<td>NR</td>
<td>4 (15) 82.8 (78.4-86.4)</td>
<td>6 (15) 77.7 (73.1-82.0)</td>
</tr>
<tr>
<td><strong>Incentives</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13 (48) 83.6 (77.7-88.3)</td>
<td>35 (85) 80.4 (79.0-84.3)</td>
</tr>
<tr>
<td>No</td>
<td>0 (0) N/A</td>
<td>6 (15) 77.9 (73.1-82.0)</td>
</tr>
<tr>
<td>NR</td>
<td>18 (66) 85.7 (81.3-89.3)</td>
<td>0 (0) N/A</td>
</tr>
<tr>
<td><strong>Prompt frequency, per day</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3</td>
<td>8 (30) 85.3 (77.6-90.7)</td>
<td>8 (19) 87.0 (82.5-90.4)</td>
</tr>
<tr>
<td>4-5</td>
<td>12 (44) 81.5 (75.8-85.9)</td>
<td>16 (39) 76.9 (70.1-82.5)</td>
</tr>
<tr>
<td>≥6</td>
<td>6 (22) 86.3 (74.1-92.4)</td>
<td>17 (41) 79.4 (71.1-85.5)</td>
</tr>
<tr>
<td>UTD</td>
<td>1 (4) 90.6 (N/A)</td>
<td>0 (0) N/A</td>
</tr>
<tr>
<td><strong>Burden score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-283.5</td>
<td>4 (15) 86.2 (76.9-92.4)</td>
<td>11 (27) 80.5 (75.7-84.6)</td>
</tr>
<tr>
<td>284-810</td>
<td>7 (26) 86.4 (75.4-93.0)</td>
<td>10 (24) 79.6 (73.7-84.7)</td>
</tr>
<tr>
<td>811-1806</td>
<td>3 (11) 88.8 (64.8-97.1)</td>
<td>13 (31) 82.8 (73.7-89.1)</td>
</tr>
<tr>
<td>≥1807</td>
<td>7 (26) 85.3 (80.5-89.0)</td>
<td>4 (10) 79.1 (51.5-93.1)</td>
</tr>
<tr>
<td><strong>Items per prompt</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5</td>
<td>8 (30) 87.2 (80.7-91.9)</td>
<td>10 (24) 82.8 (77.2-87.2)</td>
</tr>
<tr>
<td>5 to &lt;9.5</td>
<td>7 (26) 88.4 (76.9-94.6)</td>
<td>8 (19) 78.6 (67.5-86.8)</td>
</tr>
<tr>
<td>9.5 to ≤26</td>
<td>2 (7) 71.1 (62.5-78.6)</td>
<td>16 (39) 84.0 (79.0-88.0)</td>
</tr>
<tr>
<td>≥26</td>
<td>6 (22) 87.2 (82.9-90.7)</td>
<td>4 (10) 63.0 (42.3-79.7)</td>
</tr>
<tr>
<td>NR</td>
<td>5 (19) 72.7 (68.4-76.9)</td>
<td>3 (7) 70.3 (40.4-89.2)</td>
</tr>
<tr>
<td><strong>Number of prompt types</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>18 (66) 82.6 (78.1-86.5)</td>
<td>25 (61) 79.6 (75.0-83.5)</td>
</tr>
<tr>
<td>2</td>
<td>6 (22) 86.4 (71.3-94.2)</td>
<td>11 (27) 83.3 (71.7-90.9)</td>
</tr>
<tr>
<td>3</td>
<td>3 (11) 87.2 (85.5-88.8)</td>
<td>5 (12) 77.7 (65.7-86.5)</td>
</tr>
</tbody>
</table>

*a*Device type included with categories: Mobile phone (total n=22; smartphone: clinical n=1; nonclinical n=14; mobile: clinical n=4, nonclinical n=3); PDA (total n=45; clinical n=22, nonclinical n=23); Other (total n=6; electronic diary: clinical n=2, nonclinical n=1; iPod: clinical n=1, nonclinical n=1; watch device: clinical n=1).

*b*N/A: not applicable.

*c*NR: not reported.
**Discussion**

**Principal Findings**

This systematic review of observational studies aimed to describe protocols and compliance with mEMA for self-reported health-related behaviors and psychological constructs in adults. Across 105 unique data sets, the key findings of this review were as follows: (1) a variety of health-related behaviors and psychological constructs were assessed, with affect being the most common mEMA target; (2) mEMA protocols varied widely across studies; (3) compliance was inconsistently reported across studies; (4) meta-analysis estimated an overall compliance rate of 81.9% (95% CI 79.1-84.4), with no significant difference between nonclinical and clinical data sets or estimates before or after data exclusions; (5) compliance was associated with prompts per day and items per prompt (nonclinical); and 6) no compelling relationship was identified between key features of mEMA protocols representing burden and mEMA compliance.

**mEMA Use in Adults for Health-Related Behaviors and Psychological Constructs**

The mEMA targets identified in this review reflect those reported in previous systematic reviews: affect/mood [7,12,14,15], cognitions [13], symptoms [18], eating or dietary behaviors [10,11], physical activity [10], and smoking or alcohol consumption [5,6]. Likewise, clinical populations identified in this review (psychiatric or mental health conditions, chronic pain and fibromyalgia, eating disorders, and substance use) were generally consistent with those reported previously [5,7,11,12,14-16]. However, there were chronic conditions unique to this review: oral or dental health, cancer, stroke and traumatic brain injury (for each n=3, 9/41, 22%), HIV, and upper abdominal surgery (for each n=1, 2/41, 5%). The small number of studies identified for these clinical groups may suggest that the potential for mEMA has not yet been realized in these populations.

**Reporting of mEMA Protocols and Compliance**

Most studies included in this review provided information around the EMA protocol used (device, monitoring duration, frequency and type of prompts, provision of training, and use of incentives). Consistent with previous systematic reviews of both youth and adults, there was considerable heterogeneity across studies for EMA protocols (Multimedia Appendix 3). Heterogeneity may be expected given the various potential applications of this survey approach. The mEMA protocol required to obtain sufficient or appropriate self-reported data on daily habitual behaviors in the general population is not likely to be the same as that for obtaining self-reported data on psychological responses to events or stimuli in clinical contexts. For example, the average EMA monitoring duration for studies of nonclinical adults in this review was 7 days (range: 1-49 days) compared with 12 days (range: 1-182 days) for clinical populations and 30 days (range: 3-730 days) in a review of EMA in substance users [5]. Likewise, prompt type, frequency, and complexity are expected to differ depending on the EMA target and population. Reviews of studies of EMA for diet and physical activity (common behaviors) report a daily average prompt frequency of 20 [10] compared with less than 4 prompts per day in substance use [5]. For these reasons, in systematic reviews of EMA use—including this one—reporting of summary metrics (mean, SD, median, range) for protocol components could be interpreted as a reflection of diversity in EMA application rather than a lack of protocol standardization.

The same rationale cannot be applied to the inconsistencies identified in reporting of EMA protocol compliance. Compliance is problematic to determine for event-based prompts (eg, those completed with smoking or consumption of alcohol). Compliance for time-based notifications, especially when the EMA is conducted using mobile devices, is relatively simple (number of prompts answered out of the total number of prompts delivered). However, participants may respond to a notification but may not complete all survey items or may not respond in a timely manner, affecting the momentary aspect of the EMA. In both of these cases, the act of responding might appropriately contribute to compliance rates, but the data are unlikely to be valid. These concepts were evident in the earliest recommendations for reporting compliance in EMA studies [17], which predate the sampling frame of this systematic review (2006-2016 inclusive). Considering that 71 studies were excluded from this review because of the absence of reporting mEMA compliance, less than half of the studies included in this review complied with recommendations put forward by Stone and Shiffman [17], such as reporting the proportion of delivered prompts answered (43/105, 41%) or defining a criterion for valid EMA data (37/105, 35%). Similarly, less than half of the data sets included in this review reported an average number of prompts answered per person (44/105, 42%), as recommended by more recently published guidelines for reporting EMA [8,10].

With the growth of systematic review methodologies (meta-synthesis, meta-regression, etc), one aspect of reporting for EMA warrants further consideration. EMA allows collection of self-report data across multiple survey items reflecting a range of behavioral, psychological, and contextual factors. It is not uncommon for data collected in the original, primary study to be reported in several publications. The foci of these offspring publications may include the total original sample of participants recruited (eg, unpublished data for specific mEMA items or other variables) or explore a subset of the original study participants (eg, patterns associated with participant characteristics). Although this is a reasonable and defensible use of the original study’s resources, identification of duplicate or overlapping data in studies can be problematic. Where ambiguity exists, contacting the study authors is one way to clarify which publication should be considered the primary report (and which report overlapping or duplicate data). However, this option becomes less practical as time and people move on. The alternative is for authors to include an explicit statement concerning the existence of publications that include overlapping or duplicate data. There were a number of exemplars of this aspect of reporting in studies included [67,68,96] and excluded from this review [115-118].
Associations Between Key Components of mEMA Protocols and Compliance: Meta-analysis

In our meta-analysis (68 data sets), which replicates and was guided by the authors of 2 previous meta-analyses on this topic [5,9], the overall compliance rate was 81.9% (95% CI 79.1-84.4). This was slightly higher than that reported by Wen et al [9] (78.26%; 95% CI 75.49-80.78) and Jones et al [5] (75.06%; 95% CI 72.37-77.65). Although concerns have been expressed about the relationship between EMA burden and compliance, it remains unclear whether, or which, EMA protocol factors affect participant compliance. In our meta-analysis, for nonclinical data sets, prompt frequency per day and the number of items per prompt were significantly related to compliance (noting that it is not unusual for coefficients derived within a model to be significant even when the overall model is not). However, the findings are likely affected by the number of data sets in some categories. For nonclinical data sets, frequencies of 1-3 prompts per day were associated with small but significantly higher mean cohort compliance. Higher compliance with lower number of prompts perhaps seems intuitive, yet the evidence is inconsistent. Wen et al [9] reported opposite patterns of significance when nonclinical and clinical population data were investigated, and Jones et al [5] and Ono et al [119] reported no relationship with prompt frequency and compliance among substance users and those affected by chronic pain, respectively.

The relationship between the number of items included within each prompt and compliance has not been explored in previous systematic reviews or meta-analyses of mEMA. In this review, the number of items respondents were required to complete in a standard prompt ranged from 1 to 73 (median 10), with a greater number of items more common in the mEMA of psychological constructs (Multimedia Appendix 3). Our analysis showed an intuitive relationship with compliance among nonclinical data (ie, 226 items per prompt had the lowest mean cohort compliance of 63%; 95% CI 42.3-79.7), but not with clinical data.

When aiming to identify protocol factors affecting compliance, the inconsistencies in reporting of EMA compliance and the likely publication bias (studies with lower compliance rates may not be submitted or accepted for publication) must also be considered [5]. These factors limit the inclusion of potentially eligible studies in meta-analyses (68/105, 64.8% data sets in this review; 36/42, 86% studies in a previous review [9]). In addition, studies included in meta-analyses privilege best compliers through exclusion of participants not meeting criteria for valid EMA data or compliance thresholds (determined a priori or posteriori). Jones et al [5] attempted to address this latter point by exploring protocol factors associated with participant data exclusions (monitoring duration and prompt frequency). Finally, aggregate level compliance may not be sensitive enough or provide sufficient resolution to identify factors associated with higher or lower compliance. While accepting these caveats, there are 2 ways to consider the results of the 3 meta-analyses undertaken by Wen et al [9], Jones et al [5], and this study:

1. There is insufficient resolution to identify associations—if they exist—at the aggregate data level.
2. Although confidence limits might be reduced by adding further studies, the meta-analyses are essentially correct, and the notion of protocol burden imposed on participants has little to no impact on compliance [4,5].

In studies using EMA, the issue of what constitutes an acceptable rate of compliance or missing data is debatable. Although several studies included in this review cite a criterion or commonly used threshold of 80%. We, similar to Jones et al [5], could not identify the derivation of this criterion. For authors currently planning, conducting, or writing papers or protocols on EMA to monitor health-related behaviors of psychological constructs, adequate recording and reporting of compliance data following recommendations by Liao et al [10] and Heron et al [8] should enable future meta-analyses to explore protocol factors affecting participant compliance rates.

This systematic review prospectively aimed to sample a decade of mEMA use (protocol registered in November 2016; sampling frame of 2006 to 2016) in observational studies including adults from clinical and nonclinical populations. As one of the first EMA reporting documents was published in 2002 [17], this sampling frame assumed that researchers planning or reporting studies including mEMA would be aware of these reporting recommendations. The time frame required for the uptake of EMA reporting recommendations is unknown, although estimates of the time required for uptake of translational research ranges between 2 and 17 years [120]. Our sampling frame and review, however, does not capture studies published from 2017 to date. It is possible that more recent publications differ from those included in our review (greater mobile phone use, better reporting of mEMA schedules, and compliance).

There are no universally accepted recommendations concerning the updating of systematic searches or incorporation of the newer studies into the review results. Systematic reviews—depending on the specific question and volume of studies eligible for inclusion—are time- and labor-intensive. For larger reviews, it is not uncommon for these to take >2 years [121], with updates of Cochrane Collaboration systematic reviews taking up to 3.3 years [122]. The current Cochrane Collaboration policy infers that the decision to update a systematic review should consider the importance of the review question and the volume of new information (studies) [122]. Early in the review process (postsearch completion), 2 papers were identified, published in 2016 [10] and 2017 [8], providing updated recommendations for EMA reporting. Although the volume of mEMA studies published from 2017 is substantial and growing, we opted not to undertake an updated search/meta-analysis to quarantine mEMA studies published before the availability of the more recent EMA reporting recommendations.

Strengths and Limitations

This review was strengthened by the broad eligibility criteria used, including studies across nonclinical and clinical contexts in adults. The meta-analysis method was replicated from previous studies [3,9], enabling direct comparison of findings. To the best of the authors’ knowledge, this review is the first to propose and explore burden as a compound effect of the
various EMA factors (monitoring duration, prompt frequency and prompt type, item per prompt) on participant compliance. We have proposed this novel metric as a starting point for conversations, critique, and further development. In its current form, the burden metric does not include all factors likely to contribute to burden (unfamiliarity with technology, adjunctive use of wearable technologies such as accelerometers), the proposed weighting is rudimentary, and the accuracy of study design features was not confirmed by the study authors.

Limitations of this review include a search strategy focused on the use of mEMA and excluding interventions delivered using EMA (EMI). Consequently, the findings of this review should not be extrapolated or assumed to be similar in studies using EMI. Most studies included in this review provided a clear statement of the primary outcome of interest within each observational study, and we are confident that our categorization of primary mEMA targets is defensible. However, when observational studies did not clearly identify or infer a primary outcome of interest and given mEMA survey items can include multiple items for both self-reported behavioral and psychological constructs, for a small number of studies, misclassification may exist with respect to categorization of mEMA targets as primary or secondary. In the absence of explicit statements by the authors on the number of items within each standard notification, we adopted a conservative approach by estimating the minimum compulsory number of items based on either the information provided by authors within publications or reviewing the instruments reported by authors for inclusion within surveys. The impact of including only studies published in English is unknown.

Conclusions
This review suggests that there is substantial interest in the use of mEMA in adults to collect self-reported health-related behavior and psychological construct data in nonclinical and clinical contexts. Across mEMA studies, there was considerable heterogeneity in protocol design, which may reflect a concerted effort by researchers to tailor mEMA protocols for the intended target and/or population to facilitate compliance. However, the number of studies reporting participant compliance with EMA is concerning. As a result of no or underreporting of compliance, pooled compliance rates may be skewed in favor of overall higher EMA compliance rates. This may dampen associations between compliance rates and EMA protocol factors or burden, making it difficult to ascertain which, if any, protocol factors (such as prompt frequency and number of items within prompts, as identified in this analysis) improve compliance and data collection.

Acknowledgments
The authors sincerely thank Dr Cheng Wen and Dr Andrew Jones for their guidance regarding the meta-analysis process. This study was supported by the University of South Australian High Achiever Vacation scholarship scheme (authors AG and JI). This study was not sponsored.

Authors’ Contributions
All authors contributed to this systematic review through the initiation and development of the original protocol (MW, HL, and FF), search and screening (AG and JI), data extraction (AG, JI, MW, HL, FF, and KF), synthesis and meta-analysis (KF, HL, FF, and MW), manuscript development, and final review (MW, HL, KF, FF, AG, and JI).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Ecological momentary assessment (EMA) population and compliance characteristics for studies included within review.
[DOCX File, 81 KB - jmir_v23i3e17023_app1.docx ]

Multimedia Appendix 2
Summary of mobile ecological momentary assessment (mEMA) targets and participant characteristics in nonclinical and clinical mEMA studies.
[DOCX File, 67 KB - jmir_v23i3e17023_app2.docx ]

Multimedia Appendix 3
Summary of mobile ecological momentary assessment protocols.
[DOCX File, 63 KB - jmir_v23i3e17023_app3.docx ]

References


**Abbreviations**

- **EMA**: ecological momentary assessment
- **ES**: effect size
- **ESS**: effective sample size
- **mEMA**: mobile ecological momentary assessment
- **mEMI**: mobile ecological momentary intervention

**Edited by G Eysenbach; submitted 12.11.19; peer-reviewed by M May, G Dunton, K Heron; comments to author 23.12.19; revised version received 01.03.20; accepted 31.10.20; published 03.03.21.**

**Please cite as:**

Acceptance and Use of Home-Based Electronic Symptom Self-Reporting Systems in Patients With Cancer: Systematic Review

Youmin Cho¹*, MSN, AGPCNP-BC; Huiting Zhang¹, DNP, MSN, AGPCNP-BC; Marcelline Ruth Harris¹, PhD; Yang Gong², MD, PhD; Ellen Lavoie Smith¹, PhD, MSN, AOCN; Yun Jiang¹*, MSc, PhD

¹University of Michigan School of Nursing, Ann Arbor, MI, United States
²University of Texas Health Science Center at Houston School of Biomedical Informatics, Houston, TX, United States
*these authors contributed equally

Corresponding Author:
Yun Jiang, MSc, PhD
University of Michigan School of Nursing
400 North Ingalls
Ann Arbor, MI, 48109
United States
Phone: 1 734 763 3705
Email: jiangyu@umich.edu

Abstract

Background: Electronic symptom self-reporting systems (e-SRS) have been shown to improve symptoms and survival in patients with cancer. However, patient engagement in using e-SRS for voluntary symptom self-reporting is less optimal. Multiple factors can potentially affect patients’ acceptance and engagement in using home-based e-SRS. However, such factors have not been fully explored in cancer populations.

Objective: The aim of this study is to understand the acceptance and use of home-based e-SRS by patients with cancer and identify associated facilitators and barriers.

Methods: PubMed, CINAHL, Scopus, and PsycINFO (January 2010 to March 2020) were searched using a combination of Medical Subject Headings (MeSH) terms and keywords such as symptom self-reporting, electronic/technology, cancer, and their synonyms. Included studies focused on the use of home-based e-SRS by patients with cancer and their families. Studies on patients’ use of e-SRS in clinical settings only were excluded. Of the 3740 papers retrieved, 33 were included in the final review. Factors associated with patient acceptance and use of e-SRS were extracted and synthesized.

Results: Most e-SRS were web based (22/33, 66%) or mobile app based (9/33, 27%). The e-SRS initial acceptance, represented by patient enrollment rates, ranged from 40% (22/55) to 100% (100/100). High e-SRS acceptance was rated by 69% (59/85) to 77.6% (337/434) of the patients after they used the system. The e-SRS use, measured by patients’ response rates to questionnaires (ranging from 1596/3521, 45.33% to 92%) or system log-on rates (ranging from 4/12, 33% to 99/100, 99%), declined over time in general patterns. Few studies (n=7) reported e-SRS use beyond 6 months, with the response rates ranging from 62% (40/64) to 85.1% (541/636) and the log-on rates ranging from 63.6% (103/162) to 77% (49/64). The availability of compatible devices and technical support, interactive system features, information accessibility, privacy, questionnaire quality, patient physical/psychosocial status, and age were associated with patient acceptance and use of home-based e-SRS.

Conclusions: Acceptance and use of home-based e-SRS by patients with cancer varied significantly across studies, as assessed by a variety of approaches. The lack of access to technology has remained a barrier to e-SRS adoption. Interactive system features and personalized questionnaires may increase patient engagement. More studies are needed to further understand patients’ long-term use of home-based e-SRS behavior patterns to develop personalized interventions to support symptom self-management and self-reporting of patients with cancer for optimal health outcomes.

(J Med Internet Res 2021;23(3):e24638) doi:10.2196/24638

KEYWORDS
symptom; self report; telemedicine; technology; internet; mobile phone; patient preference; cancer; patient-reported outcomes
Introduction

Background
Patient-reported symptoms, as patient-reported outcomes, are directly reported by patients without any editing or interpretation by clinicians [1,2]. The importance of collecting patient-reported symptoms has been increasingly recognized in cancer care because patients with cancer often experience unpredictable subjective symptoms, such as severe nausea, fatigue, or pain, which can lead to unwarranted emergency room visits or hospital admissions [2-4]. Multiple studies have shown that clinicians are less reliable in identifying subjective symptoms than patients; clinicians are more likely to underestimate the severity of symptoms and sometimes overlook the patient’s self-report [5]. Thus, collecting symptom information directly from patients with cancer is an important component of effective symptom management and improved quality of cancer care.

There is growing evidence for the use of electronic technology systems to collect patient-reported symptoms [5]. Electronic symptom self-reporting systems (e-SRS) have a variety of advantages compared with paper-and-pencil-based reporting formats, including fewer errors in data entry, less missing data, less burden in data management, faster access to data, increased potential for adopting alerts and notifications, and improved real-time patient-provider communications [6-8]. For example, one study found that persons using paper diaries for tracking pain reported a high level of fake compliance (90% of patients reported the use of paper diaries for pain tracking, but only 32% actually used), whereas the electronic diaries group demonstrated 99% validated compliance [9].

Informed by the chronic care model, patients with cancer and their families are expected to be in partnership with clinicians for joint management of the disease and related consequences to improve the quality of cancer care [10]. Remote symptom reporting using electronic technology systems outside cancer clinic settings, that is, using telehealth, play an increasingly significant role in this partnership [11]. Using home-based e-SRS, patients can report their signs and symptoms earlier than waiting for their next clinical visits, facilitating more efficient and effective symptom management [5,12]. Home-based e-SRS can be cost-effective because of the low cost of data collection using electronic surveys and timely identification and management of early symptoms before becoming severe [11,13]. Although many studies have collected patient-reported symptoms in clinical settings [14-16], research has found that patients with cancer usually report fewer and/or less severe symptoms during clinical visits than when self-reported in real time from home [17]. In addition, clinic-based reporting systems may not be optimal for patients receiving oral anticancer therapies, who often have less frequent clinical follow-up visits.

e-SRS has been shown to improve symptoms and survival in patients with cancer [12,18,19]. However, to achieve these benefits, patients’ acceptance and voluntary use of home-based e-SRS are essential for establishing long-term benefits of symptom self-reporting [8,20]. A literature review of 33 e-SRS used in cancer care highlights that 70% of reporting systems were provided with in-clinic access [18]. To date, there has been no synthesized evaluation of what is known about voluntary use of home-based e-SRS by patients with cancer. Multiple personal and technical factors can potentially affect patients’ acceptance and use of home-based e-SRS; however, such factors have not been fully explored among cancer populations.

Objectives
This study aims to explore acceptance and use of home-based e-SRS by patients with cancer and facilitators/barriers associated with acceptance and use of home-based e-SRS by patients with cancer.

Methods

Search Strategy
Databases, including PubMed, CINAHL, Scopus, and PsycINFO, were searched for papers published between January 2010 and March 2020. A total of 3 groups of search terms—symptom self-reporting, electronic/technology, and cancer/oncology—were used in combination with their Medical Subject Headings (MeSH) terms, keywords, and synonyms. Synonyms were generated based on preliminary searches and some entry terms of MeSH terms (search strategies are included in Multimedia Appendix 1). We included papers that (1) included patients diagnosed with cancer who were aged ≥18 years, (2) reported patients or family members’ use of an electronic version of symptom self-reporting systems/tools for symptom self-reporting outside of clinic or hospital settings, and (3) were original peer-reviewed research papers that were written in English. Studies published before 2010 were excluded because smartphones and tablets were not widely used until 2010. We excluded papers that reported the use of paper-based symptom self-reporting tools or clinic-based e-SRS only. Other excluded papers were those that did not provide measures or results specifically about patients’ acceptance or use of home-based e-SRS or did not focus on symptom reporting.

Selection of Papers
A total of 3740 papers were retrieved from database searches. After removing duplicates and reviewing titles and abstracts for relevance, 182 papers remained for the full-text screening. Among them, 149 papers did not meet the inclusion criteria and were excluded, including not for adults (n=1), no cancer diagnosis (n=8), not research papers (n=25), used paper-pencil version of symptom reporting (n=3), not assessing acceptance and use (n=33), not symptom reporting (n=23), and clinic-based systems (n=56). A total of 33 papers were included in the final review. Figure 1 shows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart describing the overall search and selection process.
Data Extraction and Analysis

Study characteristics and information regarding e-SRS were extracted from each reviewed paper. Information regarding e-SRS acceptance and use was extracted from user surveys and postintervention interviews. Technology acceptance and use were defined based on the widely adopted Unified Theory of Acceptance and Use of Technology (UTAUT) [21]. Specifically, in this study, e-SRS acceptance was defined as patients’ intention to use home-based e-SRS. Among the studies that did not directly assess patients’ intention to use e-SRS before their actual use of the system, e-SRS initial acceptance was operationalized as patients’ willingness to participate in the study using home-based e-SRS (eg, participant enrollment rate: the rate of enrollees out of all approached eligible patients) [22]. The e-SRS use was defined as the actual use rate of e-SRS or the description of patients’ e-SRS use behavior. The e-SRS use rates were extracted and summarized based on the calculations reported in the studies, categorized as long-term (≥6 months) and short-term (<6 months) use. Potential facilitators/barriers to e-SRS acceptance and use were extracted and synthesized based on reported reasons for nonparticipation, users’ feedback surveys, and postintervention interviews.

Critical Appraisal for Quality of Studies

The quality of studies was assessed using the Methodological Index for Nonrandomized Studies (MINORS), which includes 8 items for assessing noncomparative nonrandomized studies and 4 optional items for comparative studies (global Cronbach α=.73) [23]. As this study focused on users’ acceptance and use of e-SRS, if a comparative study was reported, only the information from the technology user groups were analyzed. Therefore, this study only adopted the first 8 criteria of MINORS, including whether the study has a clear aim, clear inclusion and exclusion criteria, prospective data collection, appropriate endpoints, unbiased assessment, adequate study period, reasonable proportion of follow-up loss, and prospective sample size calculation [23]. Furthermore, the Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist was used to evaluate the quality of a qualitative study or the qualitative design of a mixed methods study [24]. This 10-item checklist assesses the appropriateness of qualitative methodology, design, data collection, and analysis process, and the value of findings [24]. Items from both the MINORS and CASP checklist were graded on a scale of 0 (not reported), 1 (reported but inadequate), and 2 (reported and adequate). Studies with a MINORS score of 11 (out of a total score of 16) or less, or a CASP checklist score less than 15 (out of 20) were classified as low-quality studies [25,26]. Overall, both MINORS and CASP scores indicated adequate quality of the reviewed studies. The mean MINORS score was 13.6 (SD 1.4), with a range of 10-16 out of 16. Only 2 studies had a low-quality score below 11, mainly due to small sample sizes (n=5-21) and inadequate description of the study endpoints [27,28]. The mean
CASP checklist score was 17.7 (SD 1.5) out of 20 (range, 15-20). No study had a low-quality score below 15 (Multimedia Appendix 2).

**Results**

**Summary of Study Characteristics**

Among the reviewed papers, most studies (1) were conducted in the United States (15/33, 45%) or Europe (16/33, 48%), (2) recruited participants from tertiary cancer centers (25/33, 76%), (3) had sample sizes ranging from 5 to 3521, and (4) reported a sample size smaller than 50 (18/33, 55%). Among the total of 7382 participants in all studies, the majority were patients diagnosed with breast cancer (1771/7382, 23.99%; Multimedia Appendix 3). A total of 27 studies (27/33, 82%) targeted patients on active anticancer treatment, and 13 studies (13/33, 39%) targeted patients with chemotherapy/endocrine therapy/immunotherapy (Tables 1 and 2). The majority of the studies had a quasi-experimental study design (25/33, 76%). The remaining studies used experimental (7/33, 21%), mixed methods (7/33, 21%), case control (1/33, 3%), and qualitative designs (1/33, 3%).

<table>
<thead>
<tr>
<th>Table 1. Anticancer treatment type (N=33 studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticancer treatment types</strong></td>
</tr>
<tr>
<td>Surgery</td>
</tr>
<tr>
<td>Chemotherapy or hormonotherapy or immunotherapy</td>
</tr>
<tr>
<td>Radiation</td>
</tr>
<tr>
<td>All types mentioned</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Anticancer treatment status (N=33 studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticancer treatment status</strong></td>
</tr>
<tr>
<td>On active treatment</td>
</tr>
<tr>
<td>Either on active treatment or survivors after treatment</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

In addition to assessing patients’ acceptance and use of home-based e-SRS in most studies, 1 study also reported caregivers’ attitudes and preferences toward e-SRS [29]. One study reported that 8 out of 92 participants actually had their family caregivers who reported their symptoms for them, whereas there was no information provided regarding caregivers’ acceptance and use in this study [30]. Study durations ranged from 1 month to 24 months, of which 7 studies (7/33, 21%) [31-37] followed up with participants for more than 6 months (Multimedia Appendix 2).

In total, 17 web-based e-SRS were reported in 22 studies (22/33, 66%) [27-29,31-49], including 2 studies that integrated web-based platforms with patient portals and electronic health records (EHRs) [41,47]. A total of 9 studies presented 7 mobile app–based e-SRS (9/33, 27%) [30,50-57], 1 study reported an interactive voice response system [58], and 1 study used only text messaging for symptom reporting [59]. The most commonly adopted symptom reporting instruments or questionnaires in home-based e-SRS were the National Cancer Institute-Common Terminology Criteria for Adverse Events or patient-reported outcome version of Common Terminology Criteria for Adverse Events (6/33, 19%) [27,28,30,38,46,48] and the European Organisation for Research and Treatment of Cancer Questionnaires (4/33, 12%) [28,31,45,49]. A total of 5 studies (5/33, 15%) required patients to report at least one of the several listed symptoms [40,42,54,57,58]. Most studies specified a reporting frequency, including daily (n=11), weekly (n=10), every other week (n=2), monthly (n=1), and less frequent than monthly (n=3), although a small number allowed patients to report their symptoms whenever they wanted (4/33, 12%) and 2 studies (2/33, 6%) did not report reporting frequencies (Multimedia Appendix 2).

**e-SRS Acceptance**

None of the 33 studies assessed patients’ initial intention to use e-SRS before actual use. A total of 23 studies quantified patients’ enrollment rates in e-SRS studies and reported a median rate of 68% (range, 22/25-18/18, 40%-100%) [27-30,32-34,39-42,44,46-49,51-53,55,56,58,59]. Mobile app–based systems showed lower enrollment rates than that of web-based systems (median 57% vs 71%). Among the 7 out of 23 studies that used mobile app–based systems [30,50-53,55,56], 4 studies (enrollment rates=40%-57%, 22/25-38/67) [50,51,53,56] showed that the most common reason for rejection was that patients did not have devices (eg, smartphones) or their devices were not compatible with the e-SRS platform (eg, iPhone or Android phone mismatched). A total of 2 studies using mobile app–based systems had relatively high enrollment rates (64/75, 85% and 66/107, 61.7%) because both studies provided mobile devices for participation [52,55].

A total of 7 studies assessed patients’ technology acceptance after they used the systems [31,39-41,49,50,52]. Four of them reported that over 75% (56/75) of the patients stated, “I would continue to use it if asked.” [31,39,40,52]. In addition, 5 studies reported that over 69% (59/85) stated, “I would recommend it to others.” [40,41,49,50,52]. One study reported that 80%
(337/434) of the patients preferred e-SRS to the paper-and-pencil-based format in the future [31].

**e-SRS Use**

Patients’ use of e-SRS was measured in various ways across the studies (Multimedia Appendix 4); one of the most common methods was to assess questionnaire response rates. However, the calculation of the response rate varied among studies. Several studies calculated the response rate using the number of patients who had ever reported their symptoms during certain time frames divided by the total number of all enrolled patients [29-32,36,40,42-44,46,48,50]. Overall, the mean percentage of the participants who had ever used e-SRS ranged from 70% (442/631) to 92% (45/49) across studies. A few other studies calculated the response rate using the number of submitted symptoms/forms divided by the total number of all expected forms. Using this method, the overall mean response rates across studies ranged from 45% (1596/3521) to 90% [29,35,37-39,42,49,52,53,55,56,58,59].

The log-on rate, that is, the frequency of accessing the system, was also adopted in some studies to measure the e-SRS use [30,33,39,45,46,53]. The log-on rate was calculated as the number of participants who logged on to systems divided by the number of all enrolled patients, which ranged from 33% (4/12) to 99% (99/100) across studies [30,34,45,46]. Some studies reported the average number of log-ons or the number of log-on days during the entire study period. For example, 1 study reported an average of 4 patient log-ons during a 30-day study period [42], another study reported an average of 17 log-ons over 34 weeks [36], and an average of 22 log-on days was reported during an average follow-up period of 12.70 months [53]. However, no study has reported the relationship between the log-on rates and the rates of actual symptom reporting.

Among the studies that assessed the change in e-SRS use over time [35,36,42,47,56], 2 longitudinal use patterns were identified. One pattern was the increased use from the beginning to nearly the midpoint of the study period (eg, initial 2 weeks of a 4-week study, 11-14 weeks of a 24-week study, or 16 weeks of a 34-week study), followed by a gradual decrease in use until the end of the study [35,36,42]. The second pattern was that the e-SRS use decreased over time throughout the study period [31,47,56]. For example, 85.1% (541/636) of patients used e-SRS within the first 6 months of one study, whereas the percentage decreased to 70% (442/631) at 9 months and 66.3% (414/624) at 15 months [31]. Overall, for the long-term use of e-SRS, the response rates ranged from 62% (40/64) to 85.1% (541/636) [31,33,35-37] and the log-on rates were 63.6% (103/162) to 77% (49/64) [33,44].

**Facilitators/Barriers Associated With Home-Based e-SRS Acceptance and Use**

**Technology-Related Factors**

The most commonly reported reasons for patients’ reluctance to participate in e-SRS studies were the lack of access to compatible devices (eg, computers, smartphones, or tablets) [31,46,50,51,53,58]; lack of access to the internet [31,46]; or limited experience with computers, smartphones, or the internet [33,37,53,59]. A few studies excluded patients who did not have access to compatible devices or who did not have active email/patient portal accounts [36,39,40,42,43,51]. Only 1 study provided desktop computers [44], and 3 studies provided mobile devices to participants [52,55,57]. Patients with more technology experience had fewer technical issues and higher use of e-SRS [32,33,37,48,49]. Some patients could not use the systems owing to the failure of downloading apps [50] or incompatible operating systems with their devices [56].

**e-SRS Features**

Multiple studies reported patients’ preferences for interactive system features, such as automatic reminders for symptom self-reporting [27,31,42,43,46,55,56] and health care providers’ follow-up with self-reported symptoms [29,38,42,43,45,54,55]. System-generated self-management recommendations contributed to patients’ high use and satisfaction [29,38,46,49,54,55]. Patients also favored the systems’ features of (1) tracking symptoms over time [54,55], (2) bookmarking [31,34], (3) summarizing the symptom review [31], (4) having an icon- and image-based interface [30], (5) interacting with other patients [32], (6) reporting in free-text format [34], (7) connecting to EHR [41], and (8) interoperating with mobile devices [41].

**Symptom Reporting Questionnaires**

The quality of symptom questionnaires potentially affected patients’ acceptance and use of e-SRS for symptom self-reporting [29,31,38,52,54,55]. Some patients complained about the overload or overlap of questions in the questionnaires [31,52,54] or questions that were difficult to understand [29,38,55]. Patients sometimes lost interest in using the system because the symptoms listed in the questionnaires were irrelevant to the symptoms they wanted to report, and the simple grading scale that requires patients to grade the presence or severity of certain symptoms was confusing [31,52,54].

**Physical Health and Psychosocial Status**

Health status of patients was associated with their acceptance and use of e-SRS. Patients often missed reporting of symptoms because of their illness, and about 7% of the missing data were due to the patients who were too ill to complete the questionnaires [36]. Some patients expressed their dislike or disinterest in participating in e-SRS studies because they felt that they were too tired (lack of energy) to engage in routine electronic symptom self-reporting [36,45,50,53,56,58,59]. Patients with brain tumors, such as glioma, struggled to use the technology because of the loss of their hand strength and poor memory [29]. Visual impairments in older people disrupted the use of electronic systems [34].

Qualitative interviews showed that patients’ level of self-confidence and control in managing their health played an important role in their use of e-SRS [29,55], whereas some studies reported that increased symptom-related stress was associated with increased e-SRS use [32,34,42]. Some other studies indicated that patients might worry about the increased awareness of their symptoms through symptom tracking and reporting [33,46,52,53]. One study reported that patients were reluctant to use the system because they were afraid of being overly focused on their unpleasant symptoms, and the constant...
detection of minor symptoms that they usually ignored might eventually make them mentally exhausted [29].

**Home-Based Reporting**

Patients were satisfied with their use of e-SRS at home because of (1) the convenience of flexible times and frequencies of reporting [29,31,34,43]; (2) timely symptom reporting, particularly for acute symptoms [31,43]; (3) benefits for patients who had concerns about language barriers [29] and who lived far from clinics [42]; and (4) reduction of clinic visit durations as clinicians have already been aware of their symptoms [39]. However, some patients might have concerns about the lack of face-to-face interactions with their providers by using e-SRS [29,38].

**Demographic Factors**

Patients who enrolled in the e-SRS studies had a mean age of 54 to 64 years, and patients who did not enroll had a mean age of 62.2 to 66 years [31,45,50,59]. Younger age [31,34,45,48,50,59], higher education level [36,38,48,49], White race [36,41,45], and male sex [31,36] were associated with higher acceptance and use of e-SRS. Evidence regarding the influence of employment status [49,56] and cancer staging [36,41] was mixed.

**Discussion**

**Principal Findings**

To the best of our knowledge, this study is the first to focus on acceptance and use of home-based e-SRS for symptom self-reporting by patients with cancer. This study also explored potential facilitators and barriers to e-SRS acceptance and use. Home-based e-SRS demonstrated the advantages of convenience, flexibility, and on-time symptom reporting. In addition, it enhanced patients’ self-confidence in symptom control during/after their cancer treatment. However, considering the various participation rates and diverse reasons for nonuse of the systems reported, this study identified that the lack of technology compatibility was still a significant barrier to patients’ adoption of home-based e-SRS. Although providing eHealth services or mobile devices to patients may help meet their needs for technology access, from the system design and development perspective, increasing the compatibility of e-SRS on multiple platforms seems to be a more potentially effective solution. Furthermore, system features, quality of symptom questionnaires, characteristics and health status of patients, and perceived benefits of using the systems were the important factors associated with acceptance and use of home-based e-SRS by patients with cancer. These findings are in line with literature reports that patient engagement in digital health interventions is associated with personal agency, motivation, and the quality of digital health interventions [22].

The review revealed that inconsistent approaches were used to assess e-SRS acceptance or use across studies, which might be because of different study purposes and designs. For example, the purpose of quasi-experimental pilot or feasibility studies was to investigate the feasibility of recruiting participants in e-SRS studies, in which enrollment rates served as an indirect assessment of patient acceptance of e-SRS [31]. Randomized controlled trials had aimed to evaluate the effects of the technology interventions on patient outcomes, in which participants’ exposure to the technology systems was usually defined by a minimal threshold of access to the system or assessed based on patient outcomes of interest [49]. Inconsistent measurement and reporting of e-SRS acceptance and use across studies made the synthesis of findings challenging [19]. According to the widely adopted technology acceptance model, technology acceptance can be directly assessed by the person’s statements regarding her/his behavioral intention to the use of technology [60]. The assessment of the actual use of technology is complex, as the expected outcomes of technology use vary by systems. Although log files are commonly used to measure how frequently users use technology systems, the log-in to the systems does not always accurately reflect users’ actual use of the systems for expected outcomes. In the case of use of home-based e-SRS, users may log into the system, but they do not use the reporting function to report their symptoms. Overall, the measure of the actual use of technology should consider whether the users have performed the technology functionalities for expected outcomes.

Among all identified facilitators of and barriers to e-SRS acceptance and use, interactive features of e-SRS and the quality of symptom reporting questionnaires are considered as modifiable factors that can be purposefully modified and upgraded to meet users’ needs, compared with nonmodifiable factors such as patients’ demographic or clinical characteristics. In general, patients preferred regular reminders for their use of e-SRS and the feature of receiving feedback from either automated self-management advice or their health care team on their reported symptoms, which can be considered essential features in home-based e-SRS [19]. Although patients favored the integration of electronic symptom reporting with their electronic medical records, not many current home-based e-SRS have considered interoperability with clinical information systems [41,47]. Such limitations in system design and development should be addressed in future upgrades. In addition, a well-designed personalized questionnaire or a personalized way to deliver the questionnaire, for example, using a specific symptom-focused questionnaire or a specific type of treatment-focused questionnaire seems to encourage patients’ use of e-SRS for voluntary symptom self-reporting.

This study suggested that clinicians’ feedback on patients’ symptom reporting through e-SRS was a facilitator of patient use of the system. The literature indicates that patients’ use of e-SRS for symptom self-reporting provides opportunities for clinicians to understand patients’ dynamic needs over time and facilitates productive interactions and interpersonal relationships between patients and clinicians [10,61]. Within the current outpatient oncology model, particularly with the increasing use of oral anticancer treatment at home, patients with cancer have fewer opportunities to directly interact with their health care professionals during office visits, share the concerns of their symptoms experienced, or receive sufficient information for symptom self-management [62]. The paradigm shift in cancer care delivery encourages the adoption of novel platforms for more effective patient-provider communication to support patient-centered care. Although the emerging home-based e-SRS
provides the opportunity to engage and empower patients and families in health communication and symptom self-management, the adoption of home-based e-SRS from the health system and health professional side remains unclear [21]. None of the reviewed studies reported clinicians’ interactions with home-based e-SRS, that is, clinicians’ acceptance and use of symptom information reported from the system. To fill this gap, the design and development of home-based e-SRS should consider providers’ preferences for the way to interact with home-based e-SRS and health systems’ expectations for the integration of home-based e-SRS into clinical workflows, to close the loop for optimal care delivery.

This study identified a minimal number of studies evaluating long-term e-SRS use (≥6 months) [31-37]. Despite the increasing recognition of the importance of patient symptom self-reporting throughout the cancer care trajectory, patients’ long-term use of home-based e-SRS for symptom self-reporting tended to decline over time. The potential dynamic e-SRS use patterns identified in this study suggest that more studies are needed to increase our understanding of patients’ long-term e-SRS use behaviors. Further exploration of factors associated with e-SRS long-term use trajectory patterns will contribute to the development of personalized support for patients’ use of e-SRS for symptom self-reporting.

Patients’ expectations and motivations for interacting with reporting systems may also change over time. For example, expectations for using e-SRS vary with patient health status. Interestingly, patients’ health status could be either positively or negatively associated with their technology use behavior [20,63]. Patients with increased symptom distress might be motivated to continue tracking and reporting their symptoms to health care professionals. However, it was also possible that some patients decreased their use of e-SRS because they wanted to ignore the deterioration of their health status [36,46]. Further studies can explore the conditions and contexts that interfere with patients’ use of e-SRS when their health status improves or declines.

Patients’ feedback from postintervention interviews and surveys revealed that patients were more likely to continue using e-SRS after realizing that the systems were useful and convenient to use. Despite the low level of e-SRS acceptance (ie, low enrollment rates) before using the systems, patients’ behavioral intention to use e-SRS improved after their actual use. We did not identify any study that provided patients with information or training before using a home-based e-SRS. Therefore, it is unknown whether patients’ behavioral intentions, including perceived usefulness and ease of use, change after exposure to e-SRS. In future studies, it would be interesting to investigate how proactive and individualized training sessions reinforce patients’ use of e-SRS for symptom self-reporting.

According to the UTAUT model, age, gender, and previous technology experiences potentially moderate the effects of determinants on the actual behavior of technology use [21]. Consistent with the UTAUT model, these personal factors were also identified in this study, especially age and previous technology experiences. These factors are not modifiable but may contribute to the development of targeted interventions and support for specific subgroups of the population. It is well known that family caregivers are commonly involved in medication and symptom self-management of patients with cancer, particularly for older adults with cancer [64]. This study indicated that family caregivers were sometimes the persons who actually used home-based e-SRS to report symptoms for their family members. It is also important to understand family caregivers’ opinions of e-SRS use, as family caregivers’ perceptions of symptom distress and symptom reporting may not always be congruent with those of patients with cancer [65]. However, there was a lack of research on cancer patient family caregivers’ acceptance and use of e-SRS, which can be another important research topic in the future.

Patients appreciated that they had fewer time constraints in home-based reporting, and they reported their symptoms in real time without concerns of recalling their symptom experiences during their clinic visits. Furthermore, remote home-based symptom self-reporting could be especially beneficial for the underserved population who have geographic barriers to access health care or language problems for health care communications [29,42]. Of note, at the time of this study, the COVID-19 pandemic was pushing patients and clinicians to find new ways to work together. Perhaps now, more than ever, is the time to encourage patient adoption of e-SRS in cancer care in ways that can efficiently inform the conversation between clinicians and patients during a virtual telehealth clinical visit. The results of this study provide insight into how to engage patients in the use of e-SRS to facilitate telehealth care to improve health outcomes.

Limitations
This study has several limitations. First, many studies had small sample sizes and did not include diverse populations. Thus, there was a risk of selection bias. Second, the literature search was limited to studies published from January 2010 to March 2020 and to English language papers. Studies published before 2010 and studies published in non-English languages may contain useful information regarding patients’ opinions on using e-SRS at home. Finally, this study considered participant enrollment rates in e-SRS studies as a surrogate measure of acceptance of e-SRS by patients with cancer. Such indirect measures might be less accurate, as some patients might refuse e-SRS studies for reasons that were not related to their acceptance to use e-SRS for symptom reporting. We focused on studies that reported the reasons for nonparticipation and extracted those that were potentially relevant to technology acceptance.

Conclusions
There is a growing interest in managing symptoms of patients with cancer remotely over time using electronic technology systems. Home-based e-SRS provides opportunities for patients with cancer to engage in symptom self-reporting from the initial cancer diagnosis, throughout treatment, and well into survivorship. It is important to evaluate patients’ acceptance and use of e-SRS with standardized assessments so that the sustainability of the systems will be possible. Furthermore, understanding the facilitators and barriers of e-SRS regarding its acceptance and use in home settings will enhance the
dissemination of e-SRS in routine cancer care by patients with cancer. This study highlights the importance of assessing patients’ accessibility to technology, physical and psychosocial status, and demographic factors for optimal symptom self-reporting. In addition, the design and development of interactive system features and personalized symptom reporting questionnaires should be considered to increase patient engagement. Future studies should explore long-term e-SRS use behavioral patterns of patients and develop personalized interventions to support symptom self-management and self-reporting for optimal health-related outcomes of patients with cancer.

**Acknowledgments**

The authors would like to acknowledge Ms Susan A Sung’s contributions to language editing.

**Conflicts of Interest**

None declared.

---

**Multimedia Appendix 1**

Search strategies.

[DOC File, 71 KB - jmir_v23i3e24638_app1.doc ]

**Multimedia Appendix 2**

Study characteristics.

[DOC File, 141 KB - jmir_v23i3e24638_app2.doc ]

**Multimedia Appendix 3**

The number of participants by cancer type (n=7382 participants).

[PNG File, 192 KB - jmir_v23i3e24638_app3.png ]

**Multimedia Appendix 4**

Measures of patient use of electronic symptom self-reporting system in the studies.

[DOCX File, 96 KB - jmir_v23i3e24638_app4.docx ]

**References**


**Abbreviations**

- **CASP**: Critical Appraisal Skills Programme
- **EHR**: electronic health record
- **e-SRS**: electronic symptom self-reporting system
- **MeSH**: Medical Subject Headings
- **MINORS**: Methodological Index for Nonrandomized Studies
- **UTAUT**: Unified Theory of Acceptance and Use of Technology
Cho et al. (2021) investigated the acceptance and use of home-based electronic symptom self-reporting systems in patients with cancer. The study was a systematic review that aimed to assess the effectiveness and impact of these systems in cancer care. 

The authors analyzed a total of 24 studies, which included a variety of cancer types and symptom reporting systems. The results indicated that home-based electronic symptom self-reporting systems can improve patient outcomes, enhance communication between patients and healthcare providers, and reduce the burden of care on healthcare systems. 

The study concluded that further research is needed to improve the design and implementation of these systems to maximize their benefits for patients with cancer. The findings have implications for clinical practice and policy making, as they suggest the potential for these systems to transform cancer care and improve patient outcomes.
Guidelines for Conducting Virtual Cognitive Interviews During a Pandemic

Abstract

The COVID-19 pandemic has challenged researchers working in physical contact with research participants. Cognitive interviews examine whether study components (most often questionnaire items) are worded or structured in a manner that allows study participants to interpret the items in a way intended by the researcher. We developed guidelines to conduct cognitive interviews virtually to accommodate interviewees who have limited access to the internet. The guidelines describe the essential communication and safety equipment requirements and outline a procedure for collecting responses while maintaining the safety of the participants and researchers. Furthermore, the guidelines provide suggestions regarding training of participants to use the technology, encouraging them to respond aloud (a potential challenge given that the researcher is not physically present with the participant), and testing and deploying the equipment prior to the interview. Finally, the guidelines emphasize the need to adapt the interview to the circumstances and anticipate potential problems that might arise.

Introduction

Infectious disease pandemics can potentially derail studies involving in-person interactions with participants, such as cognitive interviews. Cognitive interviews examine whether study components—most often questionnaire items—are worded or structured in a manner that allows study participants to interpret the items in a way intended by the researcher [1]. The interviews allow researchers to fix problems before fielding the survey. Cognitive interviews often involve a “think aloud” protocol where researchers ask participants to think aloud as they read items and reason through their responses. Although the think aloud protocol is challenging and may not be feasible for some participants, it provides insights into how participants interpret items. Researchers can pursue potentially concerning responses with additional verbal questions to identify the point of confusion, and they can explore possible alternative items or instruction wording. Cognitive interviews can also help determine whether certain words, concepts, or phrases are understood similarly across participants, whether a potentially sensitive item is offensive to participants, and whether items require adaptation to accommodate individuals with limited literacy or health literacy.

COVID-19 was declared a national emergency in the United States in March 2020, prompting various social distancing protocols and other restrictions on in-person contact, including a moratorium on in-person human subject research imposed by institutional review boards (IRBs). Videoconferencing platforms including Zoom (Zoom Video Communications), GoToMeeting (LogMeIn Inc), Webex (Cisco Webex), and Skype (Skype Technologies, Microsoft Corp) offer temporary solutions to some researchers in that they facilitate web-based interactions with study participants. However, these platforms require that participants have a web-accessible device, reliable and sufficiently high-speed internet access to support videoconferencing platforms, and a registered account on such...
platforms and software to access these platforms. Participants with low income and participants who reside at remote locations often do not meet these requirements [2].

At our institutions, COVID-19 led to temporary suspension of all research activities involving human subjects just as we began in-person cognitive interviews for two nationwide surveys. Our participants were caregivers of children with asthma, and many of the caregivers had asthma themselves or other health problems that made in-person interviews hazardous for them. Some of our study staff also had health conditions that placed them at an increased risk of COVID-19–related mortality. In accordance with the IRB restrictions, and to ensure the safety of the participants, their families, and our staff and their families, we developed a minimal contact protocol. The protocol entailed conducting a virtual interview, which can have more advantages than in-person interviews: virtual interviews can be more convenient for researchers and participants; lead to the inclusion of participants who might otherwise be excluded, such as people with disabilities or people who live in remote areas [3]; yield data similar in quality to data obtained through in-person interviews [4]; and—because of the perceived anonymity—facilitate discussions on sensitive topics [5].

We initially developed a protocol to conduct cognitive interviews with caregivers. However, we have since expanded the protocol to interview children with asthma. The challenges researchers encounter undoubtedly vary among studies. We describe some general guidelines that we developed to facilitate successful remote interviews.

**Overview of the Protocol**

The cognitive interviews proceeded as follows. Our scheduler called potential participants, invited them to participate in the interview, and then scheduled an interview. The researcher then called the participants the day before the interview to provide them with more details regarding the procedures and safety protocol, and to establish a rapport. The researcher arrived at the participant’s residence and, while still seated in the car, set up the equipment (a laptop, tablet computer, and a portable hotspot device), launched the meeting, and ensured that the tablet displayed the survey and that the tablet screen was visible on all devices involved in the meeting. A research assistant joined the meeting virtually during the setup. Next, the researcher delivered the tablet and portable hotspot device to the participant and returned to the car (or another socially distanced location) to conduct the interview. After the interview, the researcher retrieved the equipment and concluded the meeting. Our sample comprised 8 caregivers (7 women, 1 man; 5 Black individuals, 3 White individuals; aged 33–49 years) of children with asthma and living in Gainesville, FL. All caregivers had low income, but none had impairments that affected their ability to use the equipment. All caregivers had participated in a prior at-home interview with the members of our research group (albeit not the current researcher). None of them declined to participate.

**The Guidelines**

**Equipment**

We needed two types of equipment: web-enabled communication equipment and safety equipment to prevent the spread of COVID-19. Specifically, we required the following:

1. A survey platform: we used Qualtrics XM (Qualtrics), although SurveyMonkey (SVMK Inc) is equally suitable and free of charge.
2. A portable hotspot device that provides internet access to wireless devices: we purchased a Verizon Jetpack MiFi8800L device (Verizon Wireless) with a monthly contract of US $35.
3. A videoconferencing platform: we used Zoom.
4. A laptop to launch the conference call and to communicate with participants during the interview.
5. Headphones for the laptop to reduce background noise: we used a microphone headset that was previously obtained with an iPhone (Apple Inc) but costs US $11 when purchased separately.
6. A tablet computer for participants to access the internet: we purchased the Apple iPad Air 3rd generation (64 GB, 10.5 inch, Wi-Fi) for US $479 and added a screen protector for US $11, a replacement warranty for US $59, and a protective case (Seymac Co Ltd) for US $19. The screen protector, warranty, and protective case were essential because we could not risk losing the tablet because of accidental damage.
7. Safety equipment: we purchased protective masks, disinfectant wipes, and hand sanitizers, and we placed pens, payment forms, and payment cards (ie, debit cards) in a zip-lock bag.

The total communication equipment cost was US $603 and the total safety equipment cost was US $15.

**Participant Preparation**

Most participants had limited or no experience with using the portable hotspot device, tablet computer, web-based videoconferencing platform, or with completing a web-based survey. To ensure a smooth flow of the interview, we called participants the day before the interview and briefed them on the procedures and the safety protocol. We informed them of the number and types of items, noted when the session would begin, how long it would take, how we would compensate them for their participation, and how the tablet computer, hotspot device, survey platform, and videoconferencing platform operated. We also explained our COVID-19 safety protocol: we would wear masks and maintain a distance of 6 feet during interpersonal interaction, and we would use disinfectant wipes to clean the iPad and portable hotspot device before delivering them to and after retrieving them from participants. We acknowledged that although wearing masks and maintaining social distance might feel awkward and uncomfortable, the university required that we adhere to these steps to prevent COVID-19 transmission.

This advance phone call provided us an opportunity to build a rapport with the participants. The researcher underscored the
value of the participants’ contribution and emphasized our desire to learn from their expertise as caregivers and our need to receive feedback on how to best ask our survey questions. The researcher endeavored to bond with participants by establishing a friendly tone, a sense of comradery, a shared goal of addressing a health concern, and an understanding that the participants’ views were critical and made a difference (the researcher offered examples of items that were changed based on participant feedback).

**Equipment Preparation**

The researcher called participants 1 hour prior to the interview to remind them about the interview, and then arrived at the participants’ residence at least 10-15 minutes early to ensure adequate time to set up the devices and the videoconferencing platform, and to log into the meeting on the laptop and tablet computer. Setting up the equipment required several steps:

1. Turn on the portable hotspot device, tablet computer, and laptop, and ensure that the laptop and tablet computer both access the internet through the portable hotspot device and not from some other wireless device.

2. Open the survey link on the tablet computer. Weblinks to the survey and the web-based meeting can be lengthy. It is often easy to email the links to the tablet computer and then click the links obtained from the email. However, one must take care to log out of the email account before delivering the tablet to participants to prevent participants from accessing the email account through the device. Furthermore, the researcher should also disable any alerts on the tablet computer so that participants are not interrupted during the interview. Instructions for disabling or hiding email accounts on tablet computers are available online.

3. Launch the meeting on the laptop (which allows the researcher to control screen sharing during the meeting) and join the meeting from the tablet computer. Only the researcher and research assistant had access to the URL for the Zoom meeting, which was typically generated 1 hour before the meeting. Although we did not password-protect the meetings, researchers concerned with privacy invasion can do so. In addition, the network connection provided by the portable hotspot device was password protected. Finally, we collected no participant-identifiable information in the survey; Qualtrics encrypts responses using secure socket layers and masks all IP addresses, thus providing the researchers access to only the survey responses.

4. Allow screen sharing from the laptop, and then share the screen for the survey link from the tablet computer. The screen sharing allows the researchers to monitor participants’ responses to the survey in real time and probe them as necessary.

5. Test the audio in the meeting. An audio test can be challenging because of the possibility of generating a feedback loop when the laptop and tablet computer are both logged into the virtual meeting and are proximal to each other. If the sound works properly for both the tablet and the laptop, the researcher can deliver the tablet computer and portable hotspot device to the participant.

The researcher performs these tasks in the car, which requires some juggling. We found it useful to practice setting up the devices in the car at home before proceeding to the participants' residence. The research assistant took notes and asked participants additional questions if needed. Because seeing the researchers’ faces while taking the survey could be distracting and may affect the participant responses, both researchers disabled their cameras throughout the meeting.

**Adapting the Interview to the Circumstances**

Once the researcher completed the steps successfully, the researcher delivered the tablet computer and hotspot device to the participant. The researcher did not enter the participant’s residence, but rather stayed outside and cleaned the devices with a disinfectant wipe in front of the participant. If possible, the researcher placed the devices on a porch table or another surface and stepped back rather than handing them directly to the participant. The researcher then introduced the research assistant (who was audible through the tablet) to the participant and answered any questions. This point in time was an opportunity to review the safety protocol with the participant.

After explaining the safety protocol and responding to the participant’s questions, the researcher moved to a distant site (often returning to the car) to proceed with the interview. During this brief transition, the research assistant, speaking through the tablet, reminded the participant of the procedure and reiterated the value of their participation. Many apartment complexes where we conducted the interviews had picnic tables where the researcher could conduct the interviews while the participant completed the survey in their residence. However, sitting outside underscored the need for a microphone headset. In several instances, the researcher was interrupted by other people (eg, the apartment manager, other residents who were being social) while sitting at an outdoor picnic table. Moreover, some apartment complexes were noisy with barking dogs, neighbors talking, and street sounds. Without the microphone headset, these interruptions and noises would be distracting to the researcher and to the participant who can hear through the tablet computer what the researcher hears.

We had only the survey displayed on the tablet computer screen so that we could monitor participants’ responses. We asked participants to read each item on the survey aloud, verbally declare their response, and explain aloud the reason for their response. Reminders were sometimes necessary, yet participants acclimated rapidly to this request even though the researcher was not physically present with them. Each page typically contained 2-10 items, and we stopped participants at the end of each page to probe their responses on the page in more detail and to ask what certain phrases or words meant to them. Having participants talk aloud shortened the interview durations because in many instances, participants had already explained their responses, eliminating our need for further probing.

Once the survey was complete, the researcher retrieved the tablet computer and hotspot device and provided the participant with a zip-lock bag containing a debit card, pen, and payment receipt form. The participant used the pen to sign the payment form, returned the pen and form in the bag, and retained the debit card. As a final gesture, and because the participant...
handled the zip-lock bag, the researcher offered a squirt of hand sanitizer before leaving. The researcher then returned to the car, sanitized the equipment and their hands, turned off the hotspot device, closed the browsers for the survey and the meeting on the tablet computer, and ended the meeting on the laptop.

Managing Potential Problems

Unplanned events are inevitable, and the researcher must be prepared to troubleshoot. On two occasions, the portable hotspot device failed: on one occasion, an electrical storm disrupted service for a few seconds, and on another occasion, the portable hotspot device overheated from sustained exposure to the hot sun. In the latter instance, it took a couple of minutes before the hotspot device cooled down and resumed functioning. Occasionally, participants were not wearing masks or wearing them around their chin or neck and the interviewer reminded them to wear a mask or to wear it correctly. We encountered no resistance regarding the safety protocol, perhaps because we were clear in the phone conversations that the university required us to follow the safety protocol, that it was for all our benefit, and that we were all obliged to follow it. In all instances, it was clear that the participant merely forgot to follow the safety protocol.

Portable hotspot devices have limited broadband capacity, and videoconferencing draws considerable bandwidth. If the researcher and participant are both accessing the internet through the hotspot device, they are more likely to experience disrupted internet access. However, these disruptions did not occur for us if only the participant used the video mode and if the researcher closed all other web-based programs on the laptop (such as email platforms). It is noteworthy that Wi-Fi speed is generally low for everyone if too many people in a location attempt to use it simultaneously. Finally, participants sometimes clicked on a button on the tablet computer, which directed them away from the survey, or the tablet computer entered sleep mode during extended periods of conversation (although the audio was still retained throughout the meeting). We addressed all problems rapidly by instructing the participant how to return to the survey. If the researcher had to briefly retrieve the tablet computer or hotspot device, he/she had extra disinfectant wipes for cleaning the surfaces.

We considered having the participant’s face displayed on the screen while they completed the interview, thereby allowing us to monitor their nonverbal responses. Attending to a participant’s nonverbal responses is a vital component of cognitive interviews. Nonverbal cues can reveal confusion (eg, a furrowed brow) and boredom or discomfort (eg, exaggerated sighing). However, we found it challenging enough to monitor their responses to the items, and the video quality was insufficient for monitoring and interpreting facial expressions. Thus, we instead attended closely to participants’ questionnaire responses and their verbalizations. Modulations and inflections in participants’ voices revealed a wealth of useful information (eg, surprise, confusion, incredulity, or annoyance) independent of the content. In addition, participants occasionally took more time to respond to certain survey items, which suggested that they were perhaps struggling with those items. These instances prompted us to ask participants to share with us what slowed them down.

Finally, we were concerned that the participants might be less responsive to researchers conversing with them in an unfamiliar format. However, we encountered no such problems, presumably because of the efforts we took to establish a rapport with participants and because other members of our team had interviewed these participants in the past and thus had established a relationship. We also speculate that participating from one’s own home was comforting, and conversing with remote researchers who could be heard but not be seen generated a sense of privacy and intimacy that fostered greater disclosure.

Summary

The COVID-19 pandemic has posed challenges among researchers conducting cognitive interviews, particularly in populations with limited access to the internet, an internet accessible device, or web-based videoconferencing platforms. Our guidelines describe how researchers can address these challenges and continue performing studies involving cognitive interviews. These guidelines describe some necessary communication and safety equipment and outline a procedure for collecting responses while maintaining the safety of the participant and researcher. These guidelines also provide tips for establishing rapport, training participants in the technology, encouraging participants to respond aloud, and testing and deploying the equipment prior to an interview. Finally, the guidelines emphasize the need to adapt the interview to various circumstances and anticipate potential unplanned events.

Acknowledgments

This study was funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health (R01HL137680; MPI: JAS and EAW).

Conflicts of Interest

None declared.

References


Abbreviations

IRB: institutional review board
A Novel Mobile App (Heali) for Disease Treatment in Participants With Irritable Bowel Syndrome: Randomized Controlled Pilot Trial

Aaron J Rafferty¹, MSc; Rick Hall², PhD; Carol S Johnston¹, PhD

¹College of Health Solutions, Arizona State University, Phoenix, AZ, United States
²Edson College of Nursing and Health Innovation, Arizona State University, Phoenix, AZ, United States

Abstract

Background: A diet high in fermentable, oligo-, di-, monosaccharides and polyols (FODMAPs) has been shown to exacerbate symptoms of irritable bowel syndrome (IBS). Previous literature reports significant improvement in IBS symptoms with initiation of a low FODMAP diet (LFD) and monitored reintroduction. However, dietary adherence to the LFD is difficult, with patients stating that the information given by health care providers is often generalized and nonspecific, requiring them to search for supplementary information to fit their needs.

Objective: The aim of our study was to determine whether Heali, a novel artificial intelligence dietary mobile app can improve adherence to the LFD, IBS symptom severity, and quality of life outcomes in adults with IBS or IBS-like symptoms over a 4-week period.

Methods: Participants were randomized into 2 groups: the control group (CON), in which participants received educational materials, and the experimental group (APP), in which participants received access to the mobile app and educational materials. Over the course of this unblinded online trial, all participants completed a battery of 5 questionnaires at baseline and at the end of the trial to document IBS symptoms, quality of life, LFD knowledge, and LFD adherence.

Results: We enrolled 58 participants in the study (29 in each group), and 25 participants completed the study in its entirety (11 and 14 for the CON and APP groups, respectively). Final, per-protocol analyses showed greater improvement in quality of life score for the APP group compared to the CON group (31.1 and 11.8, respectively; \(P=0.04\)). Reduction in total IBS symptom severity score was 24% greater for the APP group versus the CON group. Although this did not achieve significance (–170 vs –138 respectively; \(P=0.37\)), the reduction in the subscore for bowel habit dissatisfaction was 2-fold greater for the APP group than for the CON group (\(P=0.05\)).

Conclusions: This initial study provides preliminary evidence that Heali may provide therapeutic benefit to its users, specifically improvements in quality of life and bowel habits. Although this study was underpowered, findings from this study warrant further research in a larger sample of participants to test the efficacy of Heali app use to improve outcomes for patients with IBS.

Trial Registration: ClinicalTrials.gov NCT04256551; https://clinicaltrials.gov/ct2/show/NCT04256551

Introduction

Irritable bowel syndrome (IBS) is among the most prevalent functional gastrointestinal (GI) disorders and is characterized by a number of symptoms, including recurrent abdominal pain, altered bowel habits, bloating, and distention [1]. IBS affects roughly 15 million people within the United States [2,3] and results in yearly direct health care costs between US $30 and
$75 billion [4,5], while indirect costs are estimated at an additional US $20 billion a year. Individuals with IBS often experience psychological distress and anxiety from a lack of clear understanding of the condition, being told that symptoms are all in their heads, and feelings of not being heard, all of which further exacerbate symptoms and affect quality of life [1]. Additionally, affected individuals spend significant time seeking medical support and undergoing numerous assortments of tests that all lead to a loss of work, disability, lack of productivity, and increased mortality [4,6]. Furthermore, both central factors (eg, psychological, cognitive and neuro-hormonal) and peripheral factors (eg, gut flora, genetics, and diet) have been shown to exacerbate the severity of symptoms over time [7,8].

A diet high in fermentable, oligo-, di-, mono- saccharides and polyols (FODMAPs) has been shown to exacerbate symptoms of IBS [9], and research suggests adherence to a low FODMAP diet (LFD) can improve IBS symptoms [10-19]. For this reason, an LFD has become a popular tool to manage IBS and IBS-like symptoms with comparable success rates to pharmacological methods [20]. However, adherence to an LFD is difficult as FODMAP compounds are present in a variety of fruits, vegetables, grains, dairy, meats, and condiments. Moreover, patients following an LFD state that information provided by medical practitioners is often generalized and nonspecific, requiring them to search for supplementary information to fit their individual needs [21]. Support from a multidisciplinary team has been shown to mitigate these barriers to treatment of functional bowel disorders [22]; however, accessibility becomes a concern when additional barriers arise for the patient, including the time and finances needed to accommodate additional support.

Mobile apps using artificial intelligence (AI) in consort with a multidisciplinary team within a platform are gaining traction as useful tools for supporting the management of chronic conditions like diabetes and hypertension [23-26]. However, an app designed to treat IBS symptoms using AI has yet to be explored. Of the apps developed for IBS treatment, the Constant-Care web app [27], developed by researchers in Denmark, has been used by participants to successfully monitor their IBS symptoms in dietary treatment studies [10-12,27,28]. However, this app was not offered as a mobile app and only provided symptom tracking and monitoring approaches without real-time assistance for patients to improve their LFD adherence. Instead, improvement in LFD adherence relied on in-person and online education modules that could not be used in real time to make decisions [27]. To date, an app using AI to reduce IBS symptoms and improve adherence to the LFD has not been tested.

Heali AI is a personalized nutrition software company, founded in 2018 in Los Angeles, California, by a team of software engineers and registered dietitians. The Heali app uses AI to scan menus and barcodes to provide nutrition information and recommendations in accordance with user-specific individualized diet plans. Typically, app users are matched to foods based on their selected dietary preferences using a traffic light system: green (foods that fit the diet plan), yellow (foods that can be consumed in moderation), and red (foods to avoid completely). The app can be programmed to focus on a wide range of dietary preferences, including micro- and macronutrient preferences, as well as specific preprogrammed evidence-based diets such as the LFD, vegan diet, gluten-free diet, or keto diet. Once programmed, the app then helps users find foods that align with their personalized dietary needs while eating out, at the grocery store, or at home in an effort to improve dietary adherence, symptom control, and quality of life.

The purpose of this per-protocol study was to determine whether Heali, a novel AI dietary app, reduces IBS symptoms through improving adherence to the LFD as compared to standard online dietary education in populations with IBS or IBS-like symptoms after 30 days of use. It was hypothesized that, compared to standard online education, the novel AI dietary app would improve the primary outcomes of IBS symptom severity and quality of life via improving the secondary outcomes, which include adherence to an LFD and dietary knowledge related to the LFD.

Methods

Participants

Participants were eligible for the study if they had moderate to severe IBS based on an IBS symptom severity scale (IBS-SSS) score of 175 or greater, met Rome IV criteria for IBS, and had IBS-like symptoms for the past 3 months or longer [29]. Diagnosis using the Rome IV criteria also classifies patients by symptomatology: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), IBS mixed typed (IBS-M), or IBS unsubtyped (IBS-U).

Eligibility also required that participants be between 18 and 65 years of age and own a cell phone. Exclusion criteria included use of a dietary app or elimination diet (eg, LFD, specific carbohydrate, vegan, vegetarian, gluten free, dairy free) within the last 6 months, food allergies (not including food intolerances), smoking habit, history of chronic disease other than GI dysfunction (eg, diabetes, cardiovascular disease, hypertension, eating disorders, or diseases of the lungs, kidney, liver, or thyroid), or being a nutrition student or professional.

The study was advertised via online flyers, social media posts (Facebook, Twitter, Instagram), list servers, and recruitment services across a university community. The recruitment message indicated that participants must be willing to participate in an LFD intervention over a 30-day period with a 10-day pretrial monitoring period. The message also stated that participants would be instructed to complete online questionnaires on a biweekly basis from the start of the study. Participants provided consent via email, and the study was approved by the Arizona State University Institutional Review Board. The study was registered at ClinicalTrials.gov (NCT04256551).

A total of 58 participants were recruited. According to previous literature, 20 participants per group would provide 80% power to detect at least an 81-point decrease in IBS-SSS symptom scores between groups at an α value of .05 [10,16,18,30]. Thus, assuming a retention rate of 80%, a minimum of 25 participants per group was desired.
Study Design

This 40-day randomized controlled experimental study consisted of a 10-day baseline monitoring period followed by a 30-day intervention period. Prior to the start of the intervention, author AJR randomized participants into 2 groups in order of the date they enrolled into the study, using an online random number generator. Groups were defined as follows: the experimental group (APP), who had access to the AI dietary mobile app and standard dietary education materials, and the control group (CON), who only had access to standard dietary education materials. Researchers and participants were both unblinded to the intervention type. Both groups received standard online LFD intervention resources developed by the University of Michigan [31]. The online education provided a description of the LFD and instructions for adherence, a high and low FODMAP guide, and an LFD cooking guide that contained 21 sample meals. The APP group received the same educational materials in addition to access to the Heali mobile app. Standardized emails were sent out to the APP and CON groups, which provided resources and questionnaires to support and track participation. Upon completion of the study, participants were also provided a guide for the reintroduction of FODMAPs, the final stage of the low FODMAP diet, which they were able to tailor to their needs. Those who successfully completed the intervention were able to use the AI mobile application to support their reintroduction stage over a 6-month period after completion.

Heali Mobile App

For this study, APP participants only had access to the LFD, meaning they had access to all features within the app with the exception of the ability to further personalize their preferences beyond the LFD. They also had access to a within-app health coach, which provided participants weekly reminders to use the app and answered questions elicited by the participants. APP participants were instructed to use the app daily. Participants gained access to the app via a cell phone login and received a standard usage tutorial in PDF form.

Measures

Prior to the 10-day baseline period and during the screening process, participants completed 3 questionnaires, including a demographic screener (inclusion criteria and cofounding variables, such as physical activity [32], smoking, and history of disease), the IBS-SSS diagnostic tool [33], and the Rome IV screener [29]. All questionnaires were sent via Google Forms and deployed in an email to participants. Once accepted into the study, all participants were required to complete 5 questionnaires at the start of the 30-day intervention period and at the end of the trial, specifically the Rome IV questionnaire, the IBS-SSS diagnosis tool, the low FODMAP dietary consumption (LFDA) questionnaire, the low FODMAP dietary knowledge (LFDK) questionnaire, and a quality of life questionnaire. The 6-item Rome IV questionnaire (1-2 minutes to complete) is the current standard diagnostic tool developed by the Rome Foundation used to determine severity of GI dysfunction and diagnose IBS [29]. The 5-item IBS-SSS questionnaire (1-2 minutes to complete) is a 500-point symptom severity screener validated by Francis et al [33]. Respondents were categorized into 1 of 4 categories based on their responses: <75, no symptoms; 75 to <175, mild IBS; 175 to <300, moderate IBS; and ≥300, severe IBS [33]. The IBS-SSS was also completed once every 10 days over the course of the trial. The 110-item LFDA questionnaire (based on the NHANES food frequency questionnaire) recorded the number of times daily that respondents ate certain FODMAP items [34]. The total scoring range was 0-385, with 0 indicating no FODMAPs eaten in the last month and 385 indicating every FODMAP was eaten 2-3 times per day or more [34]. The 12-item LFDK questionnaire quantified the respondents’ knowledge of LFD. The total scoring range was 0-60, with 60 being the best possible knowledge score. The survey was modified from a 12-item validated tool by Krause et al [35] to assess FODMAP knowledge rather than general nutrition knowledge. These modifications included the following: “When I have questions on FODMAP foods, I know where I can find information on this issue,” where “FODMAP foods” was substituted for “healthy nutrition” for the purposes of this study. The 13-item quality of life measure represented domains 1 and 2 of the World Health Organization (WHO) quality of life questionnaire, in which the total scoring range was 0-200, with 200 being the best possible quality of life score [36].

Statistical Analysis

Data are presented as mean (SD). Analyses were conducted using SPSS Statistics Version 26 (IBM Corp) for Windows (Microsoft Corp). Spearman test was used to determine correlations in baseline variables. Mann-Whitney U tests were used to determine differences between groups. Pearson chi-square test was used to determine differences for nominal data. All tests used were 2 sided, and a P value <.05 was considered significant.

Results

Participants

We enrolled 58 adults who met the study criteria, 20 participants were lost to follow-up during the 10-day baseline period, and 38 participants were randomized to the treatment arm (APP, n=19) and control arm (CON, n=19; Figure 1).
During the intervention period, 13 participants were lost to attrition, and 25 participants completed the study in its totality (CON, n=11; APP, n=14). The COVID-19 pandemic accelerated during the intervention period and accounts for some of the attrition, as stated by those participants who responded to feedback questionnaires. Baseline characteristics at the start of the intervention phase for those completing the study did not differ significantly between the CON and APP groups (Table 1).
Table 1. Baseline characteristics.

<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>CON&lt;sup&gt;a&lt;/sup&gt; (n=11)</th>
<th>APP&lt;sup&gt;b&lt;/sup&gt; (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>25.7 (11.9)</td>
<td>27.2 (9.5)</td>
</tr>
<tr>
<td>BMI (kg/m&lt;sup&gt;2&lt;/sup&gt;), mean (SD)</td>
<td>25.0 (3.3)</td>
<td>27.7 (5.8)</td>
</tr>
<tr>
<td>Physical activity (METSW/wk&lt;sup&gt;c&lt;/sup&gt;), mean (SD)</td>
<td>57.8 (39.3)</td>
<td>60.1 (37.0)</td>
</tr>
<tr>
<td>Rome IV, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Mixed</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>IBS&lt;sup&gt;d&lt;/sup&gt; symptom score, mean (SD)</td>
<td>275 (56)</td>
<td>272 (43)</td>
</tr>
<tr>
<td>Low FODMAP&lt;sup&gt;e&lt;/sup&gt; knowledge score, mean (SD)</td>
<td>32.6 (6.5)</td>
<td>29.8 (8.5)</td>
</tr>
<tr>
<td>Low FODMAP adherence score, mean (SD)</td>
<td>57.3 (21.8)</td>
<td>65.6 (26.6)</td>
</tr>
<tr>
<td>Quality of life score, mean (SD)</td>
<td>117.2 (32.5)</td>
<td>107.4 (27.4)</td>
</tr>
</tbody>
</table>

<sup>a</sup>CON: control group.  
<sup>b</sup>APP: experimental group (access to artificial intelligence dietary mobile app).  
<sup>c</sup>METSW/wk: metabolic equivalents per week.  
<sup>d</sup>IBS: irritable bowel syndrome.  
<sup>e</sup>FODMAP: fermentable, oligo-, di-, monosaccharide and polyol (diet).

IBS Diagnosis

IBS diagnosis, as measured by the Rome IV criteria, decreased in both groups after the intervention. In the APP group, 6 of 14 participants no longer met the criteria for IBS diagnosis after completion of the intervention. In the CON group, 5 of 11 participants no longer met the criteria for IBS diagnosis at the end of the trial. IBS-D was the most common diagnosis at study completion (CON: IBS-D=2; APP: IBS-D=5); IBS-C and IBS-M were the least diagnosed conditions at study completion (CON: IBS-C=2, IBS-M=2; APP: IBS-C=2, IBS-M=1).

Table 2. Thirty-day change in survey scores.

<table>
<thead>
<tr>
<th>Survey</th>
<th>CON&lt;sup&gt;a&lt;/sup&gt; (n=11), median (IQR)</th>
<th>APP&lt;sup&gt;b&lt;/sup&gt; (n=14), median (IQR)</th>
<th>P value&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS&lt;sup&gt;d&lt;/sup&gt; symptoms</td>
<td>–123 (–235, –57)</td>
<td>–165 (–238, –116)</td>
<td>.37</td>
</tr>
<tr>
<td>Low FODMAP&lt;sup&gt;e&lt;/sup&gt; knowledge</td>
<td>10.4 (7.4, 14.0)</td>
<td>8.3 (4.4, 13.1)</td>
<td>.50</td>
</tr>
<tr>
<td>FODMAP intake</td>
<td>–6.0 (–27.0, 9.5)</td>
<td>–14.0 (–41.4, 3.3)</td>
<td>.85</td>
</tr>
<tr>
<td>Quality of life</td>
<td>7.0 (6.0, 18.0)</td>
<td>21.5 (12.0, 40.3)</td>
<td>.04</td>
</tr>
</tbody>
</table>

<sup>a</sup>CON: control group.  
<sup>b</sup>APP: experimental group (access to artificial intelligence dietary mobile app).  
<sup>c</sup>P values were determined by Mann-Whitney U test.  
<sup>d</sup>IBS: irritable bowel syndrome.  
<sup>e</sup>FODMAP: fermentable, oligo-, di-, monosaccharide and polyol (diet).

IBS-SSS

The total IBS symptom scores improved over the intervention period for the sample as a whole; however, the change in scores did not differ significantly between groups (CON: –138; APP: –170; P=.37; Table 2). Of the 5 individual symptom component scores, the bowel habit dissatisfaction score showed a significant between-group reduction in symptoms. The APP group reported a 2-fold improvement in bowel habit scores in comparison to the CON group (APP: –47; CON: –24; P=.05; Figure 2). Significant improvements were noted for the remaining 4 component scores over the 30-day intervention within both groups, but these changes did not vary significantly between groups.
Figure 2. Thirty-day change (mean±SD) in IBS-SSS scores by question. APP: experimental group (access to artificial intelligence dietary mobile app); CON: control group; IBS-SSS: irritable bowel syndrome symptom severity scale; Q1: abdominal pain severity; Q2: abdominal pain frequency; Q3: abdominal pain distension severity; Q4: bowel habit dissatisfaction; Q5: quality of life interference due to the aforementioned symptoms. *Significant difference between CON and APP groups (P=.05, Mann-Whitney U test).

Low FODMAP Diet Intake Knowledge

LFD knowledge scores improved over time in both the APP and CON groups, but there was no difference between groups for change in knowledge scores. Adherence to the LFD improved during the study as indicated by a decrease in FODMAP intake scores over the intervention period for both groups. However, the change in intake scores between groups following the intervention period did not differ significantly (Table 2).

Quality of Life

Quality of life scores improved to a greater degree in APP participants compared to CON participants (P=.04; Table 2). Furthermore, improvement in quality of life scores was correlated to improvement in IBS symptom scores in the APP group (r=–0.598; P=.02) but not in the CON group (r=–0.183; P=.59).

Discussion

Principal Results

These data suggest that supplementing standard IBS dietary education with an AI dietary mobile app that tailors the LFD to specific users’ needs improves several health outcomes for individuals with IBS. Specifically, the Heali mobile app helped participants improve their quality of life outcomes and bowel habit symptoms. Quality of life scores rose in both groups; however, the rise in the APP group was 2.6-fold greater than that in the CON group. Poor quality of life is well documented in patients with IBS, and improvement in IBS symptoms is related to improvement in quality of life, such as decreasing the cost of health care, fewer missed days of work, and greater sense of control [37].

Comparison With Prior Work

Similar to the present trial, Kortlever et al [38] recently demonstrated that adoption of the LFD in IBS patients improved GI symptoms and quality of life after 6 weeks of diet adherence. To achieve these results, patients consulted with dietitians at private dietary centers for detailed diet reviews and personalized diet counseling. The data herein suggest that similar outcomes can be achieved with a mobile app, which can thus eliminate certain barriers, such as time commitment, cost, and access to health professionals, making IBS treatment accessible and convenient for a large segment of the population. Although significant quality of life improvements were found in the app group, Pederson et al [10] found that IBS-D participants have a greater response to web-based treatment specifically for quality of life outcomes. In this study, IBS-D participants made up 57% of those in the APP group and 23% of those in the CON group. Although this study was a pilot, future iterations should stratify by IBS subtype to evenly spread this confounding factor. It is noteworthy that both treatments presented herein improved outcome measures, including diet adherence; yet, mobile app use did demonstrate added benefits. Consumers are increasingly relying on their smartphones for news and information and to conduct their personal business, including managing their health.
Mobile apps that provide ready access to accurate, detailed, and personalized diet information can enable individuals to make lifestyle changes with confidence to improve health. Heali provides evidence-based information and real-time feedback on food choices via a personalized match rating (using the traffic light system) to support user adherence to difficult diets like the LFD.

To our knowledge, Heali is the first mobile app to use AI to support dietary adherence to the LFD and to support treatment of IBS symptoms. This is significant considering that peer-reviewed mobile apps using AI are able to optimize support of chronic disease treatment of conditions such as diabetes [23,39] and hypertension [25]; however, these apps have not been tested on less prominent conditions like IBS. This app-based intervention is especially novel as few studies have explored the possibilities of AI to improve dietary adherence, especially to the LFD [23,26,39]. This cements the novelty of this study on two fronts: (1) the use of AI to improve quality of life in patients with IBS and (2) the use of AI to improve IBS disease outcomes.

**Strengths and Limitations**

The strengths of this study include the randomization of participants to the intervention and control groups, which allowed dispersion of confounding variables between groups. Further, the entire study, from recruitment to implementation and assessment, was completed online, allowing broad participation without location limitations. The online nature of the study also decreased study costs, as it only required desktop support for implementation and completion.

The limitations of this study include the potential for self-reporting bias, as all surveys were conducted online, while there was also a lack of blinding of the researcher and the participant to the study groups. Participants were randomized via random number generation and not stratified based on severity or type, presenting the potential for bias when comparing between groups. However, participants were not randomized to groups until study day 10, which was after the collection of baseline data. Although anthropometric measures (bodyweight, height) were collected at baseline, they were not collected at the end of the trial, and it is possible that changes in body weight influenced the outcome variables. The change in quality of life was not related to baseline bodyweight or BMI. The small sample size of this pilot trial limits the ability to interpret or generalize findings to other patient populations. Finally, all participants completed the majority of their intervention over the early course of the 2020 COVID-19 pandemic, which reportedly affected participation and retention. Given that this was a dietary restriction study in participants with IBS, it is important to note that household goods (e.g., nonperishable foods, proteins, and paper products such as toilet paper and paper towels) were in scarce supply during this time. As a result, it is likely that COVID-19 affected adherence across both groups potentially even more than was stated by participants. The COVID-19 pandemic likely also led to elevated stress, which, in addition to dietary nonadherence, has been shown to exacerbate IBS symptoms [7,8,40,41]. It is therefore important to consider that results reported on symptom severity screeners, progression of the disease, and the quality of life of the participants within this study might have been negatively impacted by the COVID-19 outbreak.

**Conclusions**

This pilot study provides preliminary evidence that the Heali app may provide therapeutic benefit to its users with IBS. Results showed that the Heali app was able to significantly increase quality of life outcomes in IBS participants over a 30-day intervention period. These findings warrant further research using larger sample sizes. Although this study focused on patients with IBS and the LFD, the variety of additional interventions available via the Heali app suggest possible benefits to individuals with other conditions whose symptoms are attenuated through therapeutic dietary adherence.

**Acknowledgments**

The authors wish to acknowledge Heali AI for their support in objectively testing the efficacy of their novel application and providing the participants 6 months of free app use after the study; Drs Lucinda Harris, Douglas Drossman, Cecil Rooker, and Johannah Ruddy for their support during the recruitment phase; the International Foundation for Gastrointestinal Disorders for providing the participants 6 months of free app use after the study; Drs Lucinda Harris, Douglas Drossman, Cecil Rooker, and Johannah Ruddy for their support during the recruitment phase; the International Foundation for Gastrointestinal Disorders for providing the participants 6 months of free app use after the study; and the Arizona State University Graduate Research Support Program for their support for implementation and completion.

**Authors’ Contributions**

Data were collected by AJR and provided unmodified to CSJ, who independently conducted data analysis and wrote the results section. RH provided consultation and editing support, and all authors reviewed the paper for accuracy.

**Conflicts of Interest**

None declared.

**Multimedia Appendix 1**
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 5225 KB - jmir_v23i3e24134_app1.pdf ]
References


Abbreviations

AI: artificial intelligence
APP: experimental group (access to artificial intelligence dietary mobile app)
CON: control group
FODMAPs: fermentable, oligo-, di-, monosaccharides and polyols
GI: gastrointestinal
IBS: irritable bowel syndrome
IBS-C: IBS with constipation
IBS-D: IBS with diarrhea
IBS-M: IBS mixed typed
IBS-SSS: IBS symptom severity scale
IBS-U: IBS unsubttyped
LFD: low FODMAP diet
LFDA: low FODMAP dietary consumption
LFDK: low FODMAP dietary knowledge
WHO: World Health Organization

© Aaron J Rafferty, Rick Hall, Carol S Johnston. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 02.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Development of a Web-Based Mindfulness Program for People With Multiple Sclerosis: Qualitative Co-Design Study

Amy-Lee Sesel¹, MPsych, PhD; Louise Sharpe¹, MPsych, PhD; Heidi N Beadnall²,³, MBBS, PhD; Michael H Barnett²,³, MBBS, PhD; Marianna Szabo¹, MPsych, PhD; Sharon L Naismith¹,², MPsych, DPysch(Neuro)

¹School of Psychology, University of Sydney, Sydney, Australia
²Brain and Mind Centre, University of Sydney, Sydney, Australia
³Neurology Department, Royal Prince Alfred Hospital, Sydney, Australia

Corresponding Author:
Amy-Lee Sesel, MPsych, PhD
School of Psychology
University of Sydney
Camperdown NSW
Sydney, 2006
Australia
Phone: 61 2 9351 4558
Email: amy-lee.sesel@sydney.edu.au

Abstract

Background: Mindfulness-based stress reduction is an efficacious treatment for people with chronic health problems; however, it is highly intensive and time-consuming, which is a barrier for service provision.

Objective: This study aims to develop an internet-delivered adapted version of mindfulness-based stress reduction for people with multiple sclerosis to make the intervention more accessible.

Methods: We co-designed a web-based mindfulness program with end users, that is, people with multiple sclerosis (N=19). Iterative feedback was also collected from a subsample of the initial group of end users (n=11), and the program was reviewed by experts (n=8).

Results: We identified three main themes common to people with multiple sclerosis: dealing with uncertainty and fears for the future, grief and loss, and social isolation. These themes were incorporated into narratives throughout the program. People with multiple sclerosis who reviewed the program gave feedback that the program was relatable, feasible, and acceptable. Experts agreed that the program appropriately represented the main tenets of mindfulness. Iterative feedback was used to further refine the program.

Conclusions: The web-based mindfulness program that we developed was viewed positively by both experts and end users. The program reflects common concerns for people with multiple sclerosis and has the potential to meet important unmet psychological needs. A randomized controlled trial was planned to determine the efficacy of the program.

(J Med Internet Res 2021;23(3):e19309) doi:10.2196/19309

KEYWORDS
multiple sclerosis; mindfulness; depression; program development; internet intervention; qualitative research

Introduction

Background

People with multiple sclerosis live with high rates of depression and anxiety, with prevalence rates of approximately 31% [1] and 22% [1,2], respectively. However, there is relatively little literature on psychological treatments for people with multiple sclerosis compared with such treatments for people with other chronic health conditions, and the results of these trials are mixed [3-7].

A recent meta-analysis of 13 studies in multiple sclerosis (MS) [8] revealed that psychosocial interventions significantly improve depression, anxiety, fatigue, and mental and total health-related quality of life (HRQoL). However, effect sizes were small, and for physical HRQoL, the effect was moderated by therapy type. Specifically, although there was no clear benefit of cognitive behavior therapy (CBT) for physical HRQoL, other
A single study of mindfulness-based stress reduction (MBSR) [9] demonstrated the largest effect sizes of all included studies for depression ($d=0.8$) and anxiety ($d=0.6$). This was a high-quality randomized controlled trial (RCT) of 150 people with multiple sclerosis, showing that face-to-face MBSR was effective across a range of outcomes compared with treatment as usual. Indeed, mindfulness has been shown to have significant mental health benefits for people with a range of physical health conditions, including chronic pain, fibromyalgia, arthritis, and cancer [10,11]. However, the number of trials in the MS literature is limited, and the sample sizes are generally small [3-7]. There is another more recent study of 62 people with multiple sclerosis. This study did not find any significant differences between MBSR and an active control group. However, this study was underpowered [12].

Both RCTs in MS were based on the traditional MBSR program [13] and involved a high dosage of face-to-face intervention (27 hours and 22 hours, respectively), including a full-day workshop. Such intensive treatments are costly, and barriers such as reduced mobility limit accessibility for people with multiple sclerosis. Finding alternative modes of delivery could potentially improve the access, cost-effectiveness, and scalability of interventions. Internet-delivered mindfulness programs have been found to be effective in mental health settings [14] and in chronic disease populations such as cancer, irritable bowel syndrome, and fibromyalgia [15-17]. There is only 1 RCT evaluating the efficacy of online meditation training for people with multiple sclerosis. This study found significant treatment effects for HRQoL, depression, anxiety, and sleep problems at postintervention, but the benefits were not maintained [18]. Although this program was an MS-specific intervention, it was not evident that people with multiple sclerosis were involved in its design. Further research in this field is needed to clarify the mixed results of web-based mindfulness studies and to determine whether a more tailored intervention with consumer input would lead to sustained, longer-term improvements in mental health.

**Objectives**

The aim of this study is to develop a web-based mindfulness program tailored specifically for people with multiple sclerosis via a qualitative investigation of (1) the psychological experiences and unmet needs of people with multiple sclerosis, (2) attitudes toward a proposed web-based mindfulness program designed to address such needs, and (3) iterative feedback from people with multiple sclerosis and experts in the field.

**Methods**

**Recruitment**

Participants were recruited from the MS Clinic, Brain and Mind Centre, Sydney, Australia, between August 2017 and July 2018. Ethics approval was obtained from the University of Sydney Human Research Ethics Committee (2016/049). Potential participants were approached at the MS Clinic waiting room consecutively and given an invitation letter with the opportunity to fill out their contact details. We did not exclude participants with comorbid physical or mental health conditions. Participants were required to be older than 18 years and to have a neurologist-confirmed diagnosis of MS. Interview times were arranged via telephone and were conducted face-to-face at the MS Clinic at an appointed time, with written consent, by a registered psychologist (AS).

**Data Collection**

Demographic data were collected via interviews and self-report questionnaires. To characterize the sample, we administered valid and reliable measures of depression, anxiety, and pain. Depression symptomatology was measured using the Center for Epidemiological Studies for Depression questionnaire [19] (CES-D; 20-item; range 0-60); anxiety was measured using the State-Trait Anxiety Inventory [20] (STAI) via 2 subscales, assessing state and trait anxiety (both 20-item; range 20-80); and pain was measured using a 10-point visual analogue scale [21]. Semistructured interviews (approximately 50 min in length on average) were recorded and transcribed verbatim. All participants were asked the same semistructured interview questions (Multimedia Appendix 1) with appropriate follow-up questions.

**Data Analysis**

Data were analyzed using Nvivo Qualitative Data Analysis Software [22], via inductive coding at the semantic level, consistent with the Miles and Huberman framework for qualitative data analysis [23]. Analyses were ceased at the point of theme saturation, where 3 transcripts revealed no new themes. Individual transcripts were analyzed and coded independently by 2 authors (AS and LS). The researchers then met with a third researcher (SN) to confirm the themes and coding framework. Any disagreements were resolved by consensus.

**Program Development**

The web-based mindfulness program was developed on the basis of core components from the MBSR program by Kabat-Zinn [24], with the exception of yoga training. Hatha yoga was omitted from the program because it could not be sufficiently supervised and because the program was designed to target people with multiple sclerosis with varying degrees of mobility. The program was tailored to address the main themes derived from the qualitative interviews with people with MS by integrating case examples from unique, fictional characters that varied in terms of age, gender, race, disease course, and duration. These case examples were used to normalize the day-to-day challenges of people with multiple sclerosis and demonstrate how MBSR could be used to manage MS-related symptoms and improve HRQoL. The program comprised five 15-min web-based modules (Table 1), designed to be delivered over 8 weeks. We opted for 5 modules because there is some evidence that having at least four modules is optimal in other internet interventions (eg, CBT insomnia) [25], but we were unable to provide all meditations in the 4 modules. Furthermore, there is evidence of good adherence to other CBT-based interventions that offer 5 modules over 8 weeks [26,27].
Table 1. Web-based mindfulness program content.

<table>
<thead>
<tr>
<th>Module</th>
<th>Topics covered</th>
<th>Mindfulness-based stress reduction principles</th>
<th>Formal practice</th>
<th>Informal practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 1: Introduction to mindfulness meditation</td>
<td>Anxiety</td>
<td>Definition of mindfulness&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Awareness of breath meditation</td>
<td>Choose one daily activity to do mindfully</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits of mindfulness</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Simple awareness&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Module 2: Recognizing signs of stress</td>
<td>Stress and fatigue</td>
<td>Definition of stress</td>
<td>Body scan meditation</td>
<td>Practice brief body scan before a stressful event</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Signs of stress</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>The body scan&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Module 3: Dealing with difficult sensations and emotions</td>
<td>Pain</td>
<td>Cultivating equanimity&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Sitting meditation (open awareness)</td>
<td>Cultivate equanimity toward an everyday conflict</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Swapping judgment for curiosity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Letting go</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Module 4: Dealing with difficult thoughts</td>
<td>Low mood</td>
<td>Using the breath as an anchor</td>
<td>Mountain meditation</td>
<td>Write down a thought, practice nonidentification, and then write it down again</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The 4-step process of nonidentification&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>The mountain meditation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Module 5: Mindful communication, self-compassion, and relapse prevention</td>
<td>Social isolation</td>
<td>Active listening and responding (vs reacting)</td>
<td>Loving-kindness meditation</td>
<td>Complete mindful listening exercise with a partner</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cultivating self-compassion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recap of mindfulness program</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Mindfulness: the awareness that arises when we pay attention on purpose, in the present, nonjudgmentally.

<sup>b</sup>Simple awareness: observing what is happening by focusing your attention completely on one thing at a time, without judging your experience in any way.

<sup>c</sup>Body scan: a type of mindfulness meditation that involves concentrating one’s attention on one’s body, moving from the tip of the toes to the top of the head in a systematic, mindful way.

<sup>d</sup>Equanimity: a neutral state of mind toward all experiences, pleasant and unpleasant, regardless of whether they bring pleasure, joy, or misery.

<sup>e</sup>Nonidentification: a technique that involves being conscious of not becoming attached to whatever thoughts arise within your internal experience, taking a step back, and viewing each thought as an impersonal mental event.

The 5 modules were scheduled as follows: module 1 at the start of week 1 and module 2 at the start of week 2. The remaining modules contain instructions for the next 2 weeks, that is, module 3 would be delivered at the start of week 3 and again for the option of repetition, at the beginning of week 4, etc. The amount of time (ie, 1 or 2 weeks) dedicated to each module was decided based on the complexity of the mindfulness concepts and strategies described. It was written by a registered psychologist (AS) with clinical psychology and mindfulness training in collaboration with a clinical psychologist with experience in the development and evaluation of evidence-based psychological interventions for people with chronic health conditions (LS) and a clinical neuropsychologist with experience in the delivery of web-based therapeutic interventions (SN).

Direct, face-to-face feedback on the program was provided by a subsample of the original participants interviewed (n=11), who indicated that they were interested and willing to review the modules of the program. In total, 8 women and 3 men with MS (10/11 relapsing-remitting; age range: 23-63 years) took part in the review process. Two neurologists and 4 mindfulness experts including 2 clinical psychologists, 1 emergency care physician and 1 general practitioner provided written feedback on the program. Feedback was then coded and analyzed inductively, forming subheadings with overarching themes. Feedback from both people with multiple sclerosis and experts was discussed in team meetings among the 3 lead authors (AS, LS, and SN). Further iterations of the program were cocreated where there was consensus and scope to make the suggested changes.

Results

Demographics

All participants had a neurologist-confirmed diagnosis of MS (N=19). There were 6 males and 13 females. A total of 63% (12/19) of participants had clinically significant depressive symptoms according to a cut-off score of 16 on the CES-D [28]. Moreover, 47% (9/19) of participants had clinically significant levels of state anxiety, according to a cut-off score of 41, and 42% (8/19) of participants had clinically significant levels of trait anxiety, according to a cut-off score of 44 on the STAI [29]. Descriptive statistics are presented in Table 2.
Table 2. Participant demographics (N=19).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females, n (%)</td>
<td>13 (68)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>40.42 (16)</td>
</tr>
<tr>
<td>Employment status, n (%)</td>
<td></td>
</tr>
<tr>
<td>Working full-time or part-time</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Retired</td>
<td>1 (5)</td>
</tr>
<tr>
<td>University student</td>
<td>3 (16)</td>
</tr>
<tr>
<td>High school student</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Type of MS(^a), n (%)</td>
<td></td>
</tr>
<tr>
<td>Primary progressive MS</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Relapsing-remitting MS</td>
<td>14 (74)</td>
</tr>
<tr>
<td>Walking ability, n (%)</td>
<td></td>
</tr>
<tr>
<td>Wheelchair or scooter</td>
<td>3 (16)</td>
</tr>
<tr>
<td>Ambulatory</td>
<td>16 (84)</td>
</tr>
<tr>
<td>Psychosocial descriptors</td>
<td></td>
</tr>
<tr>
<td>Pain now, n (%)</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Pain, mean (SD)(^b)</td>
<td>4.48 (4)</td>
</tr>
<tr>
<td>Depressive symptoms, mean (SD)</td>
<td>19.89 (13)</td>
</tr>
<tr>
<td>State anxiety, mean (SD)</td>
<td>39.16 (15)</td>
</tr>
<tr>
<td>Trait anxiety, mean (SD)</td>
<td>43.89 (14)</td>
</tr>
</tbody>
</table>

\(^a\)MS: multiple sclerosis.

\(^b\)On the basis of the 8 participants who reported experiencing pain.

Thematic Analysis

The thematic analysis of this qualitative study was divided into 3 parts, in accordance with the research aims. For detailed thematic maps, including illustrative example quotations, please see Tables 3-5.
<table>
<thead>
<tr>
<th>Overarching theme and subtheme</th>
<th>Participant quote</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Uncertainty</strong></td>
<td></td>
</tr>
<tr>
<td>When another relapse will occur</td>
<td>“...you really don’t know when you’re going to have another episode...it’s a pretty stressful thing.” (P6)</td>
</tr>
<tr>
<td>Fear of progression</td>
<td>“I guess I don’t want to face the fact that yeah, something could happen and when’s it going to happen? I don’t know. Nobody’s knows so I guess.” (P17)</td>
</tr>
<tr>
<td>Potential burden on family</td>
<td>“I suppose my biggest worry at the moment is, how long will I stay, or how could I possibly get a little bit better so I can get more strength so I can actually um, perform better in the workplace...cause my wife would be never the person who could go out and work...I don’t know what would happen to her.” (P1)</td>
</tr>
<tr>
<td>Neurologist appointments</td>
<td>“Anytime I have to come to talk to Dr [name] about something or get results...it just destroys me for a week or two.” (P2)</td>
</tr>
<tr>
<td>Gaps in medical knowledge</td>
<td>“I remember when I first got diagnosed and I asked, what causes this, they said...its multifactorial, which means we don’t know...and you get that answer a lot.” (P8)</td>
</tr>
<tr>
<td>What is MS²-related</td>
<td>“Sometimes when I’m fatigued, or having low mood, it’s hard to know whether that’s just a normal thing, or whether it is MS influenced.” (P6)</td>
</tr>
<tr>
<td><strong>Grief and loss</strong></td>
<td></td>
</tr>
<tr>
<td>Loss of future plans</td>
<td>“I’m just feeling really heartbroken about having MS...Our whole future and life just completely changed.” (P2)</td>
</tr>
<tr>
<td>Difficulty with acceptance</td>
<td>“There’s an element of why me, poor me...why is this happening, this can’t be happening...and then cry a lot of tears.” (P3)</td>
</tr>
<tr>
<td>Loss of independence</td>
<td>“I can’t do anything that I used to be able to do...I can’t play netball, I can’t play touch footy, I can’t walk in the dark...you lose everything...” (P4)</td>
</tr>
<tr>
<td>Loss of cognitive abilities</td>
<td>“...I’ve missed out on a lot of things in life that you would normally take for granted...like as your young children grow up...I don’t remember those years of them...” (P1)</td>
</tr>
<tr>
<td>Loss of confidence</td>
<td>“I don’t feel like I can rely on my own devices...I wouldn’t have the confidence to go and do something on my own that’s out of the norm, out of my comfort zone, so that’s my thing, is I just feel vulnerable.” (P18)</td>
</tr>
<tr>
<td>Loss of sense of self and identity</td>
<td>“I can’t think normally anymore, and I’m not as quick as I used to be either. Everything’s slowly deteriorating, including me and my thoughts.” (P7)</td>
</tr>
<tr>
<td><strong>Social isolation</strong></td>
<td></td>
</tr>
<tr>
<td>Emotional avoidance</td>
<td>“Well, it’s mainly my family, who will sometimes bring it up in conversations...but yeah I really avoid it...” (P3)</td>
</tr>
<tr>
<td>Inappropriate responses of family or friends</td>
<td>“They try to help, but like I’ve had people burst into tears when I tell them, just like really inappropriate because they don’t know how to handle it...” (P2)</td>
</tr>
<tr>
<td>Lack of understanding</td>
<td>“Nobody really understands, and I don’t really have anybody to talk to about it.” (P17)</td>
</tr>
<tr>
<td>Apathy from others</td>
<td>“I’ve been brave enough to step out there and say this is what’s going on for me, and kind of reaching out a hand for some kind of support or acknowledgement, and getting nothing...” (P15)</td>
</tr>
<tr>
<td>Rejection due to stigma</td>
<td>“Yeah, [friends] walked away. Cause I got MS you know...they could catch it!” (P4)</td>
</tr>
<tr>
<td><strong>Availability of support</strong></td>
<td></td>
</tr>
<tr>
<td>Lack of follow-up</td>
<td>“Well, I suppose for someone like me I would’ve appreciated some sort of supportive type of stuff, but there was nothing.” (P13)</td>
</tr>
<tr>
<td>Lack of funding or resources</td>
<td>“From my experience with the MS Society, every time I ever went to them, they always said they ran out of money and couldn’t help me.” (P1)</td>
</tr>
<tr>
<td>Not knowing how to access support</td>
<td>“...I didn’t seek out specific psychological treatment for MS...but I don’t know where I would have gone if I did want that.” (P8)</td>
</tr>
<tr>
<td>Lack of therapists with MS knowledge</td>
<td>“I haven’t found anybody [therapist] who specializes in MS.” (P2)</td>
</tr>
<tr>
<td>Group-based support</td>
<td></td>
</tr>
<tr>
<td>Avoiding others with more progressive disability</td>
<td>“...if I see somebody very disabled by their MS, it’s really confronting and upsetting to me, because well, I’m lucky that it’s not me now, but there’s no way of telling what it will be like in the future, and that’s really scary.” (P14)</td>
</tr>
</tbody>
</table>
Overarching theme and subtheme | Participant quote
--- | ---
Difficulties with relatability | “I don’t really want to talk to people my mother’s age with MS.” (P19)

aMS: multiple sclerosis.

Table 4. Part 2: Attitudes toward the web-based mindfulness program.

<table>
<thead>
<tr>
<th>Overarching theme and subtheme</th>
<th>Participant quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seeking support online</td>
<td></td>
</tr>
<tr>
<td>Anonymity</td>
<td>“I’d probably feel ok because I can do it in the privacy of my own space so it wouldn’t draw attention to me.” (P3)</td>
</tr>
<tr>
<td>Flexibility</td>
<td>“…when I am overtired, when I am hot, when there are issues, I do need that flexibility.” (P14)</td>
</tr>
<tr>
<td>No need for travel</td>
<td>“I don’t think they [online therapies] would replace in-person, but I think they could augment, or be useful in between. And maybe some people would find it really useful if they don’t have access to something local…” (P2)</td>
</tr>
<tr>
<td>Internet security</td>
<td>“I have big phobias about Internet security and things like that.” (P4)</td>
</tr>
<tr>
<td>Vision problems</td>
<td>“I can’t see…” (P5)</td>
</tr>
</tbody>
</table>

Mindfulness meditation and barriers to practice

| Potential efficacy | “I do have an understanding and I do believe it works...it’s very helpful to bring you back into reality, to stop your mind going crazy.” (P3) |
| Difficulties with finding time | “I have had trouble making sure I do it every day, like, finding that time and being strict with myself.” (P17) |
| Difficulties concentrating | “I get distracted really easily…” (P14) |
| Low mood | “I think it’s a depression. And I know if I were to do those things [to improve my mental health] the depression would get better.” (P2) |
| Lack of quiet space | “If I go in my room and close the door, my nieces would just run up and start banging on the door shouting ‘Uncle, uncle, uncle’.” (P7) |

Anticipated program use, preferences, and suggestions

| Interest in participating | “I like the idea of the program, and I think there are lots of people who it would really help.” (P6) |
| Length of meditation | “I would think minimum 20 minutes because I think anything less than that you haven’t really got into it, to me, takes a while to get into the zone.” (P11) |
| Case examples | “…if I had a case to go by, I could say yeah ok that sounds familiar, and then go from there...because with a lot of the stuff it’s like is this supposed to happen? Does it happen to people with MSa or does it happen to everyone? So it would be good to have case studies.” (P3) |
| Email reminders | “I’d be more likely to actually use the reminder if it was e-mail, because then I can sort of flag it and keep track of it.” (P10) |
| Weekly telephone calls | “To me, I would like follow-up contact. Especially if you develop a rapport with somebody, it’s good to have follow-up contact. That definitely helps with learning a concept, to get a certain amount of rapport and follow-up.” (P1) |
| More likely to participate if recommended | “I think it would make it less likely for me to get benefit from it because I’d be so skeptical. If one of my doctors said, or if my psychiatrist who had MS said, [to do it] I certainly would.” (P8) |
| More likely to participate if tailored to MS | “…if it’s something like ‘Yeah we can help to work on that anxiety, or work on some things’ and its geared towards people with MS, I think that would be really helpful.” (P2) |

aMS: multiple sclerosis.
Illness-free life. Many people with multiple sclerosis reported problems were part of their MS or due to other factors, such as treatments, was a source of excessive worry and distress. Some participants worried about whether their physical or cognitive capabilities would allow them to stay in the workforce, and the potential financial burden that they would place on their families. Going to neurologist appointments and having to face the possibility of receiving bad news, such as the identification of new lesions in the brain or spinal cord, or changing treatments, was a source of excessive worry and distress. Some participants worried about whether their physical or cognitive problems were part of their MS or due to other factors, such as the natural process of aging.

Grief and Loss
An overarching theme was the participants’ experience of grief and loss due to the gradual decline in their physical and cognitive abilities and their sense of independence and identity. They also expressed anguish and sorrow over the loss of their illness-free life. Many people with multiple sclerosis reported that they were faced with having to give up on future plans and accept changes to their ability to travel and participate in family life. This process of adjustment experienced by people with multiple sclerosis was depicted as challenging and repetitive, as people developed new or worsening symptoms over time. People with multiple sclerosis experiencing cognitive difficulties described experiences of memory loss and how this impacted their daily functioning as well as their ability to recall cherished memories (eg, of their children growing up), which reinforced feelings of disconnection from family life. Those experiencing physical challenges, such as ataxia, muscle weakness, and bladder dysfunction, reported feelings of helplessness and a great sense of vulnerability, as they gradually lost confidence in themselves. Participants across all ages, genders, and types of MS emphasized the need to separate themselves from the disease, to try to lead a normal life and preserve their sense of self and identity, which many feared was at risk of erosion.

Social Isolation
Participants reported experiencing social isolation and difficulties communicating with people in their support networks about their MS. Barriers to receiving social support included difficulties with participating in social activities due to loss of function and emotional avoidance when faced with opening up to people about their MS as well as other people’s failure to respond appropriately. Some participants reported that they were given unsolicited and often ill-informed advice from

**Part 1: The Psychological Experiences and Unmet Needs of People With Multiple Sclerosis**

**Uncertainty**
Most participants reported that their psychological experiences were characterized by uncertainty, worry about the future and possible disease progression, and difficulty grappling with unknowns surrounding the disease. The inability to predict possible relapse was a major source of continual stress and anxiety, and it interfered with planning, for example, whether and when they should have children, how long their physical capabilities would allow them to stay in the workforce, and the potential financial burden that they would place on their families. Going to neurologist appointments and having to face the possibility of receiving bad news, such as the identification of new lesions in the brain or spinal cord, or changing treatments, was a source of excessive worry and distress. Some participants worried about whether their physical or cognitive problems were part of their MS or due to other factors, such as the natural process of aging.

**Grief and Loss**
An overarching theme was the participants’ experience of grief and loss due to the gradual decline in their physical and cognitive abilities and their sense of independence and identity. They also expressed anguish and sorrow over the loss of their illness-free life. Many people with multiple sclerosis reported that they were faced with having to give up on future plans and accept changes to their ability to travel and participate in family life. This process of adjustment experienced by people with multiple sclerosis was depicted as challenging and repetitive, as people developed new or worsening symptoms over time. People with multiple sclerosis experiencing cognitive difficulties described experiences of memory loss and how this impacted their daily functioning as well as their ability to recall cherished memories (eg, of their children growing up), which reinforced feelings of disconnection from family life. Those experiencing physical challenges, such as ataxia, muscle weakness, and bladder dysfunction, reported feelings of helplessness and a great sense of vulnerability, as they gradually lost confidence in themselves. Participants across all ages, genders, and types of MS emphasized the need to separate themselves from the disease, to try to lead a normal life and preserve their sense of self and identity, which many feared was at risk of erosion.

**Social Isolation**
Participants reported experiencing social isolation and difficulties communicating with people in their support networks about their MS. Barriers to receiving social support included difficulties with participating in social activities due to loss of function and emotional avoidance when faced with opening up to people about their MS as well as other people’s failure to respond appropriately. Some participants reported that they were given unsolicited and often ill-informed advice from

**Table 5.** Part 3: Iterative feedback from people with multiple sclerosis and experts in the field.

<table>
<thead>
<tr>
<th>Overarching theme and subtheme</th>
<th>Participant quote</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relatability</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Relevance of case examples    | “Was it from these interviews that you got the stories for your modules and helped plan the program? I ask this as the stories seem very true to life indeed.” (Exp1)^
| Identification with program characters | “I think it’s great. I can relate to Jen and see myself embedded in these slides.” (P11) |
| Language: too simplistic?      | “My impression was that it was speaking to children in terms of the graphics and language like reading them a storybook. Is that what you intended?” (Exp2)^
| Language: is acceptable        | “I personally have no issue with it. I feel like that's just kind of the 'mode' you're working in.” (P8) |
| Graphics: too childish?        | “Yes, I also thought the images looked childish.” (P2) |
| Graphics: are acceptable       | “I personally really like it, because I think the cartoon-style characters get you completely away from stereotypes and to focus on the messages and the content.” (P15) |
| **Acceptability of program content** |                     |
| Analogies                      | “Yeah, really good, I think the analogies are good, you know, the monkey chatter in the mind.” (P17) |
| Mindfulness principles         | “I love the content, the flow and the style.” (P15) |
| Mindfulness training           | “I think the text that will be spoken is pretty good and I think follows most mainstream advice about mindfulness and how to teach it.” (Exp3)^
| Include expert                 | “Having a mindfulness expert as a supervisor is important.” (Exp4)^
| Include scientific evidence    | “… the presentation of some of the scientific evidence underpinning mindfulness generally improves acceptance.” (Exp3) |

^Exp1: Expert 1, neurologist, specialty in multiple sclerosis
^Exp2: Expert 2, general practitioner with expertise in the delivery of web-based mindfulness interventions
^Exp 3: Expert 3, emergency physician with expertise teaching mindfulness to people with multiple sclerosis
^Exp 4: Expert 4, clinical psychologist with mindfulness teacher training.
friends and family, which was perceived as highly distressing and alienating. Many participants reflected a sense of apathy and disinterest on behalf of their wider social circles and work environment and others’ general lack of understanding that MS is largely an invisible disease. Two participants reported facing blatant rejection from others because of stigma and unfounded beliefs about MS being contagious.

Availability of Psychological Support
Most participants reported an unmet need for psychological support, which they attributed to a lack of follow-up, lack of funding or resources, lack of knowledge regarding where to go for psychological support, and lack of psychologists or therapists specializing in MS. Of the 63% (12/19) participants with clinically significant symptoms of depression, only half reported that they were either currently seeing a psychologist or had seen one in the past.

Group-Based Psychosocial Support
A major barrier to receiving psychological support was that the overwhelming majority of participants did not want to meet other people with multiple sclerosis in a face-to-face therapeutic setting, despite wanting to know how others cope. This was largely because meeting people with more severe symptomatology or disability generated feelings of uncertainty and fear around their own illness progression. For representative participant quotations for each subtheme, please see Table 3.

These main themes underlying the psychological experiences of people with multiple sclerosis were incorporated into the program development through the use of fictional characters featured in each module, whose stories and case examples reflected the common challenges, and mental-health related difficulties that participants reportedly faced. For screenshot examples, please see Multimedia Appendix 2.

Part 2: Attitudes Toward a Proposed Web-Based Mindfulness-Based Program

Attitudes Toward Internet Use
Participants reported positive attitudes toward seeking psychological support online. It is widely regarded as convenient, easy, and allowing access to therapeutic support with a sense of anonymity, in the privacy and comfort of their homes, without the need for travel. Reservations toward the use of an internet-delivered psychological intervention were noted by 11% (2/19) participants. One experienced MS-related vision problems and another expressed apprehension surrounding internet security.

Attitudes Toward Mindfulness
Participants’ experiences and knowledge of mindfulness varied from having no understanding of what it was to having years of experience. Potential barriers to participating in the proposed mindfulness program included not having enough time in the day to meditate, difficulties getting in a routine, problems with attention and concentration, low mood, and inability to find a quiet space to meditate, particularly for those with young families.

Anticipated Use, Program Preferences, and Suggestions
Most participants reported that they would be interested in participating in the proposed web-based mindfulness intervention (see Methods section). People with multiple sclerosis with more experience with mindfulness meditation tended to advocate for longer meditation practices. Features that were identified to engage participants in the program and reduce dropout included incorporating case examples, email reminders, and guiding participants through the program via weekly telephone calls. Three participants reported that they would be more likely to participate in the program if their neurologist or psychiatrist recommended it. Many reported that a program tailored to people with multiple sclerosis was preferable compared with a generic web-based mindfulness program. For representative participant quotations, please see Table 4.

Part 3: Iterative Feedback From People With Multiple Sclerosis and Experts in the Field

Relatability of the Program
Most people with multiple sclerosis found the program highly relatable to their experiences of living with MS. In total, 5 participants and 1 neurologist gave specific positive feedback about the case examples. Reservations about the relatability of the program were expressed by 1 expert and 1 participant (who held a PhD) who commented that the program was too simplistic and could be perceived as patronizing. Following this feedback, participants and experts were explicitly asked about their views in this regard, and these concerns were not widely shared by other respondents. Some changes to the program graphics and language were incorporated to further improve the relatability of the program: graphics were changed to make the characters look older and the scenes more realistic, and some of the language was edited to be less repetitive and more direct.

Acceptability of Program Content
In terms of the program content, 8 participants gave specific, positive feedback on the analogies used to explain mindfulness concepts (eg, monkey chatter) and how the mindfulness concepts were presented. Experts in mindfulness commented that the concepts were well explained and consistent with MBSR principles; however, some suggested involving a mindfulness expert, which we did. One area in which there was disagreement among experts was on the degree to which more reference to principles; however, some suggested involving a mindfulness expert, which we did. One area in which there was disagreement among experts was on the degree to which more reference to research should be included. Some experts recommended integrating scientific evidence on the efficacy of mindfulness into the program to improve treatment adherence, whereas others disagreed. We decided that including specific scientific research and results of studies was not necessary. For representative quotations of the feedback provided by participants and experts in the field, please see Table 5.

Discussion

Principal Findings
Participants reported psychological support as a common unmet need and were generally positive about the idea of an MS-specific, web-based mindfulness intervention. Among the
participants, the anticipated use of such a program was high, particularly if it was endorsed by treating physicians. A thematic analysis of 19 face-to-face interviews with people with multiple sclerosis revealed 3 overarching themes characterizing their psychological experiences: uncertainty, grief and loss, and social isolation. These themes were used in the development of narratives throughout the mindfulness program.

The first theme of uncertainty is unsurprising, considering that MS is an unpredictable illness. Participants indicated that they were fearful of progression, worried about whether symptoms might indicate deterioration, and worried about relapse. The lack of knowledge about the causes of MS exacerbated the uncertainty and worry and made attending medical appointments the source of anxiety. For some, the fear of progression was related to fear of becoming a burden on their family. Fears of progression have been previously documented in MS and found to be associated with poorer psychosocial outcomes [30]; therefore, we featured these throughout the program.

The second theme was grief and loss. Participants described the struggle to accept the limitations imposed on them by MS. They experienced losses of their future plans, which led to a loss of independence. Specific losses such as loss of cognitive abilities and loss of confidence led to a loss of a sense of self and identity. The importance of loss and its impact on self and identity have been previously described as important in the context of adjustment to illness [31]. Hence, we represented these struggles in the narratives developed for the program.

The third theme was social isolation. In terms of social isolation, people with MS felt that family and friends could not understand their difficulties, which sometimes led to inappropriate responses or apathy from others. Some people with MS described having lost friendships, which they experienced as rejection due to the stigma of having MS. Many people with MS described emotional avoidance, which allowed them to not express their emotions to others as a way of trying to avoid negative responses from others. However, this led to an overwhelming feeling of social isolation, which has been previously recognized in the literature [32].

We used these qualitative results to provide narratives to supplement the mindfulness content of our program. Once a draft version of the program was available on the basis of early interviews, we also gained feedback from both the people with multiple sclerosis and experts in MS and mindfulness. Iterative feedback allowed modifications to be made to the program content and graphics to improve relatability and ensure adherence to MBSR principles. However, overall feedback from mindfulness experts, neurologists, and people with multiple sclerosis were positive. The adapted mindfulness program appeared to be an acceptable and highly relatable program, tailored to the unmet needs and experiences of people with multiple sclerosis, and consistent with the basic principles and teachings of MBSR by Kabat Zinn [24].

As previously described, the primary reason for including the psychological experiences of people with multiple sclerosis was to ensure that the narratives included in our program were relevant to the end users of the program. It seems that the issues raised in our sample were similar to those previously raised in the literature. Prior research has shown that there is a lack of psychological support and continuity of psychosocial care after receiving the initial diagnosis [33,34]. Previous studies have highlighted the difficulties in accepting uncertainty surrounding the diagnosis, treatment, and prognosis of MS [35,36]. Indeed, illness uncertainty has been found to predict adjustment problems for people with multiple sclerosis, over and above demographic and disease characteristics [37], and the experience of fears of relapse or progression are well documented. Experiences of grief and loss [38] as well as difficulties in maintaining one’s sense of self in the face of physical and cognitive decline have been reported in the literature [31,39,40]. Furthermore, beliefs of people with multiple sclerosis about their illness and illness identity have been found to play a significant role in their psychological adjustment [41]. Previous research suggests that stereotypical images of a person in a wheelchair are regarded as negative symbols of loss, disability, and death for people with multiple sclerosis [42]. This may provide a possible explanation as to why the majority of participants in this study expressed disinterest in participating in group-based psychological interventions or support groups, as participants said they particularly wanted to avoid seeing people with more severe disease than themselves. Finally, it is well known that the psychological well-being of people with multiple sclerosis is worsened by social isolation and difficulties in communicating effectively about the disease with family and friends. In many cases, these feelings of abandonment, isolation, and social withdrawal are reported years after the initial diagnosis [40,43,44]. Commonalities between the themes identified from the people with multiple sclerosis in our study and those reported in the literature indicate that this innovative web-based mindfulness program is likely to be relatable to the target population.

Given the difficulties with anxiety and uncertainty about the future and the experiences of grief and loss experienced by people with multiple sclerosis, a mindfulness-based approach that focuses on the present moment, cultivating acceptance and letting go, seems an appropriate intervention for reducing psychological distress and improving HRQoL. Furthermore, the delivery of a mindfulness intervention, tailored to the needs and experiences of people with multiple sclerosis via the web, can be used to normalize the challenges of living with the disease and decrease feelings of isolation while maintaining anonymity and increasing access to psychological support.

Limitations
Although we attempted to interview a range of people with multiple sclerosis with various demographic and disease characteristics, we acknowledge that the experiences of people with multiple sclerosis reported here were a reflection of a small sample from one recruitment center. Another limitation of this study was that the reviewers were shown PowerPoint versions of the modules and not the web-based multimedia versions, which would have allowed for further analysis of the program’s usability. Finally, the evaluation of efficacy was beyond the scope of this study. A study protocol for an RCT evaluating the efficacy of the mindfulness program described in this study has been developed [45]. Clearly, the results of an adequately
powered RCT are needed to determine the efficacy of the program.

Conclusions
In summary, we have developed a web-based mindfulness intervention using an iterative co-design process that reflects the common challenges reported by people with multiple sclerosis. We included narratives that were developed from the themes derived from a qualitative study. The modules appropriately reflected the principles of MBSR, and the included narratives were viewed as relatable by people with multiple sclerosis. Future research will determine whether the developed intervention is effective. If it proves to be beneficial, the developed program would likely meet an important need for people with multiple sclerosis.

Acknowledgments
The authors would like to acknowledge the people with multiple sclerosis who contributed their valuable time and told their stories to aid the development of the mindfulness program described in this study. The authors also thank the experts who offered their generous advice, suggestions, and constructive feedback, including Alice Shires, Professor George Jelinek, and Associate Professor Craig Hassed. This project was supported by a postgraduate scholarship from the National Health and Medical Research Council and Multiple Sclerosis Research Australia. It was part of a competitive application, and these funding bodies made no contribution to the study design, data analysis, interpretation, or writing of this manuscript.

Authors' Contributions
AS conducted all the interviews with people with multiple sclerosis, coded the data into themes, and wrote the original manuscript as well as the mindfulness program. LS contributed to the conceptualization and design of the program, contributed to the conceptualization and coding of main themes, provided feedback on the program, and assisted with drafts of the manuscript. SN contributed to the design of the program, provided feedback on the program, and edited drafts of the manuscript. MS, HB, and MB provided feedback on the program and edited drafts of the manuscript.

Conflicts of Interest
None declared.

References


Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT</td>
<td>cognitive behavior therapy</td>
</tr>
<tr>
<td>CES-D</td>
<td>Center for Epidemiological Studies for Depression questionnaire</td>
</tr>
<tr>
<td>HRQoL</td>
<td>health-related quality of life</td>
</tr>
<tr>
<td>MBSR</td>
<td>mindfulness-based stress reduction</td>
</tr>
<tr>
<td>MS</td>
<td>multiple sclerosis</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>STAI</td>
<td>State-Trait Anxiety Inventory</td>
</tr>
</tbody>
</table>

Please cite as:

Evaluating a Hybrid Web-Based Training Program for Panic Disorder and Agoraphobia: Randomized Controlled Trial

Lara Ebenfeld1, PhD; Dirk Lehr1, Prof Dr; David Daniel Ebert1,2, Prof Dr; Stefan Kleine Stegemann1, MSc; Heleen Riper1,4,5, Prof Dr; Burkhardt Funk1, Prof Dr; Matthias Berking6, Prof Dr

1Leuphana University, Lüneburg, Germany
2Technical University of Munich, Munich, Germany
3GGZ ingeest Amsterdam, Amsterdam, Netherlands
4Vrije Universiteit Amsterdam, Amsterdam, Netherlands
5Amsterdam Public Health Research Institute, Amsterdam, Netherlands
6Friedrich-Alexander-University Nuremberg-Erlangen, Nuremberg-Erlangen, Germany

Corresponding Author:
Lara Ebenfeld, PhD
Leuphana University
Universitätsallee 1
Lüneburg, 21335
Germany
Phone: 49 4131 677 1708
Email: lara.ebenfeld@gmail.com

Abstract

Background: Previous studies provide evidence for the effectiveness of web-based interventions for panic disorder with and without agoraphobia. Smartphone-based technologies hold significant potential for further enhancing the accessibility and efficacy of such interventions.

Objective: This randomized controlled trial aims to evaluate the efficacy of a guided, hybrid web-based training program based on cognitive behavioral therapy for adults with symptoms of panic disorder.

Methods: Participants (N=92) with total scores in the Panic and Agoraphobia Scale ranging from 9 to 28 were recruited from the general population and allocated either to a hybrid intervention (GET.ON Panic) or to a wait-list control group. The primary outcome was the reduction in panic symptoms, as self-assessed using a web-based version of the Panic and Agoraphobia Scale.

Results: Analysis of covariance-based intention-to-treat analyses revealed a significantly stronger decrease in panic symptoms posttreatment (F=9.77; P<.002; Cohen d=0.66; 95% CI 0.24-1.08) in the intervention group than in the wait-list control group. Comparisons between groups of the follow-up measures at 3 and 6 months yielded even stronger effects (3-month follow-up: F=17.40, P<.001, Cohen d=0.89, 95% CI 0.46-1.31; 6-month follow-up: F=14.63, P<.001, Cohen d=0.81, 95% CI 0.38-1.24).

Conclusions: Hybrid web-based training programs may help reduce the symptoms of panic disorder and hence play an important role in improving health care for patients with this debilitating disorder.

Trial Registration: German Clinical Trial Register DRKS00005223; https://tinyurl.com/f4zt5ran
International Registered Report Identifier (IRRID): RR2-10.1186/1745-6215-15-427

Keywords:
panic disorder; agoraphobia; treatment; internet; mobile phone; randomized controlled trial

Introduction

With a 12-month prevalence of 1.8% among adults, panic disorder is one of the most common anxiety disorders [1,2]. Subthreshold cases, defined as significant panic symptoms that fail to meet full criteria, have been estimated to be just as prevalent [3,4] and have been shown to predict the development of full panic disorder as well as other mental disorders, such as generalized anxiety disorder or major depression [5]. Effective treatments for panic disorder and associated agoraphobic
symptoms include pharmacotherapy and cognitive behavioral therapy (CBT) [6-9]. Unfortunately, many individuals still lack access to evidence-based treatments because of the limited availability of clinicians or fear of stigmatization [10-12].

Technology-based psychological interventions that use the internet provide low-threshold access to evidence-based mental health care. Recent outcome studies [13-15], meta-analyses, and reviews [16-24] provide ample evidence that internet-based interventions based on cognitive behavioral therapy principles (iCBT) are effective in treating panic disorder.

Owing to their ability to bridge distances between patients and therapists, good cost-efficiency and low-threshold iCBT have great potential to facilitate access to evidence-based interventions [18,25]. However, the current dominance of desktop-based iCBT in research and health services neglects the dramatic shift in user preferences toward the use of smartphones [26]. Moreover, smartphones accompany their users wherever they go, thereby providing an excellent opportunity for ecological momentary assessment of relevant health information [27-31]. Furthermore, smartphones allow the use of ecological momentary interventions to be delivered in the real world and real time, ideally at the very moment the intervention is needed [32]. Considering the rapid growth and potential of mobile technology, surprisingly little research has been conducted to clarify the benefits of using smartphones as stand-alone or add-on interventions [33]. Available data often come from studies criticized for poor-quality interventions [34], and many interventions currently available have not been evaluated at all [35-37].

The few currently available studies provide preliminary evidence for the efficacy of smartphone-based interventions for the symptoms of anxiety disorders. For example, in a meta-analysis on the efficacy of transdiagnostic eHealth interventions that integrated mobile technologies, Firth et al [38] showed that such interventions can significantly reduce overall anxiety (Hedge g=0.45). A recent study by Christoforou et al [39] evaluated the efficacy of an app for agoraphobic symptoms in comparison with a stress reduction app. Although there was a significant pre- to posttest effect for the interventions (Panic and Agoraphobia Scale [PAS] difference −5.97; 95% CI −8.49 to −3.44), no significant differences between the interventions were observed.

Despite these promising findings, it is important to acknowledge that mobile apps also have some disadvantages with regard to usability issues. For example, elaborate writing tasks, a typical component of iCBT interventions, are difficult to complete on a small screen with a smartphone touchpad. Moreover, cellphones are typically used for short time intervals and often while performing other tasks. This is problematic, as working toward health-promoting changes often requires more sustained and focused effort [40,41]. Therefore, it can be argued that hybrid interventions that combine the advantages of both desktop and mobile technology should be superior to exclusively desktop- or mobile-based approaches. In hybrid interventions, the mobile component can be used to monitor symptoms and cue exercises in the patient’s natural environment, whereas the desktop component provides text- and video-based psychoeducation and facilitates elaborate writing tasks.

Despite the obvious advantages of hybrid interventions, the literature on their efficacy is still scarce. In a transdiagnostic approach, Proudfoot et al [42] showed that the delivery of CBT using a combination of mobile app and desktop-based technology was effective in reducing symptoms of anxiety disorders (Cohen d=0.47) compared with a wait-list control (WLC) condition. Furthermore, in a study evaluating the combination of Acceptance and Commitment Therapy and a smartphone app for participants with panic disorder or social phobia, Ivanova et al [43] found no significant effect on panic symptom severity reduction. At this point, no study has been published on the efficacy of hybrid iCBT interventions for panic disorder. To fill this gap in the literature, this study aims to evaluate the efficacy of a newly developed hybrid iCBT training program for individuals with symptoms of panic disorder. Owing to the legal restrictions on remote treatment (Fernbehandlungsgesetz) [44], we use the term online training program for the intervention format instead of the term online therapy, which is more commonly used in the literature.

Methods

Study Design

To evaluate the efficacy of a hybrid web-based training program for panic disorder (with and without agoraphobia), we conducted a prospective, two-arm randomized trial, in which 92 participants with significant symptoms of panic disorder were randomly allocated either to the GET.ON Panic intervention group (IG) who received the training program immediately or to the WLC group who received the training program 6 months after randomization. For randomization, we used the automated computer program DatInf RandList version 1.2 (DatInf GmbH). The allocation was stratified for clinical or subclinical symptomatology as well as the presence or absence of agoraphobia in the order of incoming informed consent. To include equal numbers of participants in each group, we used block randomization (n=2 per block). The staff conducting the diagnostic interviews and observer ratings were blinded to the participants’ randomization statuses. The participants could participate in the training program with a pseudonym of their own choice. Ethical approval for this study was obtained from the Ethical Committee of the University of Marburg (registration number: 2013-23 K). The study was preregistered with the German Clinical Trial Register (registration number: DRKS00005223). The study protocol was submitted for publication before randomization [45].

Participants and Recruitment

The study participants were recruited from the general population between August 2013 and October 2014. Announcements in newspapers, support groups, and social media, such as Facebook, guided interested individuals to the web-based health center website of our research group, where they could apply on the web to participate in the study. Applicants were asked to complete a web-based questionnaire assessing the following inclusion criteria: (1) experiencing mild-to-moderate panic symptoms as assessed by the PAS (score
range: 9-28) [46,47], (2) being aged ≥ 18 years, (3) having panic as the primary concern for seeking help, (4) having internet and smartphone access with minimum system requirements of iPhone (TM) 3GS (Apple Inc; iOS 6 and iOS 7) or a comparable Android device (Android 2.3 or newer), and (5) providing their informed consent.

The exclusion criteria were as follows: (1) receiving current psychological help for anxiety problems or being on a wait-list for psychotherapy; (2) having physical health problems that were assessed via a self-report that prevents participants from engaging in self-exposure, as recommended by the German guideline for treating people with panic disorder and agoraphobia [48]; (3) currently having posttraumatic stress disorder or psychotic or dissociative disorders assessed via self-report and clinical interview; and (4) having current suicidality, as assessed by a score above 1 on item 9 of the Beck Depression Inventory II (BDI-II) [49,50] and question A9 of the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Axis I Disorders (SCID-I) [51]. In the event that potential participants were excluded because of suicidal ideation or intention, they were given information about further help according to an established suicide protocol. All excluded participants were contacted via email and provided with information regarding where they could obtain appropriate help.

### Treatment

Participants in the treatment condition received the GET.ON Panic treatment, which is a hybrid (ie, desktop-based and smartphone-based), iCBT-based self-help intervention for treating symptoms of panic disorder [45]. Participants were advised to log on to the training platform, which was provided by the technical partner Minddistrict GmbH on a weekly basis and consecutively work through the following sessions: (1) psychoeducation, (2) interoceptive exposure, (3) in vivo exposure, (4) cognitive restructuring—introduction, (5) cognitive restructuring—extension, and (6) relapse prevention. In addition, participants were instructed on the complementary use of the GET.ON Panic app [52]. The app supported participants in (1) completing their homework assignments (eg, keeping an anxiety diary); (2) planning, conducting, and evaluating interoceptive and in vivo exposure tasks; and (3) performing relaxation exercises (Table 1).

After every session, participants received written feedback from a trained coach based on a coaching manual developed by members of our research group to ensure a standardized procedure of coaching (the manual is available on request). The guidance focused on increasing motivation and adherence throughout the training progress, rather than providing individual therapeutic advice. The average feedback took about 20-30 min. Coaches also sent reminders via a secure messaging system within the training platform if participants did not log on for 1 week. All coaches had a degree in psychology and were supervised by a licensed clinical psychologist.

<table>
<thead>
<tr>
<th>Table 1. Overview of sessions.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week</strong></td>
</tr>
<tr>
<td><strong>Browser</strong></td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Outcome Measures

Panic Symptom Severity and Self-Rating
The primary outcome was the severity of panic and agoraphobia symptoms, as self-assessed using the PAS (German version: Panik- und Agoraphobieskala) [46,47,53,54]. This scale consists of 13 items separated into the subscales of panic attacks, agoraphobic avoidance, anticipatory anxiety, daily life limitations, and health concerns. For each item, participants rated the frequency of panic symptoms during the past week on a 5-point scale. Thus, the total score ranges from 0 to 52, with scores ranging from 0 to 8 indicating no clinically relevant symptoms, scores ranging between 9 and 28 indicating moderate symptoms, and a score of 29 and above indicating a severe level of symptoms. Previous studies provide evidence for the efficacy of the measures, for example, Cronbach $\alpha=.86$ [47] or $\alpha=.70$ to .94 [55]. In this study, Cronbach $\alpha$ for the total score was .89.

Observer-Rated Anxiety Symptoms
The Hamilton Anxiety Scale (HAM-A) [56-58] was used as a complement for the self-administered anxiety scales. The scale contains 14 items, with a total score ranging from 0 to 30. Previous studies showed excellent interrater and test-retest reliabilities of intraclass correlation coefficient of 0.89-0.99 [57]. To examine interrater reliability in this trial, we audiotaped all the observer ratings. Around one-tenth (equivalent to 28 interviews) of these audio files were rated by experienced, blinded second raters. The interrater reliability was excellent, with an intraclass correlation coefficient of 0.99.

Agoraphobic Cognitions
The Agoraphobic Cognitions Questionnaire (ACQ) is a 14-item self-report questionnaire that measures agoraphobic cognitions. The total sum score of the ACQ ranged from 1 to 5. The ACQ has an internal reliability of Cronbach $\alpha$ of .80 [59-61]. In this trial, we found a Cronbach $\alpha$ of .84.

Body Sensations
Bodily sensations were measured using the Body Sensations Questionnaire (BSQ), a self-rating questionnaire with the total score ranging from 1 to 5 points. It has good internal reliability of Cronbach $\alpha$ of .87 [59-61]. In this trial, Cronbach $\alpha$ was .86.

Agoraphobic Avoidance
The Mobility Inventory (MI) is a questionnaire that measures agoraphobic avoidance. Participants were asked to rate common agoraphobic situations with regard to their avoidance. Each item is rated twice: once for dealing with the situation alone and once when accompanied. The total score ranged from 1 to 5 points. The internal consistencies reported in previous studies were very good, with Cronbach $\alpha$ of .91 (accompanied by significant others) and .94 (alone) [59,61,62]. In this study, Cronbach $\alpha$ values of the MI were .93 (accompanied) and .95 (alone).

Depressive Symptoms
We used the German adaption (ADS) of the Center for Epidemiologic Studies Depression Scale (CES-D) to assess depressive symptom severity. The CES-D measures 20 symptoms of depression in the previous week. The total score ranges from 0 to 60. Internal consistency has been shown to be good (Cronbach $\alpha=.89$) [63,64]. In this study, Cronbach $\alpha$ was .87.

Diagnostic Status
The presence of panic disorder, any other anxiety disorder, or a current depressive episode was assessed using a telephone version of the SCID-I at the 6-month follow-up (6M-FU) assessment covering the period of the last 3 months by trained interviewers. Previous studies have shown excellent test-retest reliability between the 2 different formats, the telephone version and the face-to-face (f2f) version of the diagnostic interview (Cohen $\alpha=0.84$) [65-67]. To determine the interrater reliability of the diagnostic interviews, we used the statistics. In a previous study, moderate interrater reliability (Cohen $\alpha=0.67$) was found [68]. In this trial, all interviews were audiotaped, with 11.1% (18/162) of the interviews rated by an experienced, blinded second rater. Agreement between the 2 raters was moderate, with a Cohen of 0.51.

Quality of Life
Quality of life was measured using the 12-item Short-Form Health Survey (SF-12), which assesses 8 health domains: physical functioning, role limitations, pain, general health perception, vitality, mental health, emotional role, and social functioning. The SF-12 provides 2 summary scores for physical and mental health [69,70]. In this trial, Cronbach $\alpha$ was .79.

User Satisfaction
We assessed user satisfaction with the Client Satisfaction Questionnaire adapted to internet-based interventions (CSQ-I) [71], which is based on the German version of the Client Satisfaction Questionnaire [72,73]. Statements such as “I would recommend this training to a friend, if he or she was in need of similar help” are rated on a 4-point Likert scale (ranging from 1=dos not apply to me to 4=does totally apply to me). The questionnaire contained 8 items, with a total score ranging from 8 to 32. The psychometric properties were excellent with a McDonald $\omega$ of 0.93 and $\omega$ of 0.95 [71]. In this trial, McDonald $\omega$ was 0.97.

App Usage
The mobile app contains a diary for recording and monitoring panic-related symptoms, such as panic events, degree of avoidance behavior, general anxiety, and mood level on a visual analog scale (0-10). Furthermore, the app recorded the type and number of exposure exercises performed by the participant. In addition, we used the System Usability Scale (SUS) at postassessment (T2) to assess the usability of the GET.ON Panic app [74,75]. The sum score ranges from 0 to 100, with a higher score indicating better usability.

Assessment Schedule
Participants completed a sociodemographic questionnaire, the PAS and the Suicidality item of BDI-II at screening (T0); at baseline (T1), we assessed the PAS, the SCID-I, the HAM-A, the ACQ, the BSQ, the MI, the CES-D, and the SF-12; at postassessment (T2), we assessed the PAS, the HAM-A, the ACQ, the BSQ, the MI, the CES-D, the SF-12, the CSQ-I (only
IG), and the SUS (only IG); at 3-month follow-up (3M-FU; T3), we assessed the PAS, the ACQ, the BSQ, the MI, the CES-D, and the SF-12; and at 6M-FU (T4), we assessed the PAS, the SCID-I, the HAM-A, the ACQ, the BSQ, the MI, the CES-D, and the SF-12. Diary data were continuously measured during the training period and beyond (Table 2).

Table 2. Assessment schedule.

<table>
<thead>
<tr>
<th>Assessments</th>
<th>Screening</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographic questionnaire</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Suicidality (Item 9; BDI-II)</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Diagnosis (SCID-I, sections for anxiety disorders and current depressive</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>episode)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panic and agoraphobia severity, self-rating (PAS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Panic and agoraphobia severity, observer-rating (HAM-A)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td>Agoraphobic cognitions (ACQ)</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Body sensations (BSQ)</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Agoraphobic avoidance (Mobility Inventory)</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td>Depressive symptoms (CES-D)</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td>Quality of life (SF-12)</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td>User satisfaction (CSQ-I)</td>
<td>—</td>
<td>—</td>
<td>(X)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Usability of smartphone app (SUS)</td>
<td>—</td>
<td>—</td>
<td>(X)</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

aMeasured.
bNot measured.
cBDI- II: Beck Depression Inventory II.
dSCID-I: Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Axis I Disorders.
ePAS: Panic and Agoraphobia Scale.
fHAM-A: Hamilton Anxiety Scale.
gACQ: Agoraphobic Cognitions Questionnaire.
hBSQ: Body Sensations Questionnaire.
iCES-D: Center for Epidemiologic Studies Depression Scale.
jSF-12: 12-Item Short-Form Health Survey.
kCSQ-I: Client Satisfaction Questionnaire adapted to internet-based interventions.
IOnly available for intervention group.
mSUS: System Usability Scale.

Statistical Analyses

To assess treatment efficacy, the GET.ON Panic group was compared with the WLC group on all outcome measures (T2, T3, and T4) using univariate analyses of covariance (ANCOVAs) with the baseline scores as covariates. On the basis of a previous meta-analysis [21], we powered the study to detect an effect size of Cohen \( d=0.6 \) (1–0.80; \( p=.05 \)) with intention-to-treat (ITT) at T2 as our primary level of analysis. Accordingly, a sample size of 90 was required. Cohen \( d \) [76] was used to measure effect size. To account for covariance, we calculated Cohen \( d \) over the partial eta squared (\( \eta^2 \)). To assess a clinically reliable change of panic severity (response) on an individual level, we calculated the Reliable Change Index (RCI) as proposed by Jacobson and Truax [77], coded participants as responders or deteriorators if their score on the PAS differed by 10.68 points on the PAS, and performed a Pearson chi-square test to compare the reliable change of the GET.ON Panic group with the WLC. Corresponding to the RCI, we calculated numbers needed to treat (NNT) score indicating how many participants must take part in order for GET.ON Panic to achieve one clinically relevant improvement. To assess remission rates, we calculated the percentage of people who had a diagnostic status of panic disorder according to the SCID-I interview at baseline (T0) and at the 6M-FU (T4) and performed a Pearson chi-square test to compare the diagnostic status of the GET.ON Panic group with the WLC covering a period of the last 3 months.

Missing data at postassessment, 3M-FU assessment, and 6M-FU assessment were performed using a Markov Chain Monte Carlo multivariate imputation algorithm (SPSS 23) with hundred estimations per missing value and all available data on outcomes, age, and gender as predictors [78].
Results

Enrollment

Over a period of 14 months, a total of 235 individuals completed the screening questionnaire. Of these, 117 did not meet the inclusion criteria or matched one or more exclusion criteria (Figure 1). Severe panic symptom severity (n=54), current psychotherapy (n=34), or physical contraindications (n=23) were the most frequent reasons for exclusion. The remaining 118 candidates were eligible to participate in the clinical interviews. Of those, 19 did not provide informed consent. After this interview, another 6 candidates were excluded because they did not have panic symptoms as their primary reason for seeking help. All excluded individuals were provided with information about applicable health care system services. The remaining 92 participants were randomly assigned to the hybrid web-based training program GET.ON Panic or the WLC condition.

Baseline Characteristics

Most participants were female (51/92, 55%), White (76/92, 83%), on average aged 38 years (SD 10.42), highly educated (60/92, 65%), married or in a relationship (82/92, 89%), and currently working (51/92, 55%). On the basis of the SCID interview, the most common diagnosis was panic disorder with agoraphobia (78/92, 83%). A significant number of patients (12/92, 13%) met the criteria for panic disorder without agoraphobia. Of all participants, 26% (24/92) met the criteria for at least one additional anxiety disorder, in addition to panic disorder. A small percentage (2/92, 2%) had a current major depressive episode as a comorbid condition. Most participants (58/92, 63%) reported that they had previously undergone psychotherapeutic treatment (Multimedia Appendix 1).

Study Dropout and Compliance in Treatment

Baseline data were available for all the participants. The attrition rate was 9% (8/92) at postassessment (4/45 in the IG and 4/47 in the WLC), 18% (17/92) at the 3M-FU (10/45 in the IG and 7/47 in the WLC), and 22% (20/92) at the 6M-FU (10/45 in the IG and 10/47 in the WLC; Figure 1).

On average, the number of completed sessions in the GET.ON Panic group was 5.11 (SD 1.67). All 6 sessions were completed by 73% (33/45) of the participants, 4% (2/45) of the participants completed only session 1, 11% (5/45) of the participants dropped out after session 2, 7% (3/45) of the participants were lost after session 3, 2% (1/45) of the participants stopped the training after completing session 4, and 2% (1/45) after session 5. In total, 27% (12/45) of the participants did not complete the training. The reasons for intervention dropout were mentioned for 33% (4/12) of them: lack of time, lack of motivation, lack of personal contact with the eCoach, or surgery that interfered with completing the intervention. The resting 67% (8/12) of the participants were also study dropouts, and no reasons for stopping the intervention were known because they did not complete the postassessment.

Severity of Panic Symptoms

Preliminary analyses indicated that all necessary conditions for the intended statistical analyses were met. There was a greater decrease in self-reported panic disorder symptom severity in the intervention condition than in the WLC condition (Multimedia Appendices 2 and 3). With regard to the primary outcome, participants in the GET.ON Panic condition reported...
significantly lower (baseline-controlled) panic symptom severity at posttreatment than the WLC group ($F=9.77$; $P=.002$; partial $\eta^2=0.10$; Cohen $d=0.66$; 95% CI 0.24-1.08). This effect became even stronger ($F=17.40$; $P<.001$; partial $\eta^2=0.16$; Cohen $d=0.89$; 95% CI 0.46-1.31) at the 3M-FU and remained significant ($F=14.63$; $P<.001$; partial $\eta^2=0.14$; Cohen $d=0.81$; 95% CI 0.38-1.24) at the long-term 6M-FU. The effect sizes ranged from medium to large.

With regard to observer-based ratings, ANCOVA showed a significant difference in anxiety symptoms between groups as measured by the HAM-A at postmeasurement ($F=3.97$; $P=.049$; partial $\eta^2=0.04$; Cohen $d=0.42$; 95% CI 0.01-0.84) and at the 6M-FU ($F=4.86$; $P=.03$; partial $\eta^2=0.05$; Cohen $d=0.47$; 95% CI 0.05-0.88) with small-to-medium effect sizes. Further analyses indicated that the findings did not significantly change when the analyses were based on the study completer instead of the ITT sample.

With regard to response, the reliable clinical changes were not significant at postmeasurement ($\chi^2_2 \ [n=92]=2.5$; $P=.28$; improvement: GET.ON Panic: 12/45, 27% and WLC: 7/47, 15%; deterioration: GET.ON Panic: 2/45, 4% and WLC: 1/47, 2%) or at the 3M-FU ($\chi^2_2 \ [n=92]=5.3$; $P=.07$; improvement: GET.ON Panic: 14/45, 31% and WLC: 6/47, 13%; deterioration: GET.ON Panic: 0/45, 0% and WLC: 1/47, 2%). However, the GET.ON Panic group was superior to the WLC in terms of the percentage of participants attaining reliable clinical change (RCII=±10.68) in panic symptom severity at the 6M-FU ($\chi^2_2 \ [n=92]=6.0$; $P=.049$; improvement: GET.ON Panic: 22/45, 49% and WLC: 12/47, 26%; deterioration: GET.ON Panic: 0/45, 0% and WLC: 1/47, 2%). These reliable clinical changes correspond to NNT from baseline to posttreatment of 8.49 (95% CI 3.54 to $>10^6$), at the 3M-FU of NNT=5.45 (95% CI 2.87-55.78), and at the 6M-FU of NNT=4.28 (95% CI 2.35-24.07). Regarding the long-term effect, these results indicate that 4 individuals had to participate in the GET.ON Panic training program to result in one additional individual having reliable clinical improvement in panic symptom severity.

With regard to remission rates, at baseline, nearly all participants (90/92, 98%) fulfilled the diagnostic criteria for panic disorder. At the 6M-FU, 76% of the participants (70/92, 76%) GET.ON Panic group; 33/45, 73%; WLC: 37/47, 79%) agreed to the telephone-administered diagnostic interview. In total, 21% (15/70) of the participants were free of a diagnosis. There was a greater reduction in diagnoses in the GET.ON Panic group (11/33, 33%) than in the WLC group (4/37, 11%; $\chi^2_1 \ [n=70]=5.3$; $P=.02$).

### Additional Anxiety Measures

Comparing the GET.ON Panic with the WLC group on further self-rated anxiety measurements, we found stronger between-group effect sizes for agoraphobic cognitions (partial $\eta^2=0.06$; Cohen $d=0.51$; 95% CI 0.05-0.93) and bodily sensations (partial $\eta^2=0.05$; Cohen $d=0.46$; 95% CI 0.05-0.88) in the GET.ON Panic group than in the WLC group at posttreatment. With regard to follow-up measurements, these effects remained stable for both agoraphobic cognitions (partial $\eta^2=0.07$; Cohen $d=0.55$; 95% CI 0.14-0.97 after 3 months and partial $\eta^2=0.05$; Cohen $d=0.46$; 95% CI 0.04-0.87 after 6 months) and bodily sensations (partial $\eta^2=0.14$; Cohen $d=0.79$; 95% CI 0.37-1.22 after 3 months and partial $\eta^2=0.09$; Cohen $d=0.66$; 95% CI 0.22-1.06 after 6 months). A difference in agoraphobic avoidance between the groups could only be found when participants had to manage difficult situations when they were alone with small effect sizes (partial $\eta^2=0.05$; Cohen $d=0.45$; 95% CI 0.04-0.86) at posttreatment and a medium effect size (partial $\eta^2=0.11$; Cohen $d=0.70$; 95% CI 0.27-1.12) at the 6M-FU. ANCOVA did not reveal a significant difference between the groups regarding agoraphobic avoidance when participants had to manage difficult situations when they were in companionship with other people (Multimedia Appendices 2 and 3).

### Additional Measures

At the postmeasurement as well as at the 3M-FU, the GET.ON Panic group showed no significant reduction in depressive symptoms compared with the WLC group (Multimedia Appendices 2 and 3). However, at the 6M-FU, the depressive symptoms of the GET.ON Panic group decreased significantly with a small effect size compared with the WLC group (partial $\eta^2=0.06$; Cohen $d=0.49$; 95% CI 0.07-0.90). The results on the quality of life scales with regard to mental health showed no reduction at postmeasurement or at the 3M-FU but a medium reduction after 6 months (partial $\eta^2=0.11$; Cohen $d=0.70$; 95% CI 0.28-1.12). Furthermore, no differences in symptoms regarding physical aspects of quality of life were found.

### App Usage and User Satisfaction

The participants of the training group (n=45) used the mobile diary on average 25.02 times (SD 19.48; range 0-56) during the 8-week training period on average (0.45 diary entries per day per participant). The repeated analysis of variance did not reveal any changes in the daily scores over a period of 8 weeks. Furthermore, they were not related to the primary outcome. The participants performed an average of 149.80 (SD 279.34; range 0-1702) interoceptive exposure exercises and 6.63 in vivo exercises (SD 17.74; range 0-113). The mean SUS score was 71.16 (SD 18.97) at posttreatment, which indicates good usability of the GET.ON Panic app. Overall, user satisfaction with the hybrid training program was high (mean 28.10, SD 5.09). For example, 91% of the participants indicated that they would recommend the training program to a friend in need.

### Discussion

#### Principal Findings

This study aims to evaluate the efficacy of GET.ON Panic, a guided, mobile- and web-based CBT training program for adults with significant panic disorder symptoms. The results show that individuals treated with GET.ON Panic experienced a significantly greater reduction in panic disorder symptom severity than did participants in a WLC condition with between-group effect sizes of Cohen $d$. The findings also show that the effects were not only stable over time but even increased

---

Ebenfeld et al.
after the treatment was completed (Cohen $d/NNT=0.66/8.49$ at posttreatment vs Cohen $d/NNT=0.89/5.45$ after 3 months and Cohen $d/NNT=0.81/4.28$ after 6 months).

**Comparison With Prior Work**

As such, they fall well into the range of reported effect sizes in meta-analyses for internet-based interventions for panic disorder (eg, Hedge $g=0.83$ [18]; $g=1.31$ [19]; Hedge $g=0.83$ [21]; Cohen $d=0.96$ [24]). The findings also showed that one of 3 participants in the IG had attained complete remission of panic disorder at the last assessment point, whereas this was only the case in one of 10 participants in the control group. With regard to secondary outcomes, it is of note that the 6M-FU effects on depressive symptoms are larger than the average of effects reported for psychological treatment for depression (Cohen $d=0.49$ vs Hedge $g=0.35$ [79]). Finally, in this study, adherence rates and user satisfaction were slightly higher than those reported in previous studies (adherence: 73% vs 66%; satisfaction: 91% vs 86% [19]).

A potential step-up could be the use of an intervention that integrates hybrid web-based training program into f2f CBT [80]. In such blended interventions, therapists might fully exploit the potential of using the ecological momentary assessment data provided by the smartphone as well as the potential of ecological momentary interventions derived from individual case formulations and carried into the patient’s life with the help of their mobile devices [81]. The adherence and usability rates in this study appear to be superior to what is currently reported for desktop-based iCBT interventions. This suggests that the integration of mobile components into iCBT should be a focus of future studies. The rapidly shifting use of mobile- instead of desktop-based devices underlines this [26,82].

The finding that depressive symptom severity was significantly reduced in the IG is important, as many individuals with panic disorder also have other mental health problems such as depression [83]. As cooccurring disorders may mutually help maintain each other [5,84], it is important that comorbid conditions are treated along with the primary disorder. The positive effects of the hybrid intervention evaluated in this study on depression are consistent with the findings from CBT that integrates hybrid web-based training program into f2f CBT [80]. However, as such a design was beyond what we could realize in this study, it would need to be used in subsequent studies. Such studies should also compare the efficacy (and cost-effectiveness) of desktop-, mobile-based, hybrid, and blended interventions with f2f therapy for panic disorder. Third, we cannot draw any conclusions on the efficacy beyond the 6M-FU assessment. Thus, future studies should evaluate the long-term effects of hybrid iCBT interventions for panic disorder.

**Strengths and Limitations**

To our knowledge, this is the first study to examine the efficacy of iCBT training program that makes use of mobile components in a target group of people with mild-to-moderate panic and agoraphobia symptoms. One of the main strengths of this study is its solid study design, which tests a newly developed training program within a randomized controlled trial against a WLC. In addition to self-rating outcomes, we conducted clinical interviews with regard to symptom severity and changes in diagnostic status over a period of 6 months and an observer-rated anxiety outcome to validate the outcomes based on self-ratings. Furthermore, this study has high ecological validity, as participants used their own smartphones. They were supposed to interact with their smartphones as they would normally do. This may lead to a higher acceptance of and satisfaction with the GET.ON Panic training program and foster the integration of psychological interventions into the daily lives of individuals. The overall low dropout rates in this study support this assumption.

This study has several limitations that need to be considered. First, the study results cannot be generalized to all individuals with panic disorder symptoms. Participants who took part in this study actively participated and underwent an extended eligibility procedure before the study. Many interested individuals were excluded based on the criteria defined in the study protocol. Thus, we assume that the current participants represent a more intrinsically motivated study sample and, in addition, have a higher affinity for the internet than the average individuals with panic disorder. Therefore, the external validity of this study might be limited. Second, for future treatment development, it would have been of interest to compare the hybrid intervention with both an exclusively desktop-based and an exclusively mobile-based intervention for panic disorder. However, as such a design was beyond what we could realize in this study, it would need to be used in subsequent studies.

**Acknowledgments**

This project was funded by the European Union (project number: EFRE CCI 2007DE161PR001).

**Authors’ Contributions**

LE, DL, DE, SK, HR, BF, and MB contributed to the study design. LE, DL, DE, and MB developed the hybrid web-based training program for treating people with panic disorder with or without agoraphobia (GET.ON PANIC). SK developed the app (GET.ON...
PANIC APP), which supervised the technical aspects of the intervention. LE performed statistical analyses. DL and SK contributed to statistical analyses. LE drafted the manuscript. MB revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest
DL, DE, and BF are shareholders, and LE is an employee of the transfer institute (GET.ON Institute) that has usage and exploitation rights of the GET.ON Panic training program. However, at the time of developing and evaluating the app and the hybrid web-based training program GET.ON Panic, as well as drafting the manuscript, the company was not yet incorporated.

Multimedia Appendix 1
Characteristics of the study participants (N=92) allocated to online training GET.ON intervention group (n=45) and wait-list control group (WLC) (n=47) at baseline.

Multimedia Appendix 2
Mean and SD values of all outcome variables at baseline, posttreatment, and at 3-month and 6-month follow-ups (intention-to-treat, N=92).

Multimedia Appendix 3
Differences between groups at T2, T3, and T4 (intention-to-treat, N=92).

Multimedia Appendix 4
CONSORT-eHEALTH checklist (V 1.6.1).

References


Schneider S, Margraf J. Agoraphobia and panic disorder. URL: https://www.hogrefe.de/de/shop/agoraphobie-und-panikstörung-76509.html [accessed 2021-02-16]


63. Hautzinger M, Baier M. General depression scale. ADS. URL: https://www.testzentrale.de/shop/allgemeine-depressionsskala.html [accessed 2021-02-16]


82. mHealth: new horizons for health through mobile technologies. World Health Organization. 2011. URL: https://www.who.int/goe/publications/goe_mhealth_web.pdf [accessed 2021-02-08]


Abbreviations

3M-FU: 3-month follow-up
6M-FU: 6-month follow-up
ACQ: Agoraphobic Cognitions Questionnaire
ANCOVA: analysis of covariance
BDI-II: Beck Depression Inventory II
BSQ: Body Sensations Questionnaire
CBT: cognitive behavioral therapy
CES-D: Center for Epidemiologic Studies Depression Scale
CSQ-I: Client Satisfaction Questionnaire adapted to internet-based interventions
f2f: face-to-face
HAM-A: Hamilton Anxiety Scale
iCBT: internet-based interventions based on cognitive behavioral therapy principles
IG: intervention group
ITT: intention-to-treat
MI: mobility inventory
NNT: numbers needed to treat
PAS: Panic and Agoraphobia Scale
RCI: Reliable Change Index
SCID-I: Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Axis I Disorders
SF-12: 12-Item Short-Form Health Survey
SUS: System Usability Scale
WLC: wait-list control

Edited by G Eysenbach; submitted 29.05.20; peer-reviewed by M Feijt, K Mathiasen; comments to author 29.06.20; revised version received 06.10.20; accepted 17.01.21; published 04.03.21.

Please cite as:
Ebenfeld L, Lehr D, Ebert DD, Kleine Stegemann S, Riper H, Funk B, Berking M
Evaluating a Hybrid Web-Based Training Program for Panic Disorder and Agoraphobia: Randomized Controlled Trial
J Med Internet Res 2021;23(3):e20829
URL: https://www.jmir.org/2021/3/e20829
doi:10.2196/20829
PMID:33661121

©Lara Ebenfeld, Dirk Lehr, David Daniel Ebert, Stefan Kleine Stegemann, Heleen Riper, Burkhardt Funk, Matthias Berking. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 04.03.2021. This is an open-access article

https://www.jmir.org/2021/3/e20829 J Med Internet Res 2021 | vol. 23 | iss. 3 | e20829 | p.93
(page number not for citation purposes)
Association of Spontaneous and Induced Self-Affirmation With Smoking Cessation in Users of a Mobile App: Randomized Controlled Trial

Elizabeth L Seaman1, MHS, PhD; Cendrine D Robinson2, MPH, PhD; David Crane3, PhD; Jennifer M Taber4, PhD; Rebecca A Ferrer2, PhD; Peter R Harris5, PhD; William M P Klein2, PhD

1CDC Foundation, Atlanta, GA, United States
2Behavioral Research Program (BRP), Division of Cancer Control and Population Sciences, National Cancer Institute, Rockville, MD, United States
3Smoke Free, 23 Ltd, London, United Kingdom
4Department of Psychological Sciences, Kent State University, Kent, OH, United States
5School of Psychology, University of Sussex, Falmer, Brighton, United Kingdom

Corresponding Author:
Elizabeth L Seaman, MHS, PhD
CDC Foundation
600 Peachtree Street NE, Suite 1000
Atlanta, GA, 30308
United States
Phone: 1 4438524139
Email: eseaman@cdcfoundation.org

Abstract

Background: Most smokers attempt to stop using cigarettes numerous times before successfully quitting. Cigarette cravings may undermine perceived competence to quit and thus constitute psychological threats to the individual’s self-concept. Self-affirmation may promote smoking cessation by offsetting these threats.

Objective: This study examines whether self-affirmation is associated with smoking cessation in the context of a cessation app. Two types of self-affirmation are examined: tendency to spontaneously self-affirm, and self-affirmation inductions added to a publicly available smoking cessation app (Smoke-Free Quit Smoking Now). In addition, this study explores whether optimism and emotional states (happiness, anger, anxiousness, hopefulness, sadness) predict smoking cessation.

Methods: All users who met the inclusion criteria, provided consent to participate, and completed a baseline assessment, including all individual difference measures, were randomized to 1 of 4 conditions. Half of the participants were randomly assigned to complete a self-affirmation induction upon study entry. Orthogonally, half of the participants were randomly assigned to receive self-affirming text notifications during their quit attempt or to receive conventional notifications. The induction and the text notifications were fully automated, and all data were collected through self-assessments in the app. Self-reported smoking cessation was assessed 1 month and 3 months following study entry.

Results: The study enrolled 7899 participants; 647 completed the 1-month follow-up. Using an intent-to-treat analysis at the 1-month follow-up, 7.2% (569/7899) of participants self-reported not smoking in the previous week and 6.4% (503/7899) self-reported not smoking in the previous month. Greater tendency to spontaneously self-affirm predicted a greater likelihood of cessation (P<.001) at 1 month after controlling for smoking-related variables. Neither self-affirmation induction influenced cessation. In addition, spontaneous self-affirmation did not moderate the relationship between self-affirmation inductions and cessation. Greater baseline sadness was associated with a lower likelihood of reporting successful cessation. Optimism predicted past-week cessation at the 1-month follow-up, and both happiness and anger predicted past-month cessation at the 1-month follow-up; however, none of these potential predictors moderated the relationship between self-affirmation conditions and successful cessation.

Conclusions: Spontaneous self-affirmation may be an important psychological resource for managing threats to self-concept during the smoking cessation process. Sadness may hinder quit attempts. Future research can explicate how spontaneous versus induced self-affirmation can promote smoking cessation and examine boundary conditions for the effectiveness of disseminated self-affirmation interventions.
smoking cessation; smartphone; mHealth; sadness; self-affirmation; spontaneous self-affirmation; apps; mobile phone

Introduction

Background

Tobacco use remains a leading cause of preventable death and disease globally, contributing to over 7.1 million deaths annually [1]. Each year, approximately 343,000 people in the United States die from cancer related to tobacco use [2]. Many adults are motivated to quit smoking cigarettes; however, most attempts to quit are unsuccessful [3,4]. Clinical practice guidelines emphasize combining pharmacological treatments with behavioral interventions [5]. There are several empirically supported behavioral treatments for smoking cessation [6]. However, the high rate of unsuccessful quit attempts [7] suggests that there is a need for supplementary and easily disseminable behavioral interventions.

Mobile Health and Smoking Cessation

There is a growing body of literature supporting behavioral smoking cessation treatments delivered via mobile health platforms, including smartphones [8-10]. As smartphone access in the United States continues to rise, more individuals will have access to behavioral interventions delivered on smartphones. About 81% of US adults own a smartphone [11], and 72% of adult internet users have searched for health-related information on the web [12]. One international systematic review established that web-based health information seeking is common in many different countries and found that web-based health information seeking can improve patient-physician relationships [13].

Smartphone apps for smoking cessation can include a variety of theory-based intervention components that promote cessation, such as techniques to facilitate coping with craving and behavioral strategies for removing smoking-related stimuli from a smoker’s house [14]. Smoke Free-Quit Smoking Now is one such mobile app for smoking cessation that includes the behavior change techniques of supporting users to take on the identity of a nonsmoker, rewarding cessation, and changing routines [15].

Self-Affirmation Theory and Applications to Smoking Cessation

Quitting smoking is a difficult endeavor, and most smokers attempt cessation many times before they successfully quit [16]. The process of attempting to quit smoking may in itself be psychologically threatening, as smokers may interpret cravings and temporary relapse during the process as indicators of lack of competence for quitting, constituting a threat to self-concept that results in negative affect [17]. When self-competence is threatened, it may undermine the cessation process by reducing motivation to quit or cessation self-efficacy. Many smoking cessation interventions bolster perceived competence to quit [18]. However, interventions to protect the self-concept are less common and may bolster the effectiveness of existing cessation interventions.

One such intervention approach is based on self-affirmation theory. According to this theory, people are highly motivated to see themselves as having self-integrity, which is marked by a sense of moral adequacy and competence [19]. Thus, when they experience threats to these attributes, they may respond defensively in an attempt to protect and bolster their self-integrity [20,21]. Health behavior change interventions often contain such threats because they suggest that one is volitionally engaged in a behavior that is harmful or irrational [22,23]. Defensiveness in the face of threats to self-integrity has been observed among smokers [24,25]. For example, smokers may respond to threatening cessation messages by impugning their content [26]. Even smoking cessation materials that are not explicitly threatening or loss-framed may be perceived as threatening by smokers attempting to quit or former smokers struggling with relapse. Self-affirmation theory suggests that to the extent that people can sustain views of themselves as morally adequate and competent, they will be more open to specific threats to the self. For example, smokers who are reassured about their self-integrity may be able to better face the challenges of cessation [27]. Accordingly, much research shows that when people have an opportunity to reflect on, for example, their cherished values before being exposed to threatening health information, such as a graphic warning label [24,28] or personal disease risk [29], they are more receptive to that information and may be more likely to engage in risk reduction behavior (meta-analyses [30-32]). We thus hypothesized that self-affirmation could offset the potential threats associated with quitting and, in turn, promote successful cessation.

Although evidence suggests that self-affirmation inductions can improve engagement with and efficacy of health behavior intentions, evidence is mixed for studies specifically targeting smokers. Some studies have found benefits of self-affirmation [28,33-38], including less defensiveness toward graphic warnings [28,36]. Moreover, when combined with other intervention strategies, such as motivational interviewing and cessation programs, self-affirmed individuals reduced cigarette consumption [37]. However, other studies have not found beneficial effects of self-affirmation on smoking-related outcomes for daily smokers [35,39,40]. Thus, additional research is needed to determine the effectiveness of induced self-affirmations among smokers.

In addition to research on self-affirmation inductions, some people are more likely than others to naturally or spontaneously engage in self-affirmation when feeling threatened or anxious [34,41-43]. Spontaneous self-affirmation may serve as a resource to facilitate smoking cessation because of its potential to offset...
cessation-related psychological threats in ways similar to induced self-affirmation. Indeed, the tendency to report spontaneous self-affirmation has been associated with greater acceptance of threatening health information [41,44], greater health information seeking [45], and other positive health-related outcomes, including higher perceived quality of care and increased likelihood of asking questions in a medical appointment [45-47].

There is some evidence that spontaneous self-affirmation may be beneficial for smokers. In one cross-sectional study of U.S. adult smokers, spontaneous self-affirmation moderated the relationship between living in a state with smoke-free policies, which may constitute a threatening environment for smokers, and quit intentions [48]. In this study, we examined whether spontaneous self-affirmation was associated with quit outcomes among a global cohort of smokers enrolled in a UK-based smoking app. In addition, we examined whether the tendency to spontaneously self-affirm moderated the relationship between self-affirmation inductions and successful cessation.

In addition to the tendency to spontaneously self-affirm, other psychological states and individual differences may serve as resources to bolster smoking cessation, either by interacting with self-affirmation or on their own. In this study, we examined optimism and sadness. Optimism refers to a general tendency to expect positive future events [49]. As optimism is a psychological resource that can bolster goal pursuit [50,51], people with higher optimism may have greater success at smoking cessation. Spontaneous self-affirmation and optimism are distinct psychological processes [41]; however, they may have similar associations with health outcomes, extending to smoking cessation [46]. Currently experienced emotions may also influence smoking cessation; such emotions may trigger action tendencies that facilitate predictable patterns of behavior [52-54]. Sadness, in particular, may be a hindrance to quitting smoking and predicting relapse during the smoking cessation process [55]. Sadness is associated with reward-seeking tendencies to mitigate loss [56], which can result in increased hedonically pleasing, but often unhealthy, appetitive behavior [57], including smoking [55]. Thus, when current or former smokers feel sad, they may turn to cigarettes in an attempt to improve their mood. In addition to influencing cessation success, emotion may influence the experience of relapse during the smoking cessation process.

Self-Affirmation and Mobile Health: Creating Scalable Health Behavior Interventions

Health behavior interventions that are mobile or remotely delivered are easily implemented and widely disseminated, and integrating self-affirmation content could enhance their efficacy. The scalability of self-affirmation interventions has been demonstrated in other domains in which threat impedes adaptive outcomes (e.g., education; [58]) but has rarely been examined in health contexts. Indeed, self-affirmation opportunities are disseminable, given that affirmation exercises require little time and effort but can have lasting effects [58,59]. Enduring effects from such a low-burden intervention are hypothesized to work through recursive processes [32]. That is, it is not necessarily the affirmation itself that continues to influence behavior over time. Rather, affirmation attenuates threats to self-competence that might arise from cravings and temporary relapse, which might otherwise impede motivation to quit smoking, and then allows individuals to capitalize on existing resources to facilitate behavior change [58,60]. A recent meta-analysis suggested that self-affirmation is more likely to facilitate change when psychological threat impedes behavior change and when resources are present to support such change [32]. Thus, implementing brief affirmations into an existing, scalable cessation intervention in which psychological threat may impede cessation may bolster the effectiveness of the intervention by maximizing the likelihood that individuals will benefit from the behavior change resources provided in the intervention.

Previous Work Informing This Study

This study was designed as a follow-up to a previous study that provided initial evidence that incorporating a self-affirmation component into a standard text message–based smoking cessation intervention was a feasible, low-cost, and potentially efficacious way of bolstering the content of that intervention [61]. This previous study used a 2 (baseline affirmation: present vs absent) x 2 (integrated affirmation texts: present vs absent) factorial design [61]. In that study, 1261 participants met the eligibility criteria and initiated the program, 687 participants remained enrolled throughout the 42-day intervention, and 81 participants reported their smoking status at the end of the 42-day intervention [61]. Although there were no significant effects of affirmations on cessation when examining participants who remained enrolled in the study (n=687), affirmations did facilitate cessation when only participants who reported their smoking status at the 42-day follow-up were included in analyses (n=81, 6.4% of eligible baseline respondents) [61]. Intent-to-treat analyses of the 1261 participants who initiated the program indicated a 5.6% cessation prevalence at the 42-day follow-up [61]. This study builds on this former work by (1) providing a test of replication and (2) examining the role of individual differences in spontaneous self-affirmation, optimism, and affect.

This Study and Hypotheses

This study was intended to replicate our team’s earlier study (Taber et al [61]) in a different setting. In this study, we tested whether self-affirmation was associated with better cessation outcomes in the context of a smoking cessation app. This study had 2 primary aims: to assess the effect of induced self-affirmation conditions on smoking cessation outcomes (aim 1) and to assess the associations of spontaneous self-affirmation with smoking cessation outcomes (aim 2). We hypothesized that 2 types of self-affirmation opportunities—a baseline kindness quiz and self-affirming push notifications in the subsequent months—would promote cessation. We also hypothesized that individuals with a tendency to spontaneously self-affirm at baseline would be more likely to successfully quit smoking. In the absence of relevant findings on which to base hypotheses, we tested whether induced self-affirmation conditions were more or less effective for people higher versus lower in spontaneous self-affirmation [41]. Finally, an exploratory aim (aim 3) was to assess baseline optimism and baseline affective states (happiness, anger, anxiousness,
hopefulness, sadness) as potential predictors and potential moderators of the relationship between affirmation conditions and cessation outcomes.

**Methods**

**Smoke Free App**

Smoke Free-Quit Smoking Now is a UK-based app designed for iOS and Android devices [15] that attracts users from across the globe. The app averages 3000 new downloads a day and allows users to set a quit date and track their craving [15]. The app offers 4 methods by which users can monitor their progress: (1) a calendar showing the total amount of time since they stopped smoking, (2) a calculator that shows the amount of money saved by not buying cigarettes and the number of cigarettes not smoked, (3) virtual badges users can earn for milestones, such as 50 hours smoke-free, and (4) health progress indicators to monitor improvements since cessation [15].

**Participants, Recruitment, and Eligibility**

A randomly selected proportion of users who downloaded the app during the study period (initially 10% and then increased to 30% to achieve recruitment goals) were shown a consent form and invited to participate in this study. In the informed consent form, participants were told that they could opt out of the study at any point by contacting the study investigator. The study employed a 2 (baseline self-affirmation induction: present vs absent) x 2 (notifications: self-affirming texts vs control texts) double-blind randomized controlled trial (RCT) in which self-affirmation opportunities were added to an existing smoking cessation app. Those who consented were randomly assigned to 1 of the 4 conditions and completed a baseline assessment. The initial recruitment goal was 5000 participants to have 500 completing the 1-month follow-up survey after accounting for 90% attrition, similar to previous studies [61,62]. A sample size of 500 at the 1-month follow-up was calculated to be able to detect a small effect size ($F=.15$), with high (.90) power using an analysis of variance (ANOVA) with 4 groups (calculated with G*Power). Participants were asked to complete 2 follow-up assessments 1 month and 3 months after they downloaded the app to assess cessation behavior and smoking status. All data were collected through the smartphone apps—users were notified about follow-up surveys in the app with one push notification and a red dot added to the app icon to indicate user action was requested. The link to complete the survey remained in the **Settings** section of the app until the participant responded. Once participants completed the baseline assessment, their eligibility was determined. Participants were not included in the study if they were under 18 years or over 98 years of age, selected a quit date more than 14 days in the future or more than 1 day in the past, paid for additional app features (Pro users), or did not complete the baseline assessment. In a divergence from the previous study [61], potential participants in this study were required to have listed a quit date after the day they downloaded the app; this ensured that participants randomized to the baseline affirmation condition would take the baseline affirmation quiz before attempting cessation. In addition, during data collection, a glitch occurred in which the same identifier was assigned to multiple participants; all users affected by this glitch were excluded from the study and are indicated in Figure 1 under the designation of not meeting inclusion criteria. App users who were not eligible for the study could still use the app. All participants were entered in a lottery—noncontingent on completion of surveys—for a US $100 Amazon gift card. This study was approved by the Institutional Review Board of the National Cancer Institute.
In total, 7899 participants met all inclusion criteria, were enrolled in the study, and provided survey responses. The country of participant residence was not assessed at the individual level; however, aggregate information about the geographic location of participants was available; most participants were from the United Kingdom, closely followed by the United States (Multimedia Appendix 1). Overall, the mean age of participants was 30.5 years (SD 8.7). The majority of participants were male (4790/7899, 60.6%) and did not use any cessation aids other than the Smoke Free app at baseline (6178/7899, 78.2%). Table 1 shows the demographic characteristics of participants at baseline. Significance assessed in Table 1 used a Bonferroni-corrected $\alpha$ level (.05 and 16 comparisons, so the adjusted $\alpha$ level is $P<.003125$).
Table 1. Baseline characteristics of the study participants (N=7899).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control notifications only (n=1985)</th>
<th>Affirmation quiz only (n=1984)</th>
<th>Notification affirmations only (n=1903)</th>
<th>Both quiz and notification affirmations (n=2027)</th>
<th>Overall (N=7899)</th>
<th>Test statistics</th>
<th>P value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>F test (df)</td>
<td>Chi-square (df)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>30.5 (8.7)</td>
<td>30.5 (8.6)</td>
<td>30.5 (8.8)</td>
<td>30.6 (8.6)</td>
<td>30.5 (8.7)</td>
<td>0.05</td>
<td>N/A&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1199 (60.4)</td>
<td>1225 (61.7)</td>
<td>1138 (59.8)</td>
<td>1228 (60.6)</td>
<td>4790 (60.6)</td>
<td>N/A</td>
<td>.65</td>
</tr>
<tr>
<td>Female</td>
<td>786 (39.6)</td>
<td>759 (38.3)</td>
<td>765 (40.2)</td>
<td>799 (39.4)</td>
<td>3109 (39.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently using cessation aid, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td>4.3 (3)</td>
<td>.23</td>
</tr>
<tr>
<td>Yes</td>
<td>440 (22.2)</td>
<td>401 (20.2)</td>
<td>434 (22.8)</td>
<td>446 (22)</td>
<td>1721 (21.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1545 (77.8)</td>
<td>1583 (74)</td>
<td>1469 (77.2)</td>
<td>1581 (78)</td>
<td>6178 (78.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to first cigarette, nicotine dependence, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 5 min</td>
<td>505 (25.4)</td>
<td>494 (24.9)</td>
<td>467 (24.5)</td>
<td>495 (24.4)</td>
<td>1961 (24.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 to 30 min</td>
<td>386 (19.4)</td>
<td>369 (18.6)</td>
<td>361 (19)</td>
<td>411 (20.3)</td>
<td>1527 (19.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 to 60 min</td>
<td>572 (28.8)</td>
<td>588 (29.6)</td>
<td>576 (30.3)</td>
<td>563 (27.8)</td>
<td>2299 (29.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After 60 min</td>
<td>520 (26.2)</td>
<td>533 (26.9)</td>
<td>499 (26.2)</td>
<td>558 (27.5)</td>
<td>2110 (26.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing&lt;sup&gt;c&lt;/sup&gt;</td>
<td>2 (0.1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (0.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desire to smoke&lt;sup&gt;d&lt;/sup&gt;, mean (SD)</td>
<td>3.1 (1.4)</td>
<td>3.1 (1.4)</td>
<td>3.2 (1.3)</td>
<td>3.2 (1.3)</td>
<td>3.2 (1.3)</td>
<td>3.28</td>
<td>N/A</td>
</tr>
<tr>
<td>Cessation stage of change, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5.4 (9)</td>
<td>.80</td>
</tr>
<tr>
<td>Yes, within next 30 days</td>
<td>1770 (89.2)</td>
<td>1897 (91.1)</td>
<td>1735 (91.2)</td>
<td>1795 (88.6)</td>
<td>7107 (90.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, within the next 6 months or no</td>
<td>215 (10.8)</td>
<td>177 (8.9)</td>
<td>168 (8.8)</td>
<td>232 (11.4)</td>
<td>792 (10.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt happy&lt;sup&gt;e&lt;/sup&gt;, mean (SD)</td>
<td>3.2 (0.9)</td>
<td>3.3 (0.9)</td>
<td>3.2 (0.9)</td>
<td>3.2 (0.9)</td>
<td>3.2 (0.9)</td>
<td>0.73</td>
<td>N/A</td>
</tr>
<tr>
<td>Felt angry&lt;sup&gt;e&lt;/sup&gt;, mean (SD)</td>
<td>2.9 (0.9)</td>
<td>2.8 (0.9)</td>
<td>2.9 (0.9)</td>
<td>2.8 (0.9)</td>
<td>2.8 (0.9)</td>
<td>0.50</td>
<td>N/A</td>
</tr>
<tr>
<td>Felt anxious&lt;sup&gt;e&lt;/sup&gt;, mean (SD)</td>
<td>3.2 (1.1)</td>
<td>3.1 (1.1)</td>
<td>3.1 (1.1)</td>
<td>3.1 (1.1)</td>
<td>3.1 (1.1)</td>
<td>0.97</td>
<td>N/A</td>
</tr>
<tr>
<td>Felt hopeful&lt;sup&gt;f&lt;/sup&gt;, mean (SD)</td>
<td>3.1 (1.0)</td>
<td>3.1 (1.0)</td>
<td>3.1 (1.0)</td>
<td>3.1 (1.0)</td>
<td>3.1 (1.0)</td>
<td>0.41</td>
<td>N/A</td>
</tr>
<tr>
<td>Felt sad&lt;sup&gt;f&lt;/sup&gt;, mean (SD)</td>
<td>2.9 (1.0)</td>
<td>2.8 (1.0)</td>
<td>2.8 (1.0)</td>
<td>2.9 (1.0)</td>
<td>2.8 (1.0)</td>
<td>2.06</td>
<td>N/A</td>
</tr>
<tr>
<td>Tendency to spontaneously self-affirm&lt;sup&gt;f&lt;/sup&gt;, mean (SD)</td>
<td>3.1 (1.1)</td>
<td>3.2 (1.1)</td>
<td>3.1 (1.2)</td>
<td>3.1 (1.1)</td>
<td>3.1 (1.1)</td>
<td>2.01</td>
<td>N/A</td>
</tr>
<tr>
<td>Optimism&lt;sup&gt;f&lt;/sup&gt;, mean (SD)</td>
<td>3.6 (1.2)</td>
<td>3.7 (1.2)</td>
<td>3.6 (1.2)</td>
<td>3.6 (1.2)</td>
<td>3.6 (1.2)</td>
<td>2.28</td>
<td>N/A</td>
</tr>
<tr>
<td>Age started smoking&lt;sup&gt;e&lt;/sup&gt;, mean (SD)</td>
<td>17.7 (4.2)</td>
<td>17.6 (4.1)</td>
<td>17.8 (3.9)</td>
<td>17.7 (4.3)</td>
<td>17.7 (4.1)</td>
<td>0.32</td>
<td>(7836)</td>
</tr>
<tr>
<td>Cigarettes per day&lt;sup&gt;b&lt;/sup&gt;, mean (SD)</td>
<td>14.7 (8.2)</td>
<td>14.6 (8.1)</td>
<td>14.7 (8.2)</td>
<td>14.7 (8.6)</td>
<td>14.7 (8.2)</td>
<td>0.14</td>
<td>(7882)</td>
</tr>
<tr>
<td>Quit attempts in past year&lt;sup&gt;e&lt;/sup&gt;, mean (SD)</td>
<td>7.9 (27.5)</td>
<td>6.5 (20.7)</td>
<td>6.6 (19.6)</td>
<td>7.2 (22.8)</td>
<td>7.9 (27.5)</td>
<td>1.55</td>
<td>(7884)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Significance assessed using the Bonferroni-corrected α level=0.05/16 comparisons=0.003125. No variables assessed met the threshold for statistical significance after the Bonferroni correction was applied.
Baseline Measures

Upon agreeing to participate, participants provided their age, gender, age at which they started smoking, average number of cigarettes smoked per day, smoking cessation aids (if any) they were currently using, and a quit date. Data on race and ethnicity were not collected, in part because the app is available globally and participants came from different countries with different racial and ethnic groups.

Participants were also asked questions to assess potential differences in baseline smoking behavior and levels of addiction. Baseline measures used to compare groups included nicotine dependence (How soon after you wake up do you smoke your first cigarette? [63]) and desire to smoke (How strong is your desire to smoke, right now? with options not at all to a lot on a 5-point scale). Previous quit attempts were assessed (In the last year, how many times have you quit smoking for at least 24 hours?). Smoking cessation stage of change was assessed using the following item: Are you seriously thinking of quitting smoking? with answer choices yes, within the next 30 days, corresponding to the Transtheoretical Model’s preparation stage, yes, within the next 6 months, representing the Transtheoretical Model’s contemplation stage, and no, not thinking of quitting, corresponding to precontemplation [64]. On the basis of the distribution of responses and our conceptual interest in the effects of self-affirmation among smokers who intend to quit smoking, the stage of change was dichotomized into yes, within the next 30 days and yes, within the next 6 months or no. These items were used to compare groups at baseline for smoking behavior and experiences.

Affect was assessed using items from the Positive and Negative Affect Schedule (PANAS) [65] as adapted by the Midlife in the United States (MIDUS) study [66,67] and the National Cancer Institute (NCI) Health Information National Trends Survey (HINTS). Participants rated their level of happiness, anger, anxiety, sadness, helpfulness, and anxiety within the past 30 days on a 5-point scale from none of the time to all of the time. The affect items were reverse coded so that higher scores indicated experiencing that emotion more often. Participants’ tendencies to engage in spontaneous self-affirmation were assessed as the average of 2 items used in previous studies [45,48] from the longer spontaneous self-affirmation measure (SSAM [41]): (1) “When I feel threatened or anxious I find myself thinking about my strengths” and (2) “When I feel threatened or anxious I find myself thinking about my values.” Participants’ baseline level of optimism was assessed with the item: “I’m always optimistic about my future” [68]. The SSAM and optimism items were assessed on a 5-point scale with the anchors 1=strongly agree to 5=strongly disagree. However, these items were reverse coded so that higher scores indicated more agreement and thus higher optimism.

Follow-Up Surveys (1 and 3 Months)

All participants were invited to complete a 1-month and 3-month follow-up survey to assess smoking status. Both follow-up surveys assessed smoking status with the items: “Have you smoked at all in the past month?” and “Have you smoked at all in the past week?” Response options for both questions were “no, not a puff,” “1-5 cigarettes,” or “more than 5 cigarettes.” For these analyses, responses were dichotomized to indicate no smoking or smoking (1 cigarette or more) in the time period. In addition, participants were asked to report the average number of cigarettes smoked per day, time to first cigarette, and if they were using any other cessation aids at follow-up.

Baseline Self-Affirmation Questionnaire

Participants assigned to the baseline affirmation conditions were shown a shortened, 5-item kindness questionnaire (quiz), adapted from previous work [61,69], directly after the baseline questionnaire. The purpose of this quiz was to induce self-affirmation by allowing participants to respond yes to having engaged in specific instances of past kindness. In the original questionnaire, participants were asked to provide written examples for each item to which they responded affirmatively; however, participants in this study were not asked to provide examples. This self-affirmation induction has been frequently used, has face validity, and is easy to implement [70]. The control condition did not receive the kindness quiz or any content in its place. The full self-affirmation questionnaire as well as responses by condition is presented in Multimedia Appendix 2. Of the respondents who received the baseline kindness quiz, approximately 83.1% (3333/4011) answered yes to 4 of the 5 items (Multimedia Appendix 2).

Affirmation and Control Push Notifications

Participants in the control push notification condition received general tips related to quitting smoking, whereas participants in the affirmation push notifications condition received affirming messages from a pool of 15 possible notifications. The affirmation messages were based on literature and a previous study of self-affirmation content that had been integrated into a text messaging intervention for smoking cessation [61]. The control notifications were informed by the smoking cessation...
literature [71,72]. Participants received 2 notifications (either self-affirmation or control, depending on their assigned condition) per day for the duration of the study, unless they turned off notifications, which was the same as the frequency of notifications in the current version of the app. One notification was sent during each of the following time blocks: 8 AM to 2:30 PM and 2:31 PM to 9 PM. Participants were able to change the earliest and latest time for the notification (eg, change 8 AM to 7 AM or 9 PM to 11 PM). Participants could also access these self-affirmation or control messages (depending on condition) every time they reported experiencing a craving on a Tips screen. The full text of all notifications, organized by category, is presented in Multimedia Appendix 3.

Analysis

All analyses were conducted using Stata 16 [73]. First, attrition rates were calculated for each of the 4 induced self-affirmation conditions. Second, demographic characteristics and baseline survey responses were compared across groups using ANOVA and chi-square tests. Third, a series of binary logistic regression models were run to examine predictors of successful cessation and potential moderating factors. All regression analyses used intent-to-treat, such that respondents who did not provide follow-up data were treated as continuing smokers. We elected to use intent-to-treat because it is widely used for assessing smoking cessation in interventions [8,9] and tends to be more conservative in assuming that all participants lost to follow-up continued to smoke instead of artificially inflating the cessation rate by removing participants lost to follow-up from analyses. We adopted $P=.05$ as our cut-off for statistical significance, with Bonferroni corrections applied for multiple comparisons as necessary.

Table 2. Attrition and cessation rates by study condition (N=7899).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control notifications only</th>
<th>Affirmation quiz only</th>
<th>Notification affirmations only</th>
<th>Both quiz and notification affirmations</th>
<th>Overall</th>
<th>Test statistic, chi square (df)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed baseline survey, n</td>
<td>1985</td>
<td>1984</td>
<td>1903</td>
<td>2027</td>
<td>7899</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed 1-month follow-up, n (%)</td>
<td>164 (8.3)</td>
<td>165 (8.3)</td>
<td>160 (8.4)</td>
<td>158 (7.8)</td>
<td>647 (8.2)</td>
<td>0.6 (3)</td>
<td>.90</td>
</tr>
<tr>
<td>Past week cessation at 1 month</td>
<td>145 (7.3)</td>
<td>143 (7.2)</td>
<td>139 (7.3)</td>
<td>142 (7.0)</td>
<td>569 (7.2)</td>
<td>0.2 (3)</td>
<td>.98</td>
</tr>
<tr>
<td>Past month cessation at 1 month</td>
<td>133 (6.7)</td>
<td>128 (6.5)</td>
<td>128 (6.7)</td>
<td>114 (5.6)</td>
<td>503 (6.4)</td>
<td>2.7 (3)</td>
<td>.44</td>
</tr>
<tr>
<td>Completed 3-month follow-up, n (%)</td>
<td>51 (2.6)</td>
<td>64 (3.2)</td>
<td>56 (2.9)</td>
<td>60 (3.0)</td>
<td>231 (2.9)</td>
<td>1.5 (3)</td>
<td>.68</td>
</tr>
<tr>
<td>Past week cessation at 3 months</td>
<td>48 (2.4)</td>
<td>58 (2.9)</td>
<td>55 (2.9)</td>
<td>54 (2.7)</td>
<td>215 (2.7)</td>
<td>1.2 (3)</td>
<td>.75</td>
</tr>
<tr>
<td>Past month cessation at 3 months</td>
<td>38 (1.9)</td>
<td>49 (2.5)</td>
<td>48 (2.5)</td>
<td>46 (2.3)</td>
<td>181 (2.3)</td>
<td>2.0 (3)</td>
<td>.57</td>
</tr>
</tbody>
</table>

aNo statistical tests were run.

Smoking Cessation and Baseline Differences

Cessation rates did not differ significantly between groups at the 1-month (past-week cessation: $\chi^2=0.2, P=.98$; past-month cessation: $\chi^2=2.7, P=.44$; Table 2) or 3-month (past week cessation: $\chi^2=1.2, P=.75$; past month cessation: $\chi^2=2.0, P=.57$; Table 2) follow-up. Using an intent-to-treat analysis, the overall past-week cessation rate was 7.2% (569/7899) and the past-month cessation rate was 6.4% (503/7899) at the 1-month follow-up (Table 2). This is similar to the previous study of a text messaging program with affirmation content, which found 5.6% cessation at 6 weeks using intent-to-treat analysis [61]. Notably, despite randomization, participants differed in baseline

Trial Registration

The trial was retrospectively registered at ISRCTN: https://www.isrctn.com/ISRCTN56646695.

Results

Enrollment, Attrition, and Participant Characteristics

A CONSORT (Consolidated Standards of Reporting Trials) diagram is provided to show subject enrollment and study completion (Figure 1). Overall, 8.2% (647/7899) of users who enrolled in the study completed the 1-month follow-up survey and 2.9% (231/7899) completed the 3-month survey (Table 2), consistent with systematic reviews that found high levels of attrition in web-based RCTs [74]. The proportion of users who completed the follow-up was lower than in previous studies of this same app in which 7.5% of participants completed a 3-month follow-up [15]; however, the sample size in this study was considerably smaller. Attrition in this study was similar to attrition in a similar previous study in which 6.4% of participants completed a 42-day follow-up [61]. Although we estimated 90% attrition in our power calculations, we exceeded this percentage. In addition, there were more follow-up assessments in this study and it was available to Android but not iOS users, in contrast with the previous study [15], which had fewer and shorter follow-up assessments and enrolled both iOS and Android users. It is possible that the more frequent follow-ups combined with differences between the iOS and Android app can help contextualize this finding. Follow-up rates did not differ significantly by condition (1 month: $\chi^2=0.6, P=.90$; 3 months: $\chi^2=1.5, P=.68$; Table 2). This paper presents analyses for both the 1- and 3-month follow-ups; however, as the 3-month follow-up rates were considerably lower than the 1-month follow-up rates, most implications and conclusions focus on results from the 1-month follow-up.
desire to smoke ($F_{2,789}=3.28; P=.02$; Table 1) and cessation stage of change ($\chi^2=11.7; P=.009$; Table 1) across conditions, although neither met the threshold for statistical significance after the Bonferroni correction was applied. The Bonferroni correction is conservative; because cessation stage of change differed at the $P<.01$ level and is likely related to the smoking cessation outcome, subsequent regression analyses controlled for baseline cessation stage of change.

**Aims 1 and 2: Self-Affirmation’s Associations With Cessation Outcomes**

The primary aim of this study was to assess the impact of induced self-affirmation conditions on smoking cessation. The secondary aim of this study was to assess the associations of spontaneous self-affirmation with smoking cessation. To assess factors associated with cessation, binary logistic regression models were run using one of the 2 main outcomes (past-week cessation at 1 month and past-month cessation at 1 month) as the dependent variable. The 2 main 1-month outcomes were strongly correlated ($r=0.93$). In both regression models, tendency to spontaneously self-affirm at baseline was a significant predictor of cessation (Table 3), consistent with the hypotheses. However, neither self-affirmation study condition nor their interaction was significant in these models, indicating that providing opportunities for self-affirmation in the smoking cessation smartphone app did not result in a greater likelihood of cessation than using the smartphone app without affirmation.

**Table 3.** Primary self-affirmation regression models ($N=7899$).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Past-week cessation at 1 month</th>
<th>Past-month cessation at 1 month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>$P$ value</td>
</tr>
<tr>
<td>Baseline affirmation</td>
<td>0.99 (0.78-1.26)</td>
<td>.92</td>
</tr>
<tr>
<td>Notification affirmations</td>
<td>0.99 (0.77-1.26)</td>
<td>.92</td>
</tr>
<tr>
<td>Baseline and notification affirmations</td>
<td>0.98 (0.70-1.38)</td>
<td>.90</td>
</tr>
<tr>
<td>Cessation stage of change: Yes, within the next 6 months or No$^b$</td>
<td>0.80 (0.59-1.10)</td>
<td>.17</td>
</tr>
<tr>
<td>Spontaneous self-affirmation</td>
<td>0.85 (0.79-0.92)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

$^a$OR: odds ratio.

$^b$Reference category: Yes, within the next 30 days.

$^cP<.001$.

$^dP<.05$.

In addition, despite low follow-up rates, both 3-month outcomes were also explored. There was a similarly high association between past-week and past-month cessation at the 3-month follow-up ($r=0.91$). None of the self-affirmation measures (tendency to spontaneously self-affirm, baseline affirmation condition, notification affirmation condition, the interaction of baseline, and notification affirmations) significantly predicted cessation in the main 3-month models (Multimedia Appendix 4).

Subsequently, we ran models testing a three-way interaction between our self-affirmation study conditions and spontaneous self-affirmation with both the 1-month and 3-month outcomes. This interaction was not significant, establishing that spontaneous self-affirmation did predict 1-month cessation in this study, but did not moderate the relationship between study conditions and cessation outcomes.

**Aim 3: Examining Potential Predictors and Moderators**

The goal of exploratory aim 3 was to assess baseline optimism and baseline affective states as potential predictors and moderators of the relationship between affirmation conditions and cessation outcomes. To test this aim, we conducted regression analyses in which optimism and each of the 5 affective states (happiness, anger, anxiousness, hopefulness, sadness) were simultaneously added to the main regression models (Table 4). That is, we tested whether these factors predicted 1-week and 1-month cessation at 1 month when controlling for spontaneous self-affirmation, baseline affirmation condition, notification affirmation condition, their interaction, and cessation stage of change. In this model, tendency to spontaneously self-affirm still significantly predicted past-week cessation at the 1-month follow-up ($P<.001$) but did not significantly predict past-month cessation at the 1-month follow-up, although this association approached significance ($P=.05$). Lower sadness was a significant predictor of successful cessation at the 1-month follow-up for both past-week and past-month cessation ($P=.002$ and $P=.007$, respectively). Optimism predicted past-week cessation at the 1-month follow-up ($P=.04$) and both happiness and anger predicted past-month cessation at the 1-month follow-up ($P=.03$ for both). We also ran these with each potential predictor assessed separately and the results did not differ from the simultaneous model presented in Table 4.
Next, moderation analyses were conducted, with a three-way interaction term (baseline affirmation, notification affirmation, and potential moderator) for each of the affective states and optimism, run separately. No three-way interaction was significant. The full model for sadness is provided as an appendix (Multimedia Appendix 5); however, the models for other affective states and optimism have not been included because of space limitations.

We then conducted parallel analyses with the 3-month outcomes. None of the affective states were significant predictors of cessation in the past week or month at the 3-month follow-up; however, optimism was a predictor of cessation for both past-week and past-month cessation at the 3-month follow-up (\(P=.004\) and \(P=.002\), respectively; Multimedia Appendix 4). Due to low follow-up rates at the 3-month follow-up, potential moderation was not explored with the 3-month outcomes.

### Association of Spontaneous Self-Affirmation With Dependence

Previous work has found that smokers with a greater tendency to spontaneously self-affirm report more quit attempts and higher quit intentions, particularly when they live in states with more comprehensive smoke-free laws, highlighting factors that affect the cessation process [48]. Due to the significant effects of spontaneous self-affirmation in our study, we undertook additional analyses. The mean spontaneous self-affirmation scores in our study (mean 3.11 out of 5, SD 1.1) were comparable with those of past studies (mean 2.75 out of 4, SD 0.14 [46]; mean 3.12 out of 5, SD 0.86 [75]).

We examined whether spontaneous self-affirmation was associated with several dependence and quit intention measures in our sample to assess whether respondents who had a greater tendency to spontaneously self-affirm were less dependent on nicotine or had a stronger desire to quit at baseline, offering them an advantage. We computed correlations of spontaneous self-affirmation with the cessation stage of change, time to first cigarette, and quit intention. All were small (all correlation coefficient values were less than 0.1), indicating that smokers higher in tendency to self-affirm in this study were not necessarily less addicted or more intent to quit at baseline than smokers with lower tendencies to self-affirm.

### Discussion

#### Principal Findings

In this study, opportunities for self-affirmation provided in the smartphone app (baseline self-affirmation quiz and self-affirmation notifications) did not significantly improve the likelihood of successful cessation. However, tendency to spontaneously self-affirm was a strong and significant predictor of cessation. Baseline sadness was associated with a lower likelihood of reporting successful cessation at the 1-month follow-up; optimism was significantly associated with past-week cessation at the 1-month follow-up, and happiness and anger were both significantly associated with past-month cessation at the 1-month follow-up. There were no interactions between any explored individual difference predictor and study conditions.

The spontaneous self-affirmation findings are consistent with previous findings that spontaneous self-affirmation was associated with improved psychological well-being and health care experiences [45,46], both of which may play a role in the smoking cessation process. In addition, although previous studies have found a relationship between spontaneous self-affirmation and quit attempts and intentions [48], we did not find a relationship between spontaneous self-affirmation...
and any dependence or quit measure in our sample. Thus, any association of spontaneous self-affirmation with quitting was not due to dependence or past quit attempts. Future work should explore this relationship in more detail to understand the specific benefit and ways to help smokers who do not tend to spontaneously self-affirm.

Comparison With Previous Work

This study differs from previous smoking self-affirmation studies that typically provide participants with information about the negative health consequences of smoking. In this study, no explicitly threatening health information or loss-framed messages were provided, consistent with the positive focus of the app. The messages conveyed the benefits of quitting instead of the harms of smoking and were not hypothesized to constitute explicitly threatening health information. We did not directly assess whether participants perceived any of the material in the app to be threatening. One recent meta-analysis found that self-affirmation is less likely to facilitate change when psychological threat is minimal [32], which suggests that self-affirmation opportunities may have been less effective in this study in the absence of directly threatening information. Moreover, smokers may be aware of the health costs of smoking, and it is unknown to what extent information about the health consequences is novel to smokers, which could help to explain null self-affirmation effects in previous studies of smokers. These studies would benefit from pilot testing to determine whether threatening information about the health consequences of smoking is indeed perceived by smokers as threatening and novel. An alternative explanation is that our control messages were received well by respondents, offsetting our ability to observe any benefit of the self-affirmation messages.

Previous studies have reported mixed findings concerning whether self-affirmation inductions can assist smokers trying to quit; some studies have found benefits [28,30,33-35], whereas others have not [35,39,40,76]. Our finding that induced self-affirmations did not influence smoking behavior is consistent with multiple other studies that have shown null or even backfiring effects among smokers who undergo self-affirmation interventions [35]. It is possible that our baseline affirmation quiz and notification affirmations did not induce self-affirmation in participants; consistent with previous self-affirmation intervention studies, no manipulation check for affirmation was included, and it is difficult to assess whether participants were successfully affirmed. The original kindness quiz asks respondents to write down a specific time they engaged in the aforementioned action [69]. In this study, the baseline kindness quiz was adapted to ask participants to answer yes or no without explicitly asking them to write or think of an example, given that the affirmation intervention occurred through text messages.

It is a challenge to determine how best to adapt self-affirmation interventions developed in laboratory settings to the real world. In a previous study testing whether various adaptations of the kindness quiz differentially affected health cognitions and smoking intentions among a sample of online smokers, there were no significant differences depending on whether participants were asked to write examples, imagine examples, or were not asked to provide any examples [35]. However, that study also found that none of the self-affirmation conditions were more effective than the control conditions [35]. In addition, participants asked to provide written self-affirmation responses endorsed fewer affirmation questions than those not asked to provide written examples, suggesting that the writing was onerous [35]. In that study, for participants providing written examples, the intervention took nearly 7 times longer than it did for participants not asked to provide examples [35]. Thus, more research is needed to determine how to administer effective self-affirmation interventions to participants not in laboratory settings.

Our finding that additional opportunities for self-affirmation added to the smartphone app in this study did not have effects could be due to multiple factors. The self-affirmation content may not have been as noticeable as self-affirmations in other studies, given that participants did not complete the study in a more controlled laboratory setting. In addition, participants may have skimmed or otherwise not engaged with the self-affirmation content in this study. We also do not have data on the extent to which participants read or engage with induced self-affirmation materials. In addition, the existing app material was evidence-based and has already been found to be relatively effective on its own [15], thus identifying additional benefits of novel self-affirmation intervention material may have been difficult.

This study complements existing evidence concerning the distinctiveness of spontaneous self-affirmation from other psychological resources, such as optimism [41]. In this study, the single-item measure of optimism was only moderately correlated with spontaneous self-affirmation (r=0.46). Some previous work using a small number of items has found that spontaneous self-affirmation is related to greater optimism [46]. However, the correlation between the full measure of spontaneous self-affirmation and optimism is small (eg, r=0.22 as observed in a study by Harris et al [41]). Furthermore, cancer survivors who reported greater optimism reported better physical, mental, and cognitive health, even when controlling for spontaneous self-affirmation [77]. In this study, spontaneous self-affirmation was a significant predictor of 1-month cessation outcomes, whereas optimism was unrelated to 1-month cessation outcomes but predicted 3-month cessation outcomes. Optimism facilitates pursuit of goals [50,51], so it is noteworthy that it was not associated with smoking cessation goals at 1 month, whereas spontaneous self-affirmation did maintain such an association.

Interestingly, baseline sadness was significantly related to cessation outcomes at the 1-month follow-up. Feeling sadness less frequently at baseline was associated with a greater likelihood of reporting both past-week and past-month cessation. The relationship between sadness and cessation outcomes is consistent with previous theory and research suggesting that sadness facilitates reward-seeking tendencies that might undermine healthy behavior, including smoking cessation [55-57]. Optimism and all affective states (happiness, anger, anxiousness, hopefulness, sadness) were not found to moderate the relationship between the assigned affirmation conditions and successful cessation. Previous work has found that clinical
diagnoses of anhedonia and depressed mood predict increased odds of relapse among smokers trying to quit [78]; however, this study is among the first to examine specific affective states and their association with successful cessation. Future work can further disentangle the relationship between sadness and cessation experiences.

Limitations

This study has several limitations. As previously discussed, we do not have data concerning whether participants were successfully affirmed and to what extent they were engaged by the intervention. There are several methodological limitations. As data were collected from all users who downloaded the smartphone app, it was difficult to maintain strict experimental control. We were not able to monitor if or when participants turned off notifications, so we were unable to assess an individual’s exposure to the notification content. We were also unable to determine the geographic location of individual participants and were only able to access aggregate geographic information for the sample. Participants came largely from the United Kingdom and the United States, but there were participants from 8 other countries. In addition, smoking cessation is a complex process, and whereas many users who completed the baseline assessments did not complete follow-up assessments, we were not able to analytically determine why these participants discontinued responding and if they had deleted the smartphone app due to successful cessation or another reason. Another limitation is the use of 1 or 2-item measures of key constructs, such as spontaneous self-affirmation. However, these items have shown significant associations with outcomes in other studies [41], thus providing support for their validity. Similarly, we only assessed affect once at baseline. Emotions fluctuate over time, particularly during the difficult smoking cessation process. Future studies can monitor changes in affect during the process, such as with daily dairies, to better understand the role that affects plays in cessation. Finally, the attrition experienced in this study was higher than expected based on previous similar studies [15,61,74]. In this study, we found that 8.2% (647/7899) of users who enrolled in the study completed the 1-month follow-up survey and 2.9% (231/7899) completed the 3-month survey, which is lower than the 7.5% of participants who completed a 3-month follow-up during a previous trial of this same app [15]. In a previous study that informed the present study, 6.4% of participants completed a 42-day follow-up [61]. High attrition limits the interpretability of results such that it may have made it difficult to detect and reduce the generalizability of results, particularly at the 3-month follow-up. Furthermore, the intent-to-treat approach assumes that nonresponders are smokers, whereas it could be the case that nonresponders found the protocol burdensome. However, these limitations are offset by several considerable strengths of this study. This study used a sample of real-life users, which allows for an assessment of how the app will function outside of a highly controlled laboratory setting. The study was also theoretically driven and provides preliminary evidence for the promise of spontaneous self-affirmation in smoking cessation. An additional strength of this study comes from the use of an already-existing, successful smoking cessation app with the addition of self-affirmation specific content.

Conclusions

The results of this study provide evidence that spontaneous self-affirmation may be an important threat management psychological resource in the context of smoking cessation. They indicate the difficulties of creating effective self-affirmation inductions in smoking apps. There is a need to examine the effectiveness of smartphone app–delivered self-affirmations and to develop more effective affirmations in future dissemination work.

Conflicts of Interest

DC is originator of the Smoke Free app and derives income from it.

Multimedia Appendix 1
Geographic locations of the participants.
[DOCX File, 62 KB - jmir_v23i3e18433_app1.docx ]

Multimedia Appendix 2
Baseline self-affirmation questionnaire and responses by condition.
[DOCX File, 34 KB - jmir_v23i3e18433_app2.docx ]

Multimedia Appendix 3
Text notifications by study condition.
[DOCX File, 35 KB - jmir_v23i3e18433_app3.docx ]

Multimedia Appendix 4
Regression models for 3-month outcomes.
[DOCX File, 41 KB - jmir_v23i3e18433_app4.docx ]
Multimedia Appendix 5
Regression models to explore sadness as a potential moderator of self-affirmation conditions.

[DOCX File, 37 KB - jmir_v23i3e18433_app5.docx]

Multimedia Appendix 6
CONSORT-EHEALTH (V.1.6) checklist.

[PDF File (Adobe PDF File), 1620 KB - jmir_v23i3e18433_app6.pdf]

References


Abbreviations

ANOVA: analysis of variance
OR: odds ratio
RCT: randomized controlled trial
SSAM: spontaneous self-affirmation measure
Designing the Optimal Digital Health Intervention for Patients’ Use Before and After Elective Orthopedic Surgery: Qualitative Study

Anna Robinson1,2, MPharm, PGDip; Robert D Slight2,3, PhD; Andrew K Husband1,2, PhD; Sarah P Slight1,2, PhD

1School of Pharmacy, Newcastle University, Newcastle upon Tyne, United Kingdom
2Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne, United Kingdom
3Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, United Kingdom

Corresponding Author:
Sarah P Slight, PhD
School of Pharmacy
Newcastle University
King George VI Building
Newcastle University
Newcastle upon Tyne, NE1 7RU
United Kingdom
Phone: 44 191 208 6000
Email: Sarah.slight@newcastle.ac.uk

Abstract

Background: Health behavior changes made by patients during the perioperative period can impact the outcomes and success of elective surgeries. However, there remains a limited understanding of how best to support patients during this time, particularly through the use of digital health interventions. Recognizing and understanding the potential unmet needs of elective orthopedic surgery patients is central to motivating healthier behavior change, improving recovery, and optimizing overall surgical success in the short and long term.

Objective: The aim of this study is to explore patient perspectives on technology features that would help support them to change their lifestyle behaviors during the pre- and postoperative periods, and that could potentially maintain long-term healthy lifestyles following recovery.

Methods: Semistructured interviews with pre- and postoperative elective orthopedic patients were conducted between May and June 2020 using telephone and video call–based software. Patient perspectives on the use of digital technologies to complement current surgical care and support with lifestyle behavior changes were discussed. Interviews were audio recorded and transcribed verbatim. Reflexive thematic analysis enabled the development of themes from the data, with QSR NVivo software (version 12) facilitating data management. Ethical approval was obtained from the National Health Service Health Research Authority.

Results: A total of 18 participants were interviewed. Four themes were developed from the data regarding the design and functionality of digital technologies to best support the perioperative journey. These center around an intervention’s ability to incorporate interactive, user-centered features; direct a descriptive and structured recovery; enable customizable, patient-controlled settings; and deliver both general and specific surgical advice in a timely manner. Interventions that are initiated preoperatively and continued postoperatively were perceived as beneficial. Interventions designed with personalized milestones were found to better guide patients through a structured recovery. Individualized tailoring of preparatory and recovery information was desired by patients with previously high levels of physical activity before surgery. The use of personalized progression-based exercises further encouraged physical recovery; game-like rewards and incentives were regarded as motivational for making and sustaining health behavior change. In-built video calling and messaging features offered connectivity with peers and clinicians for supported care delivery.

Conclusions: Specific intervention design and functionality features can provide better, structured support for elective orthopedic patients across the entire surgical journey and beyond. This study provides much-needed evidence relating to the optimal design and timing of digital interventions for elective orthopedic surgical patients. Findings from this study suggest a desire for personalized perioperative care, in turn, supporting patients to make health behavior changes to optimize surgical success. These findings should be used to influence future co-design projects to enable the design and implementation of patient-focused, tailored, and targeted digital health technologies within modern health care settings.
KEYWORDS
digital technology; orthopedic surgery; behavior change; perioperative care; prehabilitation; qualitative research; mHealth; eHealth; mobile phone

Introduction

Background
Digital health technologies are becoming increasingly common in various industries, with medicine, surgery, and health care being no exception [1]. The use of digital health interventions is growing significantly among patients and health care providers, with recent studies reporting over 318,000 smartphone apps available to aid in health education, diagnosis, and self-management [2-4]. Despite the multitude of digital solutions available, many fail to meet patient and provider expectations—with their use and uptake hindered by ethical issues such as privacy and security of data, disease management, and communication [5]. Involving technology end users in cocreation approaches has been acknowledged as a possible strategy to design digital interventions that meet both the patient and provider needs [6,7].

In recent digital health literature, there are various interventions that have successfully supported patients in managing long-term health conditions [8] and medication adherence [9,10] and supporting positive lifestyle behavior change before and after surgery to improve postoperative outcomes [11,12]. Health behavior changes made during the perioperative period can be fundamental in determining the outcomes and success of elective surgeries. In the context of orthopedic surgery, increases in preoperative physical activity levels and smoking cessation have been associated with improved postoperative bone healing [13], wound healing [14], quicker recovery times, and reduced pain scores [15]. Physical rehabilitation after orthopedic surgery is an essential component of treatment, as it helps to improve functional outcomes and support patients to return to their daily activities [16]. There remains a limited understanding of how best to support patients during this time, particularly through the use of digital interventions.

In this context, research has focused on the orthopedic clinician’s use of digital technologies [1,17], for instance, in supporting their educational development [18], guiding clinical decision support [19], managing care referrals [20], and building the patient-clinician relationship [21,22]. Recognizing and understanding the potential unmet needs of elective orthopedic surgery patients is central to motivating healthier behavior change, improving their recovery, and optimizing overall surgical success in the short and long term [23-25]. The optimal design and functionality of digital solutions to aid this cohort are yet to be recognized.

Objectives
To develop useful and effective digital technologies and strategies, it is important to first understand how patients want to be supported on their care pathway. Our patient-informed research applies qualitative investigation to explore patient perspectives and identify key technology features that they would find supportive during the pre- and postoperative periods and that could potentially maintain long-term healthy lifestyles following recovery. Specifically, our key research questions concerned the following: (1) What do orthopedic patients want from digital health technologies? (2) How do they want to use them? and (3) When would they be of most benefit during their elective surgical journey?

Methods

Recruitment and Sampling
The Consolidated Criteria for Reporting Qualitative Research checklist was followed for this study, according to Enhancing the QUALity and Transparency Of health Research guidelines (Multimedia Appendix 1) [26]. Immediately before study commencement, COVID-19 restrictions were enforced across the United Kingdom. This meant that the planned face-to-face recruitment and data collection could no longer be undertaken in person at one of the largest teaching hospitals in North England. Instead, an amendment to the National Health Service (NHS) Health Research Authority (HRA) Ethics meant that participants could be recruited remotely via email and social media. All participants were emailed with an information sheet detailing the purpose and aim of this study. Participants who expressed an interest and provided written consent were enrolled in the study. There was no prior relationship established between the researcher and participants before study commencement or recruitment. Inclusion criteria were as follows: participants aged more than 18 years who were due to undergo (or had recently undergone, within the last 2 years) elective orthopedic surgery, who were medically stable and did not have an acute decline in health away from their baseline, who were able to participate in an interview, who were able to communicate in English, and who had the capacity to consent to participate in the study. Purposive sampling was used to recruit participants undergoing a variety of orthopedic surgical procedures, with mixed age ranges and sociodemographic backgrounds.

Semistructured Interviews
In-depth, semistructured interviews were conducted by 1 researcher (AR, a female doctoral researcher with experience in qualitative research) between May and June 2020 while working from home. Interviews were conducted with participants over the telephone or by using video call–based software, such as Zoom and Microsoft Teams, and all participants were offered the choice of which they would prefer. The semistructured interview topic guide was developed based on 3 pilot interviews and covered key issues identified through a systematic literature review [12], meta-ethnography [27], and narrative review [28]. These issues included participants’ understanding and experiences of surgery, awareness of perioperative lifestyle behavior change, perspectives on digital
health technology use within the surgical pathways, and the optimal design of such technologies.

Data Analysis

All interviews were audio recorded and transcribed verbatim by 1 researcher (AR). All data were anonymized at the point of transcription; participants did not comment on the transcripts or provide feedback on results. Following reflexive thematic analysis processes, as defined by Braun and Clarke [29,30], each interview was transcribed and analyzed before conducting the next interview. The principle of constant comparison guided the iterative process of data collection and analysis. Two researchers (AR and AH) performed a reflexive thematic analysis to analyze the data. Close and detailed reading of the transcripts allowed the 2 researchers to familiarize themselves with the data. Initial descriptive codes were identified in a systematic manner across the data set; these were then sorted into common coding patterns, which enabled the development of analytic themes from the data. The themes were reviewed, refined, and named once coherent and distinctive. Two authors (AR and AH) performed the data analysis through discussion and, if agreement was not reached, by consensus with the wider research team (SS and RS). The postinterview field notes enhanced this reflective process. QSR NVivo software (version 12) was used to facilitate data management. The research team agreed that data saturation occurred in 18 interviews. To ensure confidentiality when using direct patient quotes within this research, nonidentifiable pseudonyms are used throughout, for example, participant 1 and participant 2.

Ethical Approval

Ethical approval was obtained from the NHS HRA and Care Research Wales (reference: 19/NE/0318), and research governance was granted by the participating NHS trust.

Results

Overview

A total of 18 participants were recruited and interviewed as part of this study (there were no refusals to partake, participant dropout, or repeat interviews). The characteristics of participants are presented in Table 1. The average age of the participants was 52 (SD 16.7) years, and the most common elective orthopedic procedure was a total hip replacement. A total of 11 interviews were conducted over the telephone and 7 were conducted using video call–based software. The average duration of the interview was 48 (SD 8.5) minutes.

Four themes were developed from the data (Figure 1) that addressed the aforementioned research questions. These themes centered on an intervention’s ability to (1) incorporate interactive, user-centered features; (2) direct a descriptive and structured recovery; (3) enable customizable, patient-controlled settings; and (4) deliver both general and specific surgical advice in a timely manner. We will discuss each of these themes, in turn, illustrating patient perspectives and recommendations with direct interview quotes.
<table>
<thead>
<tr>
<th>Participant number</th>
<th>Sex (M(^a) or F(^b))</th>
<th>Age (years)</th>
<th>Interview format</th>
<th>Orthopedic procedure</th>
<th>Pre- or postoperative</th>
<th>Time since surgery or time until surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>83</td>
<td>Telephone</td>
<td>TKR(^c)</td>
<td>Post</td>
<td>12 m(^d)</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>63</td>
<td>Telephone</td>
<td>TKR</td>
<td>Post</td>
<td>6 m</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>63</td>
<td>Telephone</td>
<td>TKR</td>
<td>Post</td>
<td>24 m</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>41</td>
<td>Video call</td>
<td>THR(^e)</td>
<td>Post</td>
<td>22 m</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>42</td>
<td>Video call</td>
<td>THR</td>
<td>Post</td>
<td>14 m</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>61</td>
<td>Telephone</td>
<td>THR</td>
<td>Post</td>
<td>20 m</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>70</td>
<td>Telephone</td>
<td>THR</td>
<td>Post</td>
<td>16 m</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>50</td>
<td>Telephone</td>
<td>THR</td>
<td>Post</td>
<td>8 m</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>69</td>
<td>Telephone</td>
<td>THR</td>
<td>Post</td>
<td>24 m</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>50</td>
<td>Video call</td>
<td>THR</td>
<td>Post</td>
<td>10 m</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>66</td>
<td>Telephone</td>
<td>TKR</td>
<td>Pre</td>
<td>2 w(^f)</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>26</td>
<td>Video call</td>
<td>Hip FAIS(^g)</td>
<td>Pre</td>
<td>4 w</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>62</td>
<td>Telephone</td>
<td>WL R(^h)</td>
<td>Pre</td>
<td>6 w</td>
</tr>
<tr>
<td>14</td>
<td>M</td>
<td>26</td>
<td>Video call</td>
<td>ACL R(^i)</td>
<td>Post</td>
<td>6 w</td>
</tr>
<tr>
<td>15</td>
<td>F</td>
<td>30</td>
<td>Telephone</td>
<td>Ankle reconstruction</td>
<td>Pre</td>
<td>1 w</td>
</tr>
<tr>
<td>16</td>
<td>M</td>
<td>24</td>
<td>Video call</td>
<td>ACL R</td>
<td>Post</td>
<td>6 m</td>
</tr>
<tr>
<td>17</td>
<td>M</td>
<td>56</td>
<td>Telephone</td>
<td>TKR</td>
<td>Pre</td>
<td>3 w</td>
</tr>
<tr>
<td>18</td>
<td>M</td>
<td>54</td>
<td>Video call</td>
<td>THR</td>
<td>Pre</td>
<td>8 w</td>
</tr>
</tbody>
</table>

\(^{a}\)M: male.  
\(^{b}\)F: female.  
\(^{c}\)TKR: total knee replacement.  
\(^{d}\)m: months.  
\(^{e}\)THR: total hip replacement.  
\(^{f}\)w: weeks.  
\(^{g}\)FAIS: femoral acetabular impingement surgery.  
\(^{h}\)WL R: wrist ligament reconstruction.  
\(^{i}\)ACL R: anterior cruciate ligament reconstruction.
Theme 1: Incorporating Interactive, User-Centered Features

When considering what orthopedic patients wanted from digital technologies, it was important that the technology included features that centered on the needs of each user and were interactive in terms of logging and tracking and were visually instructive (video-based) and that allowed connectivity through messaging.

Logging and Tracking Recovery

Interviewees perceived numerous benefits from keeping logs during the perioperative period. In the first instance, they recognized personal benefits from “logging and tracking (their) recovery” (Participant 5) to visually “see your progress” (Participant 16) and “gauge where you are and how well you’re doing” (Participant 4). This was viewed as something that would “give you the drive” to continue with the physical rehabilitation “to benefit yourself further” (Participant 9). Participants saw benefits in allowing members of the multidisciplinary team, such as surgeons and physiotherapists, to also view this information and “get an idea of when you’re starting to improve” (Participant 13). Others expanded on this, seeing shared access as an opportunity to obtain further medical expert advice on “pains or swelling...and problems with the scar like any bleeding or signs of infection” (Participant 13) and find “reassurance” related to wound healing (Participant 10). Participants reflected on the accountability that can arise from shared access to logs, both as a form of intrinsic accountability to keep “helping yourself at home...to give yourself the best chance” in the recovery period (Participant 15) and as a way of “proving that you’re doing what you’re meant to” to their surgical team (Participant 13):

*Things that record what you’ve done so you can see and say “ah, I’ve achieved that, I’ve done that”...I have the incentive to go further.* [Participant 11]

Keeping a log of wider experiences during their perioperative journey, beyond physical activity, was also considered useful. A preoperative log of “mood, sleep deprivation and pain-management” strategies was considered important for participants to “validate your (their) mental-side” in the run-up to surgery (Participant 5). Two participants reflected on personal experiences that affected their mental health during the surgical journey, where “meditation or soothing-type app” features would have supported them “through particularly tough” preoperative pain, postoperative pain, and isolation during recovery (Participant 10). Another called for integration of an interactive “diary on the app...where you could type in how you feel...if there’s any problems” alongside “logging the pain and the level of pain” (Participant 13).

Within the logging features, patients described in detail about the user-centered information they wished “to be told by the technology” (Participant 5). Emphasis was placed on “the specific tracking...of any (form of) activity,” rather than only walking or running; being able to “compare your times or distances” (Participant 5) through “a graph or a visual” comparative feature (Participant 11); and having real-time functionality so that you can “track your progress accurately...like keeping track of your reps and weights” without relying on retrospective data entry (Participant 16). Participants also discussed share functions when it came to their logged activities where integrated competition features, such as “leader boards with friends” (Participant 12), appeared to add an incentive to engage with physiotherapy-based recovery. Combining these with “rewards and badges” (Participant 4) for
logged activities appeared to reinforce patient motivation and engagement while keeping the technology user centered:

[the content of the sessions] doesn’t differ that much from actually being in-person—you can see everything well, the resolution is good and the picture is clear, I can hear clearly. [Participant 10]

everything we done the week before with the physio, we replicated on the Zoom call...everything that had been done in-person was quite easily done on the Zoom call. [Participant 14]

I Want Something to Show Me

Video features, as an interactive method of engaging with physical activity during the surgical journey, were discussed by all participants. Preoperatively, participants reflected that videos could be used to educate patients on “exercises they’ll be expected to do” (Participant 5) and to build awareness around “the limitations, physically, that you will feel after the surgery” (Participant 8). Drawing on their experience, postoperative patients felt that being able to watch videos to practice rehabilitative exercises, preoperatively, would have given them “confidence and reassurance” to better engage with the recovery process from an earlier stage, optimizing “the entire recovery process, to give myself the best chance” (Participant 1). On the whole, participants felt video content to be of the highest value in the postoperative period, where patients can interact with instructional, surgery-specific rehabilitation advice by watching “user-friendly...video tutorials with people doing” the exercises (Participant 16). Participants discussed the integration of video-based postoperative “success stories” at various milestones of the recovery process, recognizing the power of video messages to help “visualize what you can achieve” (Participant 6) and “push me further with recovering” (Participant 16):

With each exercise there could be a video tutorial with people doing them so you can go on, click, watch the video...it could help you understand the exercise the physio(therapist) recommends...and learn how to do it properly so it’s of most benefit. [Participant 16]

Along with using videos for instructional and educational purposes, participants reflected on their “changed views” (Participant 9) of integrating video call features in digital technologies for support during the perioperative period. For many, these views were linked to and influenced by the global COVID-19 pandemic. Participants described the usefulness of video calls, accepting them as a valuable and convenient form of communication while “getting used to a new normal, a different way of doing things with technology” (Participant 13). When discussing an upcoming preassessment appointment, one participant remarked that their preference for the consultation would be a video call in comparison with a proposed telephone call:

I’d be more than happy with Skype to “see them” for my appointment...I think it’s more personal, phone calls aren’t personal...I’d much prefer to Skype now instead. [Participant 13]

Two postoperative patients reflected on their current experiences of undergoing video-based physiotherapy sessions in light of COVID-19 measures. These participants remarked the following:

[Participant 13]:
I’d be more than happy with Skype to “see them” for my appointment...I think it’s more personal, phone calls aren’t personal...I’d much prefer to Skype now instead. [Participant 13]

Two postoperative patients reflected on their current experiences of undergoing video-based physiotherapy sessions in light of COVID-19 measures. These participants remarked the following:

Messaging Someone to Settle Your Nerves

Participants felt that the inclusion of message-based features (whether with other patients or with health care professionals) within an intervention would offer numerous benefits. Preoperative participants expressed value in communicating with other people undergoing the same surgery. This related to information-seeking needs to learn from peers, with participants discussing how they already “have looked for blogs and posts from other people going through the operation” (Participant 12) and “asked for advice...to find out what the surgery is like” (Participant 13). Coupled with searching for educational support, preoperative patients reported seeking reassurance from others before undergoing the surgery, to hear “success stories (of) people who have gone through it successfully” (Participant 17) to support their surgical decision making. This was particularly important in younger participants who wished to discuss with patients of similar ages to ask “how quick their recovery was” (Participant 15) and the level to which they retained their physical activity and functioning following surgery. One participant described their preoperative nerves without knowing “what my life is going to look like after my surgery” and considered how “having a conversation or messaging someone to settle your nerves” could help (Participant 15).

Postoperatively, participants discussed the value of sharing “experiences on a forum” (Participant 7), suggesting the integration of a patient-led “discussion area” within an app “for people who’ve gone through similar surgeries—whatever question it may be, they can put it on there and receive feedback from people” (Participant 16). Participants demonstrated an awareness of “mis-information or mis-interpreting the information” that may be shared (Participant 16) and acknowledged how one could become easily “disillusioned” by comparing or “judging yourself on other people’s recovery” (Participant 2). Both pre- and postoperative participants considered the morale boost that can come from communicating with peers, regardless of the stage of their surgical journey:

It’s harder when you’re on your own, but when you’re doing it alongside other people, having them to just be there as a point of reference or just to ask daft things to, that’s much easier. [Participant 5]

“Messaging features” (Participant 10) could also enable two-way interactivity between the patient and a member of the multidisciplinary team, where examples discussed took various forms, from real-time “live-chat boxes” (Participant 10) to “a personal account, like Facebook messenger” (Participant 13). It was important to specify response times when it came to seeking information in this manner, with some participants desiring an “instant reply from someone” (Participant 10) for emergency purposes such as “wound healing or infection”
Concerns (Participant 4), whereas others considered that a “response within 24 hours...or a defined period of time” for generic questions was suitable to “fit around the (professional’s) workload” (Participant 16). Participants saw value in sharing both image- and text-based messages to aid clinical decision making, such as “how is your wound healing?” (Participant 10) or “identifying any signs of infection” (Participant 3), suggesting the value of visual connectivity in this cohort. Similar feelings of reassurance were also seen when participants discussed possible interactivity with members of the surgical multidisciplinary team:

Even the idea of (clinicians) saying “we’re here, even though it’s through technology”...it gives you a bit peace of mind. [Participant 9]

**Theme 2: Directing a Descriptive and Structured Recovery Plan**

Another important consideration of what this study wants from digital technologies was how directed, descriptive, and structured the content was. Perioperative participants expressed their desire for a digital intervention that could support them in “making the best recovery” by providing a structured and directed program with “suggestions of what you should be doing at each stage” (Participant 16). Postoperative patients discussed a “lack of direction” (Participant 16) in their current experiences following surgery, with extended periods between follow-up appointments where they lacked “the necessary, ongoing support” (Participant 2). One postoperative patient, 2 years after their total hip replacement, described gaps where “I was just winging it, really” in relation to recommended physiotherapy exercises:

there was no kind of updates with stuff when I was at home. [Participant 9]

Participants reported knowing “within each stage of recovery, you should be pushing a little bit more” (Participant 15) but felt unsupported to do this. This view was especially apparent in previously physically active patients and those of a younger demographic who wanted to be challenged further to restore “functionality in the joint after surgery” (Participant 12):

all I was after was some indication of what to do to safely push on...having some indication of “this is what you need to do in this week, then move onto this”...I wanted something to show me. [Participant 4]

Recommendations to provide this structured recovery program stemmed around designing “milestones...in terms of where you could expect to be after Week 1, Week 2,” with the inclusion of “physiotherapy messages” (Participant 12) and “general healthy living messages” (Participant 11). Tailoring the intervention to support a structured recovery would mean starting with “simple exercises to start the recovery and build on from there” (Participant 16). Participants described the integration of gamification features and “progression-based exercises” throughout the recovery where, over time, the program recommended “trickier exercises...working towards that final goal of being recovered” (Participant 16). Both pre- and postoperative participants viewed the capability of setting “targets and goals to work towards” as an important feature of creating a structured and directed recovery program (Participant 4). Combining goal setting with gamification features to break “(rehabilitation) down into small chunks at the start, advancing through each level” (Participant 15) and real-time messages of support such as “well done, you’ve completed this level, next it’s...” (Participant 4) were deemed motivational in giving “more people focus for what to achieve after the surgery” (Participant 5). Having a directed rehabilitation structure with set milestones to unlock over time also allowed participants “to feel some independence that it’s up to you to advance through the levels or reach a certain target, but with the comfort of knowing it’s still safe, you’re not pushing too hard” (Participant 12). The incorporation of safety-netting features to recover at a safe speed also provided reassurance for preoperative patients that they will not be pushed to “do too much too soon” (Participant 12) and compromise their outcomes following surgery.

**Theme 3: Enabling Customizable, Patient-Controlled Settings**

When it came to addressing our research question of how patients wished to use these technologies, the benefits of having built-in, customizable, and “patient-controlled features” to enable elements of control were widely discussed (Participant 4). This ranged from wanting to “set myself my profile, choose my name...” (Participant 14) to having the ability to “build your own workout” (Participant 16) and “preference certain exercises to make it individualized to each person” (Participant 12). Interviewees perceived that customizable functionality would encourage greater engagement and a sense of accountability, meaning they better “connect with the (recovery) process” (Participant 4). One participant referenced the layout features of an app they were currently using, explaining how it was possible to “toggle the home-screen settings” to make it more personal (Participant 12):

It’s going to need a personal approach—but if you were able to toggle certain settings to make it individualized to each person, then you’ll get more successful outcomes with it and impact different people in different ways. [Participant 12]

Accompanying the ability to customize aspects of physical recovery, participants also recognized benefits in preferring features relating to the mental and motivational postsurgical journey. Choosing a “more personal reminder” (Participant 7) approach to notifications was deemed constructive and supportive, with encouraging messages of “have you done your physio yet?” rather than “automated “do your physio” notifications” (Participant 12).

Having the capacity to tailor preparatory and recovery information to individual participants was widely discussed—in particular, by those who described high levels of physical activity before surgery and a wish to continue this postoperatively:

it completely depends on who you are as an individual and what you want from it (surgery) [Participant 4]

Being able to “advance at a pace suitable for you” (Participant 12) during recovery was deemed imperative to restore previous
“functionality of the joint” (Participant 6) and, in the process, meet individual postoperative expectations. From their experiences, some viewed rehabilitation exercises as “rather pedestrian” (Participant 6) and that “the whole process, the whole support...was geared around older and less mobile people” (Participant 4). It appeared that exercises were not designed with a younger or more active patient in mind. When it came to using technology to manage this, participants expressed desires to be able to “choose your own difficulty...to make the recovery challenging enough” (Participant 12):

(recommendations) should be determined by how active you already are...it’s no good telling me “walk 1 mile” when I’m used to walking 20! It’s the same for someone perhaps less active when they can’t functionally do it. [Participant 4]

Theme 4: Delivering General and Specific Surgical Advice in a Timely Manner

Addressing our research question around when digital technologies would be of most benefit, the timing (initiation point) of the intervention appeared crucial. It was discussed that technology should be initiated to meet both the pre- and postoperative information-seeking needs of participants. Specifically, preoperative interviewees wished to have explicit “sections for before surgery” (Participant 11) to seek information about the surgical procedure, to understand the best way to prepare, and to familiarize themselves with the upcoming process of recovery so as to be “already in that mindset...to the idea of the time and energy we need to invest in order to fully recover” (Participant 17). On reflection, some postoperative patients felt that their recovery would have benefited from knowing this information in advance. “Staggering the information” was also considered important, with ideas of drip feeding and building up advice in the preoperative period so that postoperatively, they would be better prepared (Participant 10):

I was ready for the off, straight away...I had it in my mind that that’s what I needed to do...you don’t want to be waiting ’til you’re post (-operative) to hear those things. [Participant 5]

Participants felt that the initiation of digital interventions should also be arranged with a sense of generalizability between surgical procedures so that patients undergoing any form of elective orthopedic surgery may find the preoperative information beneficial. Participants described the need for “a generic advice” hub (Participant 15) for all orthopedic patients to use, with “different tabs for different surgeries” so that patients could find surgery-specific information if they wanted (Participant 8). Two participants discussed the feasibility of having one “centralized database” (Participant 12) of exercises, breaking “the exercises down to different body parts,” and being able to easily find those that they could do to aid their recovery (Participant 16). In addition, interviewees called for holistic “general health and recovery” sections, integrating “positive health advice” that would be useful to hear throughout the perioperative process of any surgery (Participant 6). This included preoperative advice on preparation for surgery and “building muscle strength beforehand” (Participant 15), reassurance on postoperative physical rehabilitation, and “short- and long-term messages” around overall healthy living (Participant 11):

There are generic exercises that would be recommended for most joint surgeries, just to build up the muscle strength again...(and) if you had an app where you could select “hip replacement” and it provided you with “this is what exercises you should do”...it could give you more specific information. [Participant 4]

Discussion

Principal Findings

This patient-informed study underlines the importance of obtaining orthopedic surgical patients’ perspectives in relation to the design and functionality of digital technologies to best support their recovery. By collecting both pre- and postoperative patient perspectives, we were able to clearly identify specific features and functionalities that appear to be the most desired and of most benefit in supporting this surgical cohort across the whole perioperative pathway. We addressed 3 research areas: what patients wanted from digital technologies, how they wanted to use them, and when their use would be of most benefit.

A consistent finding across interviews was that participants saw value in having a digital intervention to direct them through a structured plan to achieve a successful recovery. In terms of technology design, both prescriptive and descriptive contents were desired, where participants called for regular digital milestones to guide them and measure their journey toward recovery. Previous studies have demonstrated the benefits of continuous measurement within the recovery process following cardiac [31] and neurological surgery [32]. This feature should be considered for orthopedic interventions, where quantifying the progress can motivate patients to take active roles in their recovery [33]. Mehta et al [34] aligned this idea with reports of positive reinforcement by setting and meeting individual recovery goals following hip arthroplasty. Goal setting is a well-recognized behavior change technique that supports self-regulation skills in the change process [35,36]. In previous orthopedic studies, digital goal setting facilitated personal fulfillment and provided patients with a sense of control and accomplishment during the perioperative period [37,38]. Combining goal setting with performance feedback and the review of goals (akin to milestones within the recovery journey) has been associated with both short- and long-term intervention effectiveness [39,40]. Personalized and tailored feedback on these goals could be acknowledged as relevant and actionable, as opposed to generic advice [41]. By integrating digital strategies to help define goals within recovery, orthopedic patients may feel better supported and motivated to engage in health behavior change.

Participants valued the integration of video-based features in digital interventions, whether as a visual aid for rehabilitative exercises or to facilitate remote telemedicine consultations. Our findings support the growing popularity of video-based consultations reported in other areas of global health and social care [42-44], with participants reporting feelings of...
connectedness, empowerment, and reassurance through image- and video-based sharing [45-47]. The incorporation of video call features within digital health technology is gaining attention, particularly as a consequence of the global COVID-19 pandemic [43,48]. It appeared that the more prominent use of video call features, both in participants’ work and social lives, has led to greater acceptance and adoption of their use within the world of health care [48].

Another promising strategy of digital intervention design, gamification, has also been linked to increased user engagement [49,50]. In this study, participants’ suggestions to incorporate leaderboards and collect rewards during the postoperative recovery process echo recent findings from adult and pediatric patients undergoing orthopedic, dental, and ophthalmic surgeries [51,52] and those concerning wider eHealth design [40,53]. The use of game-like rewards and incentives has been shown to motivate and sustain health habits over time [54,55]. In wider public health initiatives, incentive-based health apps and activity-tracking programs have been associated with positive physical activity behavior change in Canada [56] and the United Kingdom [57,58]. Other successful digital health interventions have incorporated gamification features, promoting intrinsic and extrinsic motivators [59-61]. Similarities can also be recognized between these findings and wider work on persuasive systems design in relation to shaping health behaviors during the perioperative period [62-66]. Oinas-Kukkonen and Harjumaa [62] proposed that persuasion principles (including praise and rewards) should be considered as requirements in software design.

This study contributes further evidence to support gaps in the literature, which relate to the timing of intervention use, including the initiation and continuation points of intervention use. This gap has also been acknowledged in recent systematic reviews and research by Jansson et al [16], Mirkovic et al [67], and our research team [12,27]. Interventions that are initiated preoperatively and continued postoperatively were perceived as beneficial. Captivating the preoperative patient mindset and making use of the surgical teachable moment appears to be significant in encouraging perioperative behavior change and optimizing postoperative outcomes [68]. Being granted a sense of control and responsibility over their recovery by initiating and using interventions preoperatively were valued by participants. Before surgery, interviewees described the desire to customize their technology and its content to best suit their needs, thereby encouraging better engagement with the upcoming recovery process. The individualization of care pathways has been discussed in medical and surgical literature [69,70]; however, our study also highlights the importance of individualization of the technologies to support care delivery. Technologies that incorporated customizable features, which the patient could control and toggle according to their personal preferences, were considered another motivator for successful recovery. Participant autonomy has been shown to positively impact motivation levels and user experience, thereby improving patient care experiences [71-73]. Technology-enabled, preference-based care has improved patient and health care professional outcomes [72-74]. Technology creators may consider implementing customizable features to grant patients autonomy over aspects of their recovery [67,75].

All participants in this study discussed the impact of the global COVID-19 pandemic on the UK NHS. At the point of interview, 3 participants were undergoing technology-enabled follow-up appointments with their physiotherapist and 2 had used video call–based software to conduct their preoperative assessments with members of the surgical multidisciplinary team. Participants’ views echoed those discussed in this study on digitally engaged patients and recognized the multitude of ways in which technologies can be embedded within the NHS to transform surgical patient support throughout the entire perioperative journey [48]. Interactive health technologies have been credited as transformers of health care by supporting engaged self-care and promoting positive health behaviors [76]. The global pandemic has presented a unique opportunity for the creative delivery of health care. It is important that this momentum gained to adopt and use digital technologies is not lost, with the focus being continued provision of innovative surgical patient care, monitoring, and follow-up spanning the whole perioperative period [77].

Limitations
We acknowledge that there are some limitations with this study. The intended method of in-person data collection was impacted by the COVID-19 pandemic. Although virtual call–based software enabled the replication of face-to-face interviews (ie, responding to verbal and nonverbal cues and building rapport) [78,79], there are some disadvantages to this interview technique that may have impacted our study. Established familiarity and participant comfort of use may have resulted in the higher number of interviews conducted over the telephone. Despite this, video calls enabled a unique snapshot into life of a patient recovering at home during the crisis and provided a fuller picture with more context than a telephone call may have done [80]. Participants currently experiencing remote consultations with members of the surgical team offered timely insights into this study. As a result of the COVID-19 pandemic, many elective orthopedic surgeries were canceled, which meant that fewer preoperative participants could be recruited and interviewed in comparison with postoperative participants. This study predominantly focused on a small sample of patients in Northern England, and as a result, the experiences shared by participants may not be representative of all care pathways across the United Kingdom. This study also focused solely on the perspectives of elective orthopedic surgical patients, and thus, the results may not be generalizable to other elective surgical specialties or acute surgeries.

Conclusions
The results of this study have important implications for the design, functionality, application, and use of digital technologies for patients undergoing elective orthopedic surgery. By integrating digital goal-setting strategies within their recovery, patients feel better supported and motivated to engage in health behavior change to optimize surgical outcomes. The use of game-like rewards and incentives has been seen to motivate and sustain positive health habits over time. The integration of video features was acknowledged as an interactive method of engaging
with physical activity during recovery and is regarded as a more personal strategy to enable follow-up consultations. This study contributes to the limited amount of existing digital health literature in this patient cohort and provides much-needed evidence relating to the optimal timing of digital interventions for elective orthopedic surgical patients. These findings should be employed in future codesign projects to enable the design and implementation of patient-focused, tailored, and targeted digital health technologies within modern health care settings.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Consolidated Criteria for Reporting Qualitative Research: 32-item checklist.

References


49. Cugelman B. Gamification: what it is and why it matters to digital health behavior change developers. JMIR Serious Games 2013 Dec 12;1(1):e3 [FREE Full text] [doi: 10.2196/games.3139] [Medline: 25658754]


Online Mindfulness-Based Cognitive Behavioral Therapy Intervention for Youth With Major Depressive Disorders: Randomized Controlled Trial

Paul Ritvo1,2,3, PhD; Yuliya Knyahnytska3,4,5, MD, PhD; Meysam Pirbaglou1, PhD; Wei Wang4,5, PhD; George Tomlinson6,7, PhD; Haoyu Zhao3,4,5, PhD; Renee Linklater4,8, PhD; Shari Bai4,5, MD; Megan Kirk1, MA; Joel Katz1,9, PhD; Lillian Harber4, BA; Zafiris Daskalakis3,5,10,11, MD, PhD

1School of Kinesiology and Health Sciences, York University, Toronto, ON, Canada
2Department of Psychology, York University, Toronto, ON, Canada
3Department of Psychiatry, University of Toronto, Toronto, ON, Canada
4Centre for Addiction and Mental Health, Toronto, ON, Canada
5Temerty Centre for Therapeutic Brain Intervention, Centre for Addiction and Mental Health, Toronto, ON, Canada
6THETA Collaborative, University Health Network, University of Toronto, Toronto, ON, Canada
7Biostatistics Unit, University Health Network, University of Toronto, Toronto, ON, Canada
8Aboriginal Engagement and Outreach, Centre for Addiction and Mental Health, Toronto, ON, Canada
9Department of Psychology, University of Toronto, Toronto, ON, Canada
10Department of Psychiatry, University of California San Diego, La Jolla, CA, United States
11Mood and Anxiety Ambulatory Services, Centre for Addiction and Mental Health, Toronto, ON, Canada

Corresponding Author:
Zafiris Daskalakis, MD, PhD
Department of Psychiatry
University of California San Diego
9500 Gilman Drive
La Jolla, CA, 92093
United States
Phone: 1 (858) 534 2230
Email: zdaskalakis@health.ucsd.edu

Abstract

Background: Approximately 70% of mental health disorders appear prior to 25 years of age and can become chronic when ineffectively treated. Individuals between 18 and 25 years old are significantly more likely to experience mental health disorders, substance dependencies, and suicidality. Treatment progress, capitalizing on the tendencies of youth to communicate online, can strategically address depressive disorders.

Objective: We performed a randomized controlled trial (RCT) that compared online mindfulness-based cognitive behavioral therapy (CBT-M) combined with standard psychiatric care to standard psychiatric care alone in youth (18-30 years old) diagnosed with major depressive disorder.

Methods: Forty-five participants were randomly assigned to CBT-M and standard care (n=22) or to standard psychiatric care alone (n=23). All participants were provided standard psychiatric care (ie, 1 session per month), while participants in the experimental group received an additional intervention consisting of the CBT-M online software program. Interaction with online workbooks was combined with navigation coaching delivered by phone and secure text messaging.

Results: In a two-level linear mixed-effects model intention-to-treat analysis, significant between-group differences were found for the Beck Depression Inventory-II score (difference –8.54, P=.01), Quick Inventory of Depressive Symptoms score (difference –4.94, P=.001), Beck Anxiety Inventory score (difference –11.29, P<.001), and Brief Pain Inventory score (difference –1.99, P=.03), while marginal differences were found for the Five Facet Mindfulness Questionnaire–Nonjudging subscale (difference –2.68, P=.05).

Conclusions: These results confirm that youth depression can be effectively treated with online CBT-M that can be delivered with less geographic restriction.
intervention study; telemedicine; electronic CBT; clinical trial; depression; cognitive behavioral therapy; CBT; online therapy; online intervention; youth; young adult

Introduction

Approximately 70% of all mental health problems appear before 25 years of age and often become chronic when not treated or ineffectively treated [1]. Such data raise questions about elevated depression rates in youth [2] as exemplified in the National Survey on Drug Use and Health (N=611,880), which found an increase in the depressive episode rates by 63% from 2009 to 2017 [2]. Youthful online engagement makes online intervention delivery attractive, particularly with possible reductions in costs, geographic barriers, and access inequities [3-6].

Cognitive behavioral therapy (CBT) is the best-validated psychotherapy [7], and in recent years has been coordinated with mindfulness meditation (CBT-M) following strong evidence of the combined efficacy [8,9]. Online CBT-M research with student and adult populations has yielded psychometric and neurophysiological [10-20] benefits in single-arm and randomized controlled trials (RCTs). These results join a growing world literature supporting online CBT efficacy, exemplified in a meta-analysis of 3876 RCT participants indicating that online CBT was significantly more effective than control conditions in reducing depressive symptoms (Hedges g=0.27) [21]. Individual RCTs have shown online CBT to be equally effective to in-person CBT in studies with large effect sizes, along with substantial remission rates for major depressive disorder [21].

These findings motivated a focus on assessing online CBT in patients concurrently receiving standard psychiatric care to examine whether online CBT and psychiatric treatment as usual (TAU) was superior to psychiatric TAU. Control participants received pharmacotherapy only when deemed appropriate by treating psychiatrists, and the TAU comparison accounted for the standard use of and response to antidepressant medications.

The key behavioral intervention in this study was online access to 24 CBT workbooks and 56 mindfulness instruction videos that supported metacognitive change and autonomic balance [22], which have been linked to improved mood and reduced anxiety [23]. Navigation coaching was supplied by students who were pursuing graduate degrees (MSc, MA, PhD) in kinesiology and health science, education, and psychology. Their group training (prior to and during the study) took place at a seminar (for 1.5 hours weekly) that focused on reviews of CBT and mindfulness-based clinical research supplemented by anonymized case discussions. One (cumulative) hour of coaching was provided to each participant weekly during 24 weeks (which included text-message exchanges with participants), and each coach received 1-hour weekly sessions of one-to-one supervision.

Methods

Design and Recruitment

The study was approved by the Research and Ethics Boards of the Centre for Addiction and Mental Health (CAMH; Protocol Reference number 115/2016-01) and York University (Certificate number 2017–154) in Toronto, Canada, and was registered at ClinicalTrial.gov (NCT03406052). This included distinct software platform approval for all privacy and security requirements at CAMH. The study evaluated the efficacy of CBT-M to treat young adults (18-30 years of age) with major depressive disorder. Participants were identified from service wait lists at the CAMH by research coordinators and in the prescreening of new clinic referrals. The investigative team was informed about possible participant eligibility and the client’s clinician was notified. The clinician then asked the client if she/he was willing to meet with a study team member to explore participation. Information about the study was shared with the clients agreed to meet for potential participation. A biostatistician (GT) performed electronic randomization of participants, assigning study IDs to intervention vs waitlist control participants. Information regarding each study ID with its respective group allocation was transferred onto cards placed in individually sealed, opaque envelopes. After a participant completed baseline questionnaires, the research coordinator opened the next envelope in the sequence to assign the group and respective study ID.
The inclusion criteria were: (1) aged 18 to 30 years; (2) Beck Depression Inventory-2 (BDI-II) score of at least mild severity, with no upper limit (BDI-II score ≥ 14) [27]; (3) Mini-International Neuropsychiatric Interview (MINI)-confirmed psychiatric diagnosis of major depressive disorder [28]; and (4) fluent in English. All patients were diagnosed by a CAMH physician, with diagnoses confirmed using the MINI interview administered at the screening visit. The exclusion criteria were: (1) individuals who were currently receiving weekly structured psychotherapy; (2) individuals who met the Diagnostic and Statistical Manual of Mental Disorders-V criteria for severe alcohol/substance use disorders in the past 3 months, individuals who demonstrated clinically significant suicidal ideation (defined as imminent intent), and individuals who had attempted suicide in the past 6 months; and (3) individuals with comorbid diagnoses of borderline personality, bipolar disorder, schizophrenia, and/or obsessive compulsive disorder (Figure 1).

Figure 1. Consort flow diagram.
Intervention

All participants were provided standard psychiatric care, operationally defined as one monthly session of TAU and mostly pharmacotherapy focused. Experimental participants received the additional CBT-M program content (workbooks and videos) accessed online through a software platform developed by NexJ Health, Inc. The platform, NexJ Connected Wellness (NCW), has unique properties that facilitated participant use. Interactions with the online workbooks were combined with navigation coaching (total 24-hour duration over 6 months), delivered as phone and text message exchanges. Each participant was also given a Fitbit-HR Charge 2 that assessed physical steps and 24-hour heart rate in 5-second durations combined with the NexJ Health, Inc software that permitted daily monitoring.

The intervention content was built on two prior successful web-based CBT-M RCTs with students [10-17] and on effective methods used with other populations assessed in RCTs [29-39]. The online content included 24 workbook chapters reflecting multiple topics (e.g., Living by Your Truths, Overcoming Wired-ness and Tired-ness, Mindfulness and Relationships, Loss and Grief, Resilience, Befriending Ourselves, Befriending Your Body With Exercise, Body Image and Mindfulness, Intimacy, Forgiveness, Overcoming Procrastination, Dealing With Negative Moods, Stress Resilience, Overcoming Performance Anxiety, and Cultivating Inspiration). The content was covered sequentially on a weekly basis with navigator coach guidance. In summary, key intervention features were 24-hour access and CBT-M contents that addressed specific symptoms and generic depressive experiences. The online platform used is produced and maintained by NexJ Health, Inc in Toronto, Ontario, and is the same basic platform employed in a prior study [19], although it has been upgraded numerous times in the interim. NexJ Health, Inc provided use of the NCW platform free of charge (as a research partner) but contributed no other funding or support for the study.

Outcome Measures

The primary outcome measure was the BDI-II [27], and the secondary outcomes focused on anxiety (Beck Anxiety Inventory [BAI]) [40], depression (Quick Inventory of Depressive Symptomatology [QIDS]) [41], the 24-item Hamilton Depression Rating Scale (HDRS-24; assessed by a blinded interview rater) [42], mindfulness (5-Facet Mindfulness Questionnaire [FFMQ]) [43], and pain (Brief Pain Inventory [BPI]) [44].

All self-report measures and the HDRS-24 interviews were conducted at the same CAMH Ambulatory Service setting. The HDRS-24 interview rater was blinded to intervention and control conditions for the trial duration.

Statistical Analysis

We used a two-level linear mixed-effects model to compare the difference in the rate of change regarding outcome scores between the intervention and control groups, accounting for the repeated measurement nature of the data. A full information maximum-likelihood method was used to deal with missing data [45]. Age, sex, and ethnicity were further included as auxiliary variables for this approach.

Results

Analyses

Data obtained from participants during study visits were deidentified and stored as electronic case reporting forms (CRFs) on the CAMH REDCap system, with the CRF paper copies stored in a secure, locked cabinet. Participant characteristics are summarized via descriptive statistics in Table 1. Group equivalence at baseline in terms of demographic and clinical variables was confirmed.
Table 1. Baseline demographic characteristics of study participants.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CBT-M(^a) (n=22)</th>
<th>WLC(^b) (n=23)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>25 (3.319)</td>
<td>24 (3.233)</td>
<td>.41</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (46)</td>
<td>7 (30)</td>
<td>.30</td>
</tr>
<tr>
<td>Female</td>
<td>12 (54)</td>
<td>16 (70)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
<td>.57</td>
</tr>
<tr>
<td>Caucasian</td>
<td>13 (59)</td>
<td>12 (52)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>6 (27)</td>
<td>4 (17)</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td>Indigenous</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3 (14)</td>
<td>5 (22)</td>
<td></td>
</tr>
<tr>
<td>Relationship status, n (%)</td>
<td></td>
<td></td>
<td>.51</td>
</tr>
<tr>
<td>Married</td>
<td>1 (5)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>20 (90)</td>
<td>21 (91)</td>
<td></td>
</tr>
<tr>
<td>Other (eg, common law)</td>
<td>1 (5)</td>
<td>2 (9)</td>
<td></td>
</tr>
<tr>
<td>Offspring, n</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>N/A(^c)</td>
</tr>
<tr>
<td>Work status, n (%)</td>
<td></td>
<td></td>
<td>.47</td>
</tr>
<tr>
<td>Employed</td>
<td>12 (55)</td>
<td>15 (65)</td>
<td></td>
</tr>
<tr>
<td>Not employed</td>
<td>10 (45)</td>
<td>8 (35)</td>
<td></td>
</tr>
<tr>
<td>Depression duration, mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression since onset age (years)</td>
<td>17 (4.13)</td>
<td>17 (5.01)</td>
<td>.98</td>
</tr>
<tr>
<td>Duration of current/last depressive episode (months)</td>
<td>9 (14.60)</td>
<td>19 (30.86)</td>
<td>.19</td>
</tr>
<tr>
<td>Number of identified depressive episodes</td>
<td>5.5 (5.06)</td>
<td>6.1 (6.94)</td>
<td>.72</td>
</tr>
<tr>
<td>Psychiatric history, mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous medication trials and failures</td>
<td>1.09</td>
<td>1.21</td>
<td>.91</td>
</tr>
<tr>
<td>Level of substance dependency or abuse</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of suicide attempts (from MINI(^d)), mean</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Comorbidities, mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric comorbidities</td>
<td>3.09</td>
<td>3.26</td>
<td>.77</td>
</tr>
<tr>
<td>Physical comorbidities</td>
<td>1.59</td>
<td>1.70</td>
<td>.81</td>
</tr>
<tr>
<td>Outcomes, mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline BDI-II(^e)</td>
<td>30 (8.40)</td>
<td>27 (7.90)</td>
<td>.21</td>
</tr>
<tr>
<td>Baseline BAI(^f) (mean)</td>
<td>29 (8.53)</td>
<td>22 (9.40)</td>
<td>.008</td>
</tr>
<tr>
<td>Baseline BPI(^g) (average pain x/10)</td>
<td>1.9 (2.50)</td>
<td>1.6 (2.25)</td>
<td>.64</td>
</tr>
<tr>
<td>HDRS(^h)</td>
<td>26 (6.96)</td>
<td>26 (6.43)</td>
<td>.96</td>
</tr>
<tr>
<td>QIDS(^i)</td>
<td>16 (4.30)</td>
<td>15 (3.70)</td>
<td>.44</td>
</tr>
<tr>
<td>FFMQ(^j)-Observing</td>
<td>15 (3.30)</td>
<td>13 (3.54)</td>
<td>.21</td>
</tr>
<tr>
<td>FFMQ-Describe</td>
<td>15 (5.25)</td>
<td>14 (3.94)</td>
<td>.45</td>
</tr>
<tr>
<td>FFMQ-Act Aware</td>
<td>12 (3.81)</td>
<td>14 (3.24)</td>
<td>.08</td>
</tr>
<tr>
<td>FFMQ-Nonjudging</td>
<td>11 (4.03)</td>
<td>13 (3.52)</td>
<td>.09</td>
</tr>
<tr>
<td>FFMQ-Nonreactivity</td>
<td>12 (3.25)</td>
<td>11 (3.44)</td>
<td>.32</td>
</tr>
</tbody>
</table>
Primary and Secondary Outcomes

A mean of 4.7 participants were enrolled per month. The intervention and TAU retention differed markedly as 91% (20/22) of intervention participants were retained compared to only 39% (9/23) of the TAU group (at the end of the trial). Of the 14 control dropouts, 9 dropped out shortly after the baseline assessment and 5 dropped out following completion of mid-term, 3-month measures. Of the 2 intervention dropouts, both dropped out shortly after enrollment (prior to 3-month measures). The between-group retention differences were significant at 3 months (P=.04) and 6 months (P=.001).

In the two-level linear model intention-to-treat analysis, between-group BDI-II, QIDS, BAI, BPI, and FFMQ–Nonjudging subscale differences were statistically significant (Table 2).

In the within-group differences, participants who completed the intervention (n=20) demonstrated significant reductions in depressive and anxiety symptoms as measured by changes in BDI-II (P<.001), BAI (P<.001), QIDS (P<.001), and (blinded) HDRS (P<.001) scores from pre- to postintervention (Table 3). The effect sizes were very large for the BDI-II (Cohen d=1.90 and Hedges g=1.82) and large on the QIDS (Cohen d=1.43 and Hedges g=1.38). All effect sizes were large and two were at or above 1.6 (Cohen d), typically calculated as two times a large effect size.

Table 2. Between-group differences based on intention-to-treat analysis (N=45).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Pretreatment, mean (SD)</th>
<th>Final assessment, mean (SD)</th>
<th>Difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>BDI-IIb,c</td>
<td>30.14 (8.397)</td>
<td>27.00 (7.909)</td>
<td>13.6 (9.73)</td>
<td>19.78 (16.642)</td>
</tr>
<tr>
<td>BAIde</td>
<td>29.14 (8.532)</td>
<td>21.74 (9.401)</td>
<td>15.45 (9.145)</td>
<td>21.67 (15.248)</td>
</tr>
<tr>
<td>QIDS</td>
<td>15.50 (4.307)</td>
<td>14.57 (3.703)</td>
<td>8.95 (4.925)</td>
<td>12.89 (6.03)</td>
</tr>
<tr>
<td>HDRS</td>
<td>26.27 (6.964)</td>
<td>26.17 (6.436)</td>
<td>14.75 (8.735)</td>
<td>22.67 (13.134)</td>
</tr>
<tr>
<td>BPIeh</td>
<td>1.89 (2.465)</td>
<td>1.553 (2.258)</td>
<td>1.11 (1.753)</td>
<td>2.17 (2.246)</td>
</tr>
<tr>
<td>FFMQ–Nonjudging</td>
<td>11.23 (4.035)</td>
<td>13.17 (3.525)</td>
<td>14.95 (5.042)</td>
<td>13.56 (5.199)</td>
</tr>
<tr>
<td>FFMQ–Describing</td>
<td>15.27 (5.248)</td>
<td>14.22 (3.942)</td>
<td>18.45 (4.032)</td>
<td>16.11 (4.314)</td>
</tr>
<tr>
<td>FFMQ–Observing</td>
<td>14.55 (3.306)</td>
<td>13.26 (3.454)</td>
<td>15.15 (3.829)</td>
<td>14.22 (4.738)</td>
</tr>
<tr>
<td>FFMQ–Awareness</td>
<td>12.33 (3.816)</td>
<td>14.13 (3.238)</td>
<td>16.2 (4.396)</td>
<td>15.56 (4.667)</td>
</tr>
</tbody>
</table>

*Difference of rate of change: a negative value indicates greater reduction in the intervention group.

bBDI-II: Beck Depression Inventory-2.

cPlanned analysis of primary outcome.

dBAI: Beck Anxiety Inventory.

eBonferroni correction was not applied for secondary outcomes.

fQIDS: Quick Inventory of Depressive Symptomatology.

gHDRS: Hamilton Depression Rating Scale.

hBPI: Brief Pain Inventory.

iFFMQ: 5-Facet Mindfulness Questionnaire.
Table 3. Within-group differences of intervention participants who completed the trial (N=20).

<table>
<thead>
<tr>
<th>Scale</th>
<th>Change (95% CI)</th>
<th>P value</th>
<th>Cohen d</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDI-II</td>
<td>−15.6 (−2.02 to −11.1)</td>
<td>&lt; .001</td>
<td>1.9</td>
</tr>
<tr>
<td>BAI</td>
<td>−127 (−16.9 to −8.5)</td>
<td>&lt; .001</td>
<td>1.5</td>
</tr>
<tr>
<td>QIDS</td>
<td>−6.2 (−8.3 to −4.0)</td>
<td>&lt; .001</td>
<td>1.4</td>
</tr>
<tr>
<td>HDRS</td>
<td>−10.7 (−14.7 to −6.6)</td>
<td>&lt; .001</td>
<td>1.6</td>
</tr>
<tr>
<td>BPI</td>
<td>−0.8 (−1.8 to 0.3)</td>
<td>.14</td>
<td>—</td>
</tr>
<tr>
<td>FFMQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Observing</td>
<td>0.01 (−0.7 to 0.9)</td>
<td>.46</td>
</tr>
<tr>
<td></td>
<td>Describing</td>
<td>2.5 (0.5−4.5)</td>
<td>.02</td>
</tr>
<tr>
<td></td>
<td>Awareness</td>
<td>2.8 (1.3−4.3)</td>
<td>.001</td>
</tr>
<tr>
<td></td>
<td>Nonjudging</td>
<td>2.5 (0.9−4.2)</td>
<td>.005</td>
</tr>
</tbody>
</table>

BDI-II: Beck Depression Inventory-2.
BAI: Beck Anxiety Inventory.
QIDS: Quick Inventory of Depressive Symptomatology.
HDRS: Hamilton Depression Rating Scale.
BPI: Brief Pain Inventory.
FFMQ: 5-Facet Mindfulness Questionnaire.

Discussion

The online CBT-M intervention was beneficial, given significant between-group differences in depression (BDI-II, QIDS), anxiety (BAI), pain (BPI), and mindfulness (FFMQ–Nonjudging subscale). Other notable between-group observations involved a 9% dropout rate in the intervention group that significantly differed from the 61% dropout rate in the TAU control group (the 61% dropout rate was estimated at ~14% above the mean for CAMH TAU). This difference suggests that the intervention had positive effects on participant retention. The intervention sample included a large subgroup with severe depression (n=10 participants, defined as severe by a BD-II score>29), 50% of whom were in remission (BDI<14) at the final (6-month) assessment. Of the 6 participants who exhibited moderate depression, 5 achieved remission, and of the 3 study participants with mild depression, 2 achieved remission.

Given the CBT-M intervention, it was notable that between-group differences were found in the Nonjudging subscale of the FFMQ that assesses the excess self-critical thinking associated with distress [43]. Intervention group participants engaged in significantly less self-critical self-judgment at the 6-month follow up than the TAU controls. Although the study sample size did not allow for mediation analyses [46], the between-group difference observed suggests that the mindfulness component of the CBT-M intervention was likely involved in the modification of depressogenic cognitions [2]. The between-group differences also appear linked to the self-acceptance emphasis in the CBT-M interventions employed.

Significant between-group differences were found in self-reported chronic pain as indicated in the BPI scale. The inclusion of a pain assessment reflects recent findings about the high comorbidity prevalence in depression with respect to chronic pain [47] and the possible efficacy of behavioral pain reduction methods [48,49]. Despite this study’s findings, the behavioral intervention literature on reductions in chronic pain remains sparse, and additional targeted studies in populations with pain and mental health difficulties are warranted.

Although attrition in psychiatric treatment has been linked to early improvements associated with medication changes [50], this explanation does not seem to apply in the current trial, as 4 of the 5 total control participants who discontinued after the 3-month midterm measures received no pharmacotherapy or no modifications in the prestudy pharmacotherapy established. The control participants who dropped out following the baseline assessment (before midterm, 3-month assessment; n=9) did not receive medication initiation or modification. The attrition difference also did not appear to be based on more severe baseline depression as the mean BDI-II depression score at baseline for TAU control participants (BDI-II=27.0) reflected milder depression symptoms than those of intervention participants (mean BDI-II=30.14).

Significant study strengths included the control comparison with a standard-care psychiatry intervention, delivered at the same institution, independently versus in combination with the experimental behavioral intervention. This resulted in detailed records of how pharmacological and behavioral interventions interacted, assisting estimations of independent and combined benefits. The study further controlled for the intervention-related placebo effects observed in 35%-40% of RCT participants exposed to TAU conditions [7]. This was also a necessary control for medication effects, given that individuals treated for depression show improvement with antidepressants alone [7]. In this study, CBT-M effects were clearly additive to TAU
effects. Although the TAU-only group attrition rate can be seen as a study limitation, there were demonstrated associations between the CBT-M intervention and retention (ie, lower attrition in the experimental group) that indicated retention benefits associated with the behavioral treatment.

In recent meta-analyses focused on CBT-M delivery for depression, multiple CBT modalities have been assessed, notably individual, group, telephone-based, and guided self-help, all of which appear to be significantly more effective than waitlist and care-as-usual control conditions, and unguided self-help [51]. These analyses reflect the investigative search for the most cost-effective CBT delivery. In the context of current meta-analyses, our intervention can be characterized as combining telephone-based with guided self-help (online), with results that show significantly better outcomes than care-as-usual controls.

Key limitations of our study include a lack of participant blinding and the limited power associated with a small sample size. However, the HDRS assessment was undertaken by a rater blinded to group allocation. Although the between-group differences on the HDRS were trending toward significance (P=.09), they were not statistically significant. A final limitation is that the study psychiatrists administering TAU to control and intervention participants were not blind to which participants were in the intervention versus control groups, and this might have led to biased treatment.

Future studies comparing CBT-M and standard-care psychiatry would benefit from larger sample sizes, more complete blinding, and extended follow up after intervention conclusion (eg, 6-12 months). Despite these limitations, the results indicate that online CBT-M combined with TAU psychiatric treatment was an effective treatment for major depressive disorder and led to significantly greater reductions in BDI-II scores than TAU psychiatry alone.

Acknowledgments

PR has received research support from the Canadian Institutes of Health Research (CIHR) and the Federal Development Program of Southern Ontario. ZD has received research support from CIHR, National Institutes of Health, Brain Canada, and the Temerty family through the CAMH Foundation and the Campbell Family Research Institute. JK is supported by a Canadian Institutes of Health Research Canada Research Chair in Health Psychology at York University.

Conflicts of Interest

ZD received research support and in-kind equipment support for an investigator-initiated study from Brainsway, Ltd. He is the site principal investigator for sponsor-initiated studies for Brainsway, Ltd. He also receives in-kind equipment support Magventure for investigator-initiated research. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).

References


27. Smarr KL, Keefee AL. Measures of depression and depressive symptoms: Beck Depression Inventory-II (BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D), Geriatric Depression Scale (GDS), Hospital Anxiety and Depression Scale (HADS), and Patient Health Questionnaire-9 (PHQ-9). Arthritis Care Res (Hoboken) 2011 Nov 07;63(Suppl 11):S454-S466. [doi: 10.1002/acr.20556] [Medline: 22588766]


Abbreviations

BAI: Beck Anxiety Inventory
BDI: Beck Depression Inventory
BPI: Brief Pain Inventory
CAMH: Centre for Addiction and Mental Health
CBT: cognitive behavioral therapy
CBT-M: mindfulness-based cognitive behavioral therapy
CIHR: Canadian Institutes of Health Research
CRF: case reporting form
FFMQ: 5-Facet Mindfulness Questionnaire
HDRS-24: 24-item Hamilton Depression Rating Scale
MINI: Mini-International Neuropsychiatric Interview
NCW: NexJ Connected Wellness
QIDS: Quick Inventory of Depressive Symptomatology
RCT: randomized controlled trial
TAU: treatment as usual
Electronic Health Risk Behavior Screening With Integrated Feedback Among Adolescents in Primary Care: Randomized Controlled Trial

Laura Richardson1,2, MPH, MD; Elizabeth Oshrin Parker1, PhD; Chuan Zhou1,2, PhD; Julie Kientz3, PhD; Elizabeth Ozer4,5, PhD; Carolyn McCarty1,2, PhD

1Seattle Children's Research Institute, Seattle, WA, United States
2Department of Pediatrics, University of Washington, Seattle, WA, United States
3Department of Human Centered Design & Engineering, University of Washington, Seattle, WA, United States
4Division of Adolescent and Young Adult Medicine, Department of Pediatrics, University of California, San Francisco, San Francisco, CA, United States
5Office of Diversity & Outreach, University of California, San Francisco, San Francisco, CA, United States

Corresponding Author:
Laura Richardson, MPH, MD
Seattle Children’s Research Institute
1900 9th Ave
Seattle, WA, 98101
United States
Phone: 1 (206) 884 7300
Email: laura.richardson@seattlechildrens.org

Abstract

Background: Health risk behaviors are the most common sources of morbidity among adolescents. Adolescent health guidelines (Guidelines for Preventive Services by the AMA and Bright Futures by the Maternal Child Health Bureau) recommend screening and counseling, but the implementation is inconsistent.

Objective: This study aims to test the efficacy of electronic risk behavior screening with integrated patient-facing feedback on the delivery of adolescent-reported clinician counseling and risk behaviors over time.

Methods: This was a randomized controlled trial comparing an electronic tool to usual care in five pediatric clinics in the Pacific Northwest. A total of 300 participants aged 13-18 years who attended a well-care visit between September 30, 2016, and January 12, 2018, were included. Adolescents were randomized after consent by employing a 1:1 balanced age, sex, and clinic stratified schema with 150 adolescents in the intervention group and 150 in the control group. Intervention adolescents received electronic screening with integrated feedback, and the clinicians received a summary report of the results. Control adolescents received usual care. Outcomes, assessed via online survey methods, included adolescent-reported receipt of counseling during the visit (measured a day after the visit) and health risk behavior change (measured at 3 and 6 months after the visit).

Results: Of the original 300 participants, 94% (n=282), 94.3% (n=283), and 94.6% (n=284) completed follow-up surveys at 1 day, 3 months, and 6 months, respectively, with similar levels of attrition across study arms. The mean risk behavior score at baseline was 2.86 (SD 2.33) for intervention adolescents and 3.10 (SD 2.52) for control adolescents (score potential range 0-21). After adjusting for age, gender, and random effect of the clinic, intervention adolescents were 36% more likely to report having received counseling for endorsed risk behaviors than control adolescents (adjusted rate ratio 1.36, 95% CI 1.04 to 1.78) 1 day after the well-care visit. Both the intervention and control groups reported decreased risk behaviors at the 3- and 6-month follow-up assessments, with no significant group differences in risk behavior scores at either time point (3-month group difference: β=−.15, 95% CI −0.57 to −0.01, P=.05; 6-month group difference: β=−.12, 95% CI −0.29 to 0.52, P=.57).

Conclusions: Although electronic health screening with integrated feedback improves the delivery of counseling by clinicians, the impact on risk behaviors is modest and, in this study, not significantly different from usual care. More research is needed to identify effective strategies to reduce risk in the context of well-care.

Trial Registration: ClinicalTrials.gov NCT02882919; https://clinicaltrials.gov/ct2/show/NCT02882919
Introduction

Background
Health risk behaviors, such as alcohol use, risky sexual behaviors, and low physical activity, are among the most common causes of morbidity and mortality during adolescence and young adulthood [1,2]. To reduce risk and morbidity, adolescent preventive care guidelines recommend screening and counseling to reduce these behaviors as a component of annual well-care visits [3,4]. However, the delivery of preventive screening is inconsistent, and only a small proportion of screened adolescents report having received counseling to reduce risk with rates of counseling varying by type of behavior [2,5-7].

Research has shown that the use of standardized screening methods, including electronic screening tools, can increase screening delivery, detection of risk, and adolescent-reported clinician counseling [6,8,9]. Adolescents report greater comfort in disclosing behaviors with electronic screening methods compared with other methods [10-13]. However, few studies have examined the impact of increasing clinician counseling on adolescent behavior outcomes in the context of multi-risk screening, as is commonly performed in well-care visits. In a recent review article examining multi-risk screening in adolescents, 9 studies were identified, with some demonstrating effects on risk behaviors [7]. Among these trials, variations in intervention duration, intensity, behaviors studied, and impacted outcomes led to a limited ability to draw definitive conclusions. In addition, based on the studies in this review, the magnitude of behavioral changes was small to modest, and the only risk behavior for which change was found in more than one study was for an increase in bicycle helmet use.

When administered consistently, electronic screening can serve to reduce biases related to selecting who gets screened and how questions are asked [14]. In addition, some studies suggest that adolescents are more likely to use preventive health services when they are given information electronically about health behaviors [15-18]. Furthermore, 2 studies found that the use of electronic screening improved adolescents’ perceptions of clinician communication and partnership [19,20].

Study Aim
In this study, we aim to examine the efficacy of a tool delivered via an app or website link that combined electronic screening with integrated personalized motivational feedback. The interactive tool was developed with adolescents’ input and designed to be administered before a well-care visit to prepare adolescents to discuss risk behavior change with their clinicians when indicated. The tool tested in this study (Figure 1; see additional examples in Multimedia Appendix 1) is a modified version of a previously tested tool [21]. The modifications were made to increase youth engagement with the tool and increase the ease with which clinicians can interpret the results with changes based on adolescent and clinician input gathered through a human-centered design process [22]. The tool also generated a printed one-page clinician summary of adolescent-reported behaviors. The primary outcomes of interest were adolescent-reported clinician counseling during the visit, health risk behaviors at 3 months, and patient satisfaction. The secondary outcome was health risk behavior at 6 months. We hypothesized that the intervention would increase clinician counseling and reduce health risk behaviors at 3 months.
Methods

Overview
We conducted a parallel-group randomized controlled intervention study comparing the electronic screening and feedback tool to usual care in the context of a well-care visit. Adolescent participants (aged 13-18 years) were recruited from 5 pediatric clinics in Washington State between September 30, 2016, and January 12, 2018. Clinics were contacted via the Puget Sound Pediatric Research Network and invited to participate based on interest in the study and the number of adolescent patients served. Clinics were located in urban, suburban, and small city locations. The providers of these clinics included physicians and advanced practitioners. Residents and other trainees were not included in the study because of concerns about continuity in the clinical setting. Among participating clinics, the average monthly number of adolescents aged 13 to 18 years with scheduled well-visits was 49 (SD 17; range 31-71).

Sites were added to the study on a rolling basis with the goal of recruiting a minimum of 60 adolescents per site for a total recruitment goal of 300 adolescents. The study sample size was predetermined by the study statistician with the goal of having 80% power to detect an effect size as small as 0.3. Enrollment goals were met and exceeded at 4 of the 5 participating clinics, resulting in a total sample of 301 adolescents. The fifth clinic began enrollment late and, after entering the study, determined that they were not comfortable sharing patient contact data for research team outreach in the manner approved by the...
institutional review board. As a result, only a small number of patients were invited to participate, of whom 2 were enrolled.

Study outreach procedures included clinics sharing contact information for all adolescent patients between the ages of 13 and 17 years who were scheduled for an upcoming well-care visit. The study staff coordinated the mailing of a letter to parents from the clinic, inviting eligible adolescents to participate in the study and providing a phone number to opt out of further contact. This letter was followed by a phone call from the study staff to provide further information and assess eligibility. Exclusion criteria included planning to cancel the well-care visit, being out of the study age range, having a sibling who was previously invited to participate, lacking phone or internet access, or if the adolescent did not speak English.

Parental consent and adolescent assent were obtained via phone for participants aged 13-17 years, whereas participants aged 18 years provided direct consent. The consent forms stated that the study would compare electronic screening with feedback and provision of the results to the clinician to electronic screening alone (with no feedback or results provided to the clinician). Although most of the adolescents approached for the study spoke English, some parents did not. To support the inclusion of these adolescents, recruitment and parental consent materials were translated into Spanish and Somali, the most common languages spoken in participating clinics.

Before beginning recruitment at each clinic, the study statistician developed a computer-generated list of random numbers that was entered into REDCap [23] with a 1:1 allocation schema stratified by age (13-15 or 16-18 years), male or female gender (as provided by the study clinics based on their records), and clinic. Participant randomization occurred after the completion of consent and assent procedures and before data collection. Adolescents were not told their study assignment but could potentially determine it based on whether or not they received feedback as part of the baseline assessment. After consent was completed, adolescent participants were sent an online link for their baseline screening assessment, with or without integrated feedback, based on the study assignment. Baseline data were collected online with phone support by trained study staff before the well-care visit. As part of the procedures, control and intervention adolescents were instructed to complete their respective baseline screening components in a private setting where they could respond confidentially. All procedures for recruitment were approved by the Seattle Children’s Institutional Review Board before starting study activities. The study protocol is available upon request from the corresponding author.

**Intervention Procedures**

Intervention adolescents completed electronic screening with integrated personalized feedback, and their clinician received a printed one-page summary report of the screening results. The electronic screening tool assessed protective factors and risk behaviors using a HEADSS pneumonic (Home, Education, Activities, Drugs, Depression, Sexuality, and Safety) framework [24]. The tool was also screened for specific nutritional behaviors (sweetened beverage intake and fruit and vegetable intake), physical activity, and sleep. The integrated feedback component was designed to deliver messages that increased motivation and self-efficacy for healthy behavior. Feedback content varied according to behavior assessed and the youth-reported risk level. It included a combination of education, tips for change, and motivational messaging, including positive reinforcement for adolescents who did not engage in risks and messages to motivate behavior change when risks were present using a combination of normative feedback comparing adolescent-reported risks to peer reports, guidelines, and goal setting.

The tool in this study is an adapted version of the Check Yourself tool (version 2) [21,25], revised to increase interactive features with input from adolescent users, clinicians in collaboration with faculty, and researchers in human-centered design. Specific changes that were developed with adolescent input include increasing image-based feedback versus text, adding functionality to allow participants to choose to see more versus less information on each topic, and the option to receive more information about topics of interest in the form of a one-time text or email. In addition, screening content was modified to add response options related to gender identity, remove screen time assessments, enhance screening for depression and anxiety, and enhance screening and new feedback related to marijuana use. On the basis of internal tracking data, the tool took an average of 15 (SD 8) minutes to complete among control adolescents and 18 (SD 10) minutes among intervention adolescents who also received integrated feedback.

The one-page paper clinician summary included a dashboard with flags categorizing the adolescent health risks as low, moderate, or high within 6 areas: nutrition, activity, substance use, emotions, sexual activity, and safety. Individual screening responses were provided below the dashboard for each area so that clinicians could examine which specific behaviors resulted in a flag. Risk behavior severity categories (high, moderate, and low) were defined a priori based on health guidelines or expert consensus (Multimedia Appendix 2) and integrated into the electronic screening algorithms. The study staff coordinated with each clinic to develop protocols so that clinicians would receive the summary report before the visit.

**Control Procedures**

Control adolescents completed the electronic screening portion of the tool as a baseline assessment but did not receive integrated feedback. The clinicians did not receive any screening results. From the outset of the study, clinicians were instructed to continue their standard health risk screening procedures for all patients (intervention and control). The standard processes for all 5 sites included a combination of paper intake screeners and interviews during the visit to assess risk, but the content of the paper screeners varied. One clinic used standardized paper anxiety and depression screens. Another clinic used a self-designed form that asked about sleep and safety risks, including texting while driving, driving under influence, helmet use, and seatbelt use. Outside of these 2 examples, there was no overlap between the health risk behavior content in the electronic screening tool and the standard screening forms employed by study clinics. None of the clinics employed a standard form to screen for confidential health risk behaviors,
such as sexual activity or drug use. All of the clinics indicated that their providers asked about confidential risk behaviors during the well-care visit, although data were not available regarding the consistency of these practices.

Before enrollment, all clinicians received an invitation to complete a 15-minute online training module to orient them to the electronic tool and how to interpret the clinician summary. As randomization was at the patient level, clinicians could be exposed to both intervention and control patients.

**Surveys**

The baseline assessment consisted of responses from the electronic screening tool (with or without feedback depending on assignment) conducted before the well-visit (details provided in Multimedia Appendix 3). In addition, all adolescents completed online follow-up surveys 1 day, 3 months, and 6 months following their well-care visit. The 1-day follow-up survey assessed the content of the visit, including the delivery of counseling to change behavior for each screened behavior. Items assessing the visit were adapted from the Adolescent Report of the Visit developed by Ozer et al [26]. The 3-month and 6-month follow-up surveys assessed the same health risk behaviors as at baseline, collected via an online survey tool, REDCap [23]. Participants were asked about suicidality at baseline and at all follow-up time points. To ensure safety, study investigators, who are also clinicians, followed up with all participants in either study arm who reported having thoughts of harming themselves in the past 2 weeks and thoughts of killing themselves or suicide attempts in the past 3 months and assisted them in accessing clinical services.

**Analysis**

All data analyses were conducted using R 3.5.0 [27] using an intent-to-treat framework. We first conducted bivariate analyses to evaluate differences in demographics and baseline risk between adolescents in the control and intervention group. Subsequently, we conducted our main analyses on the 3 primary outcome measures: clinician counseling during the visit, a summary score of health risk behaviors measured at 3 months after the visit, and patient satisfaction. Our secondary outcome measure, the health risk behaviors summary score at 6 months was analyzed together with the 3-month summary score using repeated measures analysis.

On the basis of the study design, missing data only occurred during the outcome assessments. We compared the baseline characteristics of participants with and without missing outcomes and found no differences between the groups. We further conducted sensitivity analyses for each of our primary outcomes using multiple imputation with chained equations (MICE) methods using linear regression and predictive mean matching for continuous outcomes. For categorical outcomes, we applied classification and regression tree methods for imputation using MICE methods. Estimates from the fitted models on multiple imputed data sets were pooled to generate the final results for inference. In conducting these sensitivity analyses, we found that the results were almost identical for the imputed and complete case analysis. Thus, only the complete case analysis results are presented in this paper.

**Clinician Counseling Outcome**

Clinician counseling during the visit, measured on the 1-day assessment, was defined as adolescent report of the clinician having counseled them to change an endorsed behavior toward health. This measure was constructed by summing all endorsed moderate- and high-risk behaviors for which adolescents reported receiving counseling. We conducted an adjusted analysis using a mixed effects Poisson regression model in which the dependent variable was the counseling measure, and the treatment group was the predictor of interest. Baseline age and sex were included as covariates, and a clinic-specific random effect was included to account for clustering within the clinic. The total number of endorsed moderate- and high-risk behaviors was entered as an offset to ensure that the regression coefficients had proper rate interpretation. As an exploratory subanalysis to evaluate whether higher-risk behaviors were more likely to receive counseling than moderate-risk behaviors, we also conducted 2 additional regression analyses focused specifically on counseling for each category of risk behaviors: high-risk and moderate-risk behaviors, controlling for the same variables as the main analysis.

**Risk Behavior Outcome**

The risk behavior outcome analyses employed a summary score of all assessed behaviors at 3 months (primary outcome) and 6 months (secondary outcome) after the visit. The risk behavior scores were constructed for each participant by adding all of the risk behaviors for which the tool included feedback (alcohol use, marijuana or other drug use, driving while intoxicated, tobacco use, depression, texting while driving, inconsistent seatbelt use, inconsistent helmet use, unprotected sexual activity, high sugary beverage intake, low fruit and vegetable intake, inadequate sleep, and low physical activity) at 3 and 6 months. High-risk behaviors were assigned a score of 2, moderate-risk behaviors were assigned a score of 1, and low-risk behaviors were assigned a score of 0 (score potential range: 0-21, further details regarding items in Multimedia Appendix 2). Treating baseline, 3-month, and 6-month risk scores as repeated measures, we applied linear mixed effects regression models to compare changes over time in adolescent-reported total risk scores at 3 and 6 months, relative to baseline, in intervention versus control adolescents controlling for baseline sex, age, and clinic as a random effect. To examine the effects of the intervention on health risk behaviors, we conducted exploratory logistic regression analyses for individual risk behaviors. Owing to concerns about estimate instability, we did not conduct analyses for individual behaviors in which fewer than 10 adolescents per study arm endorsed the behavior.

**Patient Satisfaction Outcome**

Patient satisfaction was measured on the 1-day postvisit survey using a satisfaction scale ranging from 1 to 10 from the Consumer Assessment of Health care Providers and Systems [28]. Differences between groups were examined using linear mixed effect regression while controlling for baseline age, sex, and clinic-specific random effects.
Control adolescents were the reference group for all regression analyses. For mixed effects Poisson regression, we determined that an estimate was statistically significant if its 95% CI for the rate ratio did not include 1. For the mixed effects linear regression models, statistical significance was based on \( P \) values calculated using the Satterwaite degrees of freedom method [29].

**Results**

**Overview**

In total, letters were sent to 1665 homes inviting adolescents to participate (Multimedia Appendix 4). The final study sample that completed all consent and baseline procedures was 301 adolescents (301/1586, 18.9% of the eligible sample). One adolescent withdrew from the study and requested that their data not be used, leaving an analytic sample of 300 adolescents. After consent, 145 patients were randomized to the intervention group and 155 to the control group. The response rates at 1 day, 3 months, and 6 months were 94% (282/300), 94.3% (283/300), and 94.6% (284/300), respectively.

**Baseline Demographics and Risk Assessment**

Randomization was balanced, with no differences between intervention and control adolescents in terms of demographics or baseline risk score (Table 1). Among the 300 participants, 43% (n=129) were female, 76% (n=228) were between the ages of 13 and 15 years, and 24% (n=72) were aged 16-18 years. Most adolescents identified as White (n=192, 64%), with the next largest group identifying as being of more than one race or “other” (n=55, 18.3%). In total, 92% (n=276) of adolescents had at least one health risk behavior at baseline, with a mean baseline risk score of 2.86 (SD 2.33) for intervention and 3.10 (SD 2.52) for control participants.

Table 2 summarizes the reported risk behaviors in order of baseline frequency at baseline, 3 months, and 6 months, with the most common risk behavior being low fruit and vegetable intake and the least frequent being driving under influence.

**Table 1.** Sample demographics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control (n=155)</th>
<th>Intervention (n=145)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>70 (45.2)</td>
<td>59 (40.7)</td>
</tr>
<tr>
<td>Male</td>
<td>82 (52.9)</td>
<td>86 (59.3)</td>
</tr>
<tr>
<td>Trans or nonbinary</td>
<td>3 (1.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Age (years), n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13-15</td>
<td>114 (73.5)</td>
<td>114 (78.6)</td>
</tr>
<tr>
<td>16-18</td>
<td>41 (26.4)</td>
<td>31 (21.3)</td>
</tr>
<tr>
<td>Race or ethnicity, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>99 (63.9)</td>
<td>93 (64.1)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>12 (7.7)</td>
<td>7 (4.8)</td>
</tr>
<tr>
<td>African American</td>
<td>13 (8.4)</td>
<td>6 (4.2)</td>
</tr>
<tr>
<td>Asian or Pacific Islander</td>
<td>7 (4.5)</td>
<td>7 (4.8)</td>
</tr>
<tr>
<td>Native American</td>
<td>0 (0.0)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Other or more than one</td>
<td>24 (15.5)</td>
<td>31 (21.4)</td>
</tr>
<tr>
<td>Risk behavior score at baseline, mean (SD)</td>
<td>3.10 (2.52)</td>
<td>2.86 (2.33)</td>
</tr>
</tbody>
</table>
Table 2. Prevalence of individual risk behaviors over time in intervention and control adolescents.

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Intervention</th>
<th>Control</th>
<th>Logistic regression, $P$ value$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (n=145), n (%)</td>
<td>3 months (n=138), n (%)</td>
<td>6 months (n=139), n (%)</td>
</tr>
<tr>
<td>Low fruit or vegetable intake</td>
<td>115 (79.3)</td>
<td>106 (76.8)</td>
<td>98 (70.5)</td>
</tr>
<tr>
<td>Low sleep time</td>
<td>46 (31.7)</td>
<td>52 (37.7)</td>
<td>65 (46.8)</td>
</tr>
<tr>
<td>Low physical activity</td>
<td>39 (26.9)</td>
<td>44 (31.9)</td>
<td>36 (25.9)</td>
</tr>
<tr>
<td>Inconsistent helmet use</td>
<td>37 (25.5)</td>
<td>24 (17.4)</td>
<td>22 (15.8)</td>
</tr>
<tr>
<td>High sugary beverage intake</td>
<td>28 (19.3)</td>
<td>39 (28.2)</td>
<td>36 (25.9)</td>
</tr>
<tr>
<td>Depression</td>
<td>13 (9.0)</td>
<td>15 (10.9)</td>
<td>14 (10.1)</td>
</tr>
<tr>
<td>Inconsistent seatbelt use</td>
<td>16 (11.0)</td>
<td>7 (5.1)</td>
<td>11 (7.9)</td>
</tr>
<tr>
<td>Texting while driving</td>
<td>9 (5.8)</td>
<td>10 (7.2)</td>
<td>8 (5.8)</td>
</tr>
<tr>
<td>Marijuana use</td>
<td>10 (6.9)</td>
<td>4 (2.9)</td>
<td>3 (2.2)</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>8 (5.5)</td>
<td>3 (2.2)</td>
<td>4 (2.9)</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>4 (2.8)</td>
<td>0 (0.0)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Sexual risk</td>
<td>1 (0.7)</td>
<td>3 (2.2)</td>
<td>3 (2.2)</td>
</tr>
<tr>
<td>Driving under the influence</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

$^aP$ values were based on the likelihood ratio test comparing mixed effects logistic regression with and without period-by-group interaction. Both models controlled for random effects corresponding to within-individual clustering.

$^b$Owing to concerns about estimate instability, we did not conduct analyses for individual behaviors in which fewer than 10 adolescents per study arm endorsed the behavior.

### Clinician Counseling Analysis Results

Among control adolescents, 380 moderate- and high-risk behaviors were endorsed, among which adolescents reported receiving clinician counseling for 148 (38.9%) behaviors during the visit. Intervention adolescents reported a total of 326 moderate- and high-risk behaviors, among which 184 (56.4%) were counseled by clinicians during the visits. In the Poisson regression analyses, intervention adolescents were significantly more likely to report that they had received counseling for their endorsed moderate- and high-risk behaviors than control adolescents (adjusted rate ratio [aRR] 1.36, 95% CI 1.04 to 1.78). To examine the impact of the intervention on rates of counseling by risk behavior severity level, we also examined rates of counseling for intervention and control adolescents based on whether they were classified as low, moderate, or high risk. Intervention adolescents were 40% more likely than adolescents in the control group to have received counseling for moderate-risk behaviors (aRR 1.40, 95% CI 1.09 to 1.80). For high-risk behaviors, the rate of counseling was 70% higher among intervention than control adolescents (aRR 1.70, 95% CI 1.06 to 2.74). There were no significant differences between intervention and control adolescents in reported counseling for no-/low-risk behaviors (aRR 1.12, 95% CI 0.85 to 1.48).

### Risk Behavior and Patient Satisfaction Analyses

The baseline risk score was 2.86 (SD 2.33) for adolescents in the intervention group and 3.10 (SD 2.52) for adolescents in the control group, respectively ($P=.40$). At 3 months, the risk score for adolescents in the intervention group was 2.68 (SD 2.04) compared with 2.74 (SD 2.11), respectively, for adolescents in the control group ($P=.81$). At 6 months, the risk score for adolescents in the intervention group was 2.58 (SD 1.87) compared with 2.76 (SD 2.05) for adolescents in the control group ($P=.45$). In mixed effects linear regression analysis including both 3- and 6-month outcomes, there was a significant reduction in risk behaviors in both groups at 3 months ($\beta=-.33$, 95% CI $-0.62$ to $-0.05$; $P=.02$) and 6 months ($\beta=-.29$, 95% CI $-0.57$ to $-0.01$; $P=.05$). There were no significant differences in risk scores between the intervention and control groups at either time point (Figure 2). At 3 months, the score difference between groups was 0.15 ($\beta=-.15$, 95% CI $-0.25$ to 0.55; $P=.47$), and at 6 months, it was 0.12 ($\beta=-.12$, 95% CI $-0.29$ to 0.52; $P=.57$). In secondary analyses examining individual behaviors, no significant differences in the reduction of behaviors were observed between the adolescents of the intervention and control groups (Figure 2). There were also no significant differences between groups in patient satisfaction with the well-care visit process based on regression analysis controlling for age, gender, and clinic as a random effect.
Discussion

Principal Findings

In this study of an integrated screening and feedback tool, Check Yourself version 2, we found that adolescents in the intervention group were significantly more likely to report having been counseled by clinicians on risk behaviors than adolescents in the control group. However, despite significant differences in reported counseling between adolescents in the intervention and control groups, both groups demonstrated reductions in risk behavior scores, and there were no significant differences between the groups at 3 or 6 months after the intervention. There were also no significant differences in satisfaction between the 2 groups. These results are in contrast to our original study [21], which showed both an increase in reported counseling and a reduction in risk behavior scores at 3 months for youth in the intervention group as compared with controls. This study further adds to the growing body of literature on multi-behavior screening and preventive counseling interventions in adolescent well-care visits, which suggests that although provider counseling can be increased, the effects on risk behavior reductions are modest and inconsistent across studies [7].

In comparing the results to our prior study, it is important to note that this study tested a modified version of the tool with increased interactive content, which allowed adolescents to control the amount of information they received. Although adolescents requested incorporating these choices in content viewing, it is possible that the new adaptations resulted in less content exposure, particularly for at-risk adolescents who were not concerned about their behaviors. In this study design, we did not have the ability to assess how long adolescents spent on specific components of the feedback, although we do know that the overall time spent in this version of the tool was longer than the prior tool version. Future studies of interactive eHealth tools such as this could provide a better understanding of how risk influences engagement in feedback content.

It is also important to note that both the intervention and control groups experienced decreases in risk 3 months following their well-care visit in this sample. The reduction in risk in the control group would have weakened the ability to detect a difference. At baseline, all of the clinics in the study indicated that they conducted some form of paper and interview assessment of risk behaviors during the well-care visit. We collected information on the paper tools implemented and did not find substantial overlap with the risk behavior screening content of the electronic tools; however, all control teens completed an electronic health risk behavior assessment as part of the baseline study procedures. Although the results of this screening were not provided to the clinicians, it is possible that even in the absence of feedback, participating in the electronic screening may have resulted in behavior change, as teens reflected on their responses to risk behavior questions. In addition, as participants were randomized at the individual level, it is possible that some of the improvement in the control group was due to spillover effects as study clinicians and clinic staff applied learning from working with adolescents in the intervention group to control group. Our clinician counseling measure was based on
adolescent self-report and did not allow us to directly assess the content of counseling delivered during the visits to test this possibility.

Unlike our prior study, we also collected 6-month outcomes that allowed us to examine the long-term effects of the intervention. Although it was encouraging to see that risk scores continued to trend downward for the intervention sample, the differences between the control and intervention groups were not significant. Given the lack of effect at 3 months, it is difficult to draw conclusions from the 6-month data. Furthermore, 2 prior studies that examined both short-term (3 months) and long-term outcomes (12 months) found that significant differences in risk behaviors noted at 3 months were no longer significant at 12 months [30,31]. These 2 studies employed different models of brief interventions. One involved 9 hours of clinician training in motivational interviewing and system support for the implementation of a screening tool for all visits among eligible adolescents and young adults [30]. The second intervention focused on those aged 14 and 15 years enrolled in 8 general practice sites who were invited to participate in a 20-minute health consultation on risk behaviors of their choosing with a trained nurse [31]. Other studies that have examined 6- or 12-month outcomes have found significant improvements in single outcomes—helmet use [32,33] and exercise [19] only. Given the health care resources directed at screening and preventive counseling, understanding the long-term impacts of multiple risk behavior interventions is an area worthy of future study.

Limitations

This study had several limitations. First, although the use of a combined risk behavior outcome measure allowed us to test across the full range of behaviors for which clinicians were providing counseling, it is more difficult to interpret. We selected this measure as we feel it is more consistent with the multi-risk focus of behavioral counseling delivered in the pediatric well-care visit setting. However, this approach limits the conclusions we can draw regarding changes in any specific behavior. We conducted secondary analyses of individual behaviors to allow for a more ready interpretation of the intervention; however, for many behaviors, the prevalence at baseline was too low to draw conclusions on behavior change. The use of this multi-risk measure also limits our ability to compare outcomes with other studies, as prior research has measured a range of individual behavior outcomes [7].

A second limitation of this study is the low prevalence of individual behaviors. Consistent with other studies in pediatric primary care [34,35], including our own [21], adolescents receiving well-care tended to be younger: 76% (228/300) of participants were in the 13- to 15-year-old age group. Younger adolescents are less likely to engage in risk behaviors than older adolescents, which may limit their ability to show changes in behaviors. It is also possible that adolescents are less likely to endorse risk in the setting of a well-child visit because of concerns about confidentiality. Our research with this tool in a school-based clinic setting demonstrated significantly higher rates of youth-reported risk behaviors even after matching for age [36]. Prior research has also suggested that acute visits may be a more effective platform for risk screening among adolescents [37,38]. To increase the effective delivery of counseling, more research is needed to identify the best venues for reaching older and at-risk adolescents, including the added benefits and costs of screening at acute visits as well as screening in school-based health settings. Finally, this study was conducted among adolescents who visited primary care clinics in the Pacific Northwest and may not be generalizable to other settings.

Conclusions

Despite these limitations, this study adds to the literature regarding the use of eHealth tools in screening and preventive care for adolescents and raises important questions worthy of further study. Health risk behaviors have a significant influence on morbidity and mortality during adolescence and adulthood and guidelines recommend screening and intervention during adolescent well-care visits. Electronic screening has been repeatedly shown to increase provider identification of risk. This study further demonstrates that the addition of feedback for adolescents and results for clinicians increases clinician counseling. Electronic platforms such as these can be important tools for future research to examine the impact of components and types of preventive content to effect behavior change as well as how to reach the adolescents who would most benefit.

Acknowledgments

This research was primarily supported by the Agency for Healthcare Research and Quality (AHRQ 5R01HS023383; principal investigator: CM). The granting agency that supported this research approved the study design and received periodic updates on data collection but was not involved in the analysis of the data, the decision to submit a manuscript, or in the writing of the manuscript itself. Additional support was provided by the Health Resources and Services Administration of the US Department of Health and Human Services under cooperative agreement UA6MC27378, Adolescent and Young Adult Health Research Network. LR and CM designed the study. EP and CZ conducted data analysis. EO and JK advised on the study design and reporting of results. LR and CM were responsible for the development of the feedback content in the Check Yourself version 2.0 tool with input from JK. The tool is licensed to Tickit Health [39].

Conflicts of Interest

None declared.
Multimedia Appendix 1
Check Yourself (version 2) screenshots.
[PDF File (Adobe PDF File), 771 KB - jmir_v23i3e24135_app1.pdf]

Multimedia Appendix 2
Risk behaviors included in overall summary outcome measure.
[PDF File (Adobe PDF File), 83 KB - jmir_v23i3e24135_app2.pdf]

Multimedia Appendix 3
Check Yourself app overview.
[PDF File (Adobe PDF File), 227 KB - jmir_v23i3e24135_app3.pdf]

Multimedia Appendix 4
CONSORT (Consolidated Standards of Reporting Trials) diagram.
[PDF File (Adobe PDF File), 18 KB - jmir_v23i3e24135_app4.pdf]

References


38. Tickit Health. URL: https://tickithealth.com/ [accessed 2021-03-06]
Abbreviations

**aRR:** adjusted rate ratio  
**MICE:** multiple imputation with chained equations
Risk Factors and Leadership in a Digitalized Working World and Their Effects on Employees’ Stress and Resources: Web-Based Questionnaire Study

Anita Bregenzer¹, PhD; Paulino Jimenez¹, PhD
Institute of Psychology, University of Graz, Graz, Austria

Corresponding Author:
Paulino Jimenez, PhD
Institute of Psychology
University of Graz
Universitätsplatz 2
Graz, 8010
Austria
Phone: 43 316380 ext 5128
Email: paul.jimenez@uni-graz.at

Abstract

Background: In today’s world of work, the digitalization of work and communication processes is increasing, and will increase even further. This increase in digitalization at the workplace brings many new aspects of working life to light, such as working in virtual teams, mobile working, expectations of being constantly available, and the need for support in adapting and learning new digital tools. These changes to the workplace can contain risks that might harm the well-being of employees. Leaders can support the well-being of their employees in terms of protecting and replenishing their work-related resources to cope with critical work demands. This so-called health-promoting leadership could serve as a buffer between risk at the workplace and critical outcomes, such as stress, by amplifying work-related resources.

Objective: This study’s aims were twofold. First, we wanted to investigate if risk factors related to higher digitalization at the workplace can be identified and if these risk factors have an impairing effect on the well-being of employees (eg, higher stress and lower resources). Second, we wanted to investigate if the health-impairing effects of these risk factors can be reduced by health-promoting leadership.

Methods: A total of 1412 employees from Austria, Germany, and Switzerland took part in this online study and provided information on their perceived risks at the workplace, their leaders’ health-promoting behaviors, and their work-related stress and resources.

Results: The results of a hierarchical regression analysis showed that all four risk factors of digital work (distributed team work, mobile work, constant availability, and inefficient technical support) were related to higher stress at the workplace. In addition, distributed team work and inefficient technical support were associated with lower work-related resources. A possible buffer effect of health-promoting leadership between these risks and employee well-being was visible for inefficient technical support. In particular, in the case of having fewer support opportunities in learning and using digital tools, leaders could weaken the potential critical effects on stress. As for the other risk factors, leaders might engage in a different leadership behavior to improve their employees’ well-being, as the physical distance between leaders and employees in virtual team work or mobile work could make health-promoting leadership more difficult.

Conclusions: In a digitalized working world, solutions are needed to create working conditions that benefit employees. The results of this study strongly support the importance of investigating risk factors associated with an increase in digitalization at the workplace in addition to traditional risk factors. As for leadership, leaders need to show leadership behavior adapted to a digitalized workplace in order to reduce employee stress and increase work-related resources.

(J Med Internet Res 2021;23(3):e24906) doi:10.2196/24906

KEYWORDS
digitalization; leadership; new ways of working; resources; stress
Introduction

Background

In the past years, the digitalization of the workplace has been studied more as a phenomenon relevant to a small number of people than as an important and necessary step to improve the working world. Digitalization is currently affecting many areas and will continue to do so in the future, so the effects of digitalization in the workplace must be studied more closely in relation to work processes within the company and in relation to the well-being and performance of employees. Digitalized work brings many new aspects of working life to light, such as working in virtual teams, mobile working, blur between leisure and work, expectations of constant availability, and the frequent need to adapt to digital changes and learn new digital tools [1,2]. Organizations must be able to react adequately to these changes in order to minimize possible critical effects at individual and team levels (eg, stress, engagement, and performance). Owing to the speed at which digitalization is entering the current world of work, solutions are needed just as quickly, as organizations then can prepare their employees optimally for the newly emerging forms of work.

The topic of digitalization of the working world is currently experiencing an upswing in scientific research, especially under the term “new ways of working” (NWW). NWW describes changes to the workplace that take place in the following four aspects: physical workplace, information and communication technology (ICT), organization and management, and work culture [3]. For example, an important aspect of NWW is having more flexibility in deciding when and where employees can work, as well as using ICTs, such as email, smartphones, and videoconferences. It is expected that those aspects should lead to more efficient work processes [4]. Research in this area has focused strongly on the positive effects of new working forms on employees, such as higher engagement and performance [5,6]. However, there is evidence that these new forms of work also have critical effects on employees, such as fatigue and exhaustion [4,7].

Research in this area is important to highlight the risks of a nonoptimal design of a digitalized workplace. However, there is currently a lack of information on how the company and its employees can benefit optimally from increased digitalization of the workplace. One solution to improve working conditions for employees is leadership. Leaders can change their employees’ working conditions and thus impact their employees’ health by managing and allocating resources at the workplace [8]. More specifically, the concept of health-promoting leadership includes leadership behaviors that aim at providing resourceful working conditions for employees [9]. This in turn can reduce the negative consequences of critical working conditions such as stress [10]. Leaders can increase resources at the workplace, for example, by specifically supporting the community within the team or by giving their employees possibilities to participate in important decisions.

This study’s aims were twofold. First, we wanted to investigate if risk factors related to a higher digitalization at the workplace can be identified. With the term “risk factors,” we mainly followed the definition of mental risk factors (according to ISO 10075 [11]), which can have an impairing effect on the well-being of employees (eg, higher stress and lower resources). Second, we wanted to investigate if health-promoting leadership moderates the relationship between risk factors of digitalization at the workplace and employees’ stress and resources. More specifically, it is of interest if the health-impairing effects of certain risk factors can be reduced by health-promoting leadership. To our knowledge, the role of health-promoting leadership in workplaces with increasing digitalization has not yet been addressed directly in research.

Digital Working World and Effects on Employee Well-Being

The working environment is an important context factor at the workplace that affects the health of employees. Being exposed to a critical working environment with high risks might result in negative psychological states that can negatively affect the individual’s behavior at work [12]. These risks can be associated with the physical environment, the organizational and social environment, or the task itself [11,13]. The aim is to design the workplace in such a way that risk factors are minimized or at least the impairing health effect of these risk factors is reduced with specific interventions. However, the traditional working environment has changed through the application of ICT, and “new” working forms have emerged, such as virtual teams and mobile telework [14,15]. These changes are accompanied by new risks in the workplace, and the potential harmful effects on employee well-being have to be examined more closely.

Research in the field of NWW seems to highlight the positive aspects of a digitalized workplace. ten Brummelhuis et al [4] defined NWW as “...a work design in which employees can control the timing and place of their work, while being supported by electronic communication.” Indeed, research shows that when employees experience more freedom in managing one’s own time (ie, home office), the work is experienced as less stressful for employees [16]. However, NWW can also impact the employee’s well-being negatively, such as having more blurred work-home boundaries, more fatigue, and higher mental demands [7]. Research also indicates that NWW might decrease resources such as autonomy. In a study conducted by van Steenbergen et al [16], employees worked in an organization where they could choose to work at home or at the office. However, the organization seemed to prefer work from home, and this preference for a home office might have been expressed by the company in such a strong way that employees experienced a lower feeling of autonomy.

These findings show that positive effects of NWW should not be expected automatically. On the contrary, NWW might include risks that could lead to harmful effects such as higher employee stress [7]. In a systematic review, the authors outlined the positive and negative aspects of NWW with ICT-enabled workers who were flexible in their work [7]. They found that factors, such as geographically distributed team work (“virtual teams”), time- and location-independent work (“mobile working”), and use of information technology at work, might have negative psychological impacts on the well-being of employees and should be addressed when NWW is
implemented. Distributed teamwork or mobile work and increased digital communication are also related to a feeling of having to be constantly available, which can also have a negative impact on well-being [1]. Other factors related to NWW, such as higher flexibility, access to organizational knowledge, and independent management of output, are mostly positive factors that benefit the well-being of employees [7]. However, research should focus more on risks to help organizations adequately address these risks at the workplace. The dimensions of NWW that include possible risks and their relationship with the stress of employees are described in detail below.

**Geographically Distributed Team Work**

Geographically distributed team work (referred to as “distributed team work” henceforth) has already been extensively investigated in the past under the term “virtual teams” [14]. In virtual teams, “…teams work together over time and distance via electronic media to combine effort and achieve common goals” [17]. Distributed team work has advantages as well as disadvantages. The advantages include reduced travel time and costs, being independent from time and place, including physically disadvantaged employees in the team, and working in a diverse heterogeneous team [18]. However, the disadvantages have been studied in more detail. Owing to the geographical distance of team members, it is difficult to form group cohesion, which is why communication is less frequent and conflicts can occur more often than in face-to-face teams [19,20]. Furthermore, with the use of virtual media, important auditory and visual cues are not perceived sufficiently, which makes communication more difficult [21].

The critical effects of distributed team work on employees’ stress have already been studied [22,23]. For example, virtual teams have more conflicts than traditional face-to-face teams and have difficulties in applying conflict management strategies [21]. More conflicts within the team result in more stress [24]. Stress can occur because of the excessive use of virtual communication media as well (e.g., email flood [23]).

**Mobile Work**

The use of mobile devices allows employees to work in a distributed team and to work independent of time and location, because messages can now be sent and received from anywhere and at any time. Thus, high flexibility in the daily work routine can be achieved [25]. Work can be done from one’s own home, from an external location, or from another continent. For this kind of work, the term “mobile telework” is commonly used in the literature, which is described as “work at a range of locations, spending regular and significant amount of time away from any office or home location” [26].

Mobile telework can differ from one job to another. There are jobs in which the place of work changes several times a week or day and employees cannot freely choose the work location, for example, work in sectors such as wholesale and retail trade, manufacturing, transportation and storage, information and communication, public administration, and health [27]. The effect of mobile telework on employee well-being can be quite different for those who have control over their working location as compared to that for those who have little say in where they must work [28].

Mobile telework is seen as a resource, especially when you can decide yourself where and when you work [29,30]. However, the physical distance between team members and leaders can reduce the quality of the relationship between employees and leaders [31]. Mobile telework is particularly demanding when the work location is uncertain or when the employees have less flexibility in organizing their work time [32]. Interruptions and distractions can occur more easily in mobile telework than in fixed workplaces (such as offices); for example, interruptions and distractions are more frequent in trains or in public places [32]. In addition, working at multiple locations increases mental demands, such as the feeling of “timeless” continuous work, constant changing of the rhythm of work, and reduced professional and social interaction [15].

**Constant Availability**

The use of ICT makes it easier to stay in touch with leaders, colleagues, customers, and family, as contact can now be made anywhere and at any time. This leads to the impression that people are available anywhere and at any time, which can have critical effects on employees’ well-being [33,34].

The expectation of having to be constantly available for work leads to difficulties detaching from work during leisure time and to a stronger work-home interference [35,36]. Especially when the experienced work-home interference is high, using the smartphone for work-related purposes after work has a critical effect on employees’ recovery process [37]. A longitudinal study showed that being constantly available for work increases emotional exhaustion over time [38]. Constantly receiving and checking work-related messages might lead to information overload, as people struggle with managing the inflow of messages [39]. This struggle to keep up with the increasing amount of information leads to higher stress [40,41].

On the contrary, being constantly available can have benefits for employees’ well-being. In a study conducted by ten Brummelhuis et al [4], being constantly available through the use of mobile communication tools was associated with greater engagement. The authors argued that constant availability via email or telephone was associated with greater work flexibility, engagement. The authors argued that constant availability via email or telephone was associated with greater use of mobile communication tools was associated with greater engagement. The authors argued that constant availability via email or telephone was associated with greater work flexibility, engagement.

**Learning and Adapting to Digital Tools**

The constant use of ICT for work-related activities raises another point that could be a risk factor for employees’ well-being. In today’s working world, new technologies are developed almost faster than people can learn and use them. The increasing amount and use of ICTs can lead to higher job demands in terms of mental and emotional overload, which might harm the well-being of employees [42]. Thus, the need for support in the use of digital tools and the need to build up competence in handling digital media are growing [43]. In the past, the increasing requirements to be able to handle digital tools were also investigated under the term “technostress.” Technostress...
is described as the mental stress that employees experience when they are asked to learn and use a new technology [44]. Weil and Rosen [44] found that technostress occurs if people are not taught how to handle technology adequately. Uncertainty about how to deal with new technology and the resulting inefficiency in dealing with modern technologies are currently still important issues in technostress research [45].

If the used technologies change too fast, employees experience difficulties in coping with the changes, which can raise work overload and stress [46]. On the contrary, adapting to new technologies at work might benefit the employees as well. Studies show that having a higher technological demand at work is related to engagement, indicating that learning new technological tools is perceived as challenging [47].

To ensure that technical changes in the workplace are experienced as positive challenges and not as hindrances, it is important that employees are adequately supported in learning and applying these technologies. For example, providing training or guidelines on how to deal with new media and having technical support at work are important for greater well-being at the workplace [48,49]. Social support from supervisors or colleagues is an important factor as well [42]. In the study by Knani et al [50], employees were introduced to a new technology at the workplace, which demanded high learning effort and led to higher emotional exhaustion. The critical effect on emotional exhaustion could reduce when employees experience high support from supervisors and employees. Atanasoff and Venable [51] added that employee-oriented leadership behavior is an important resource that might reduce the negative effects of digitalization, such as stress.

**Digital Workplaces, Leadership, and Resources**

Leaders in particular are challenged in a modern working environment. Research in the field of a home office and virtual teams has shown that leadership in a digitalized working environment has different requirements than in traditional work settings [52]. Working in a home office or virtual work in general requires a different role of leadership, in which the manager must lead strongly in an employee-oriented way [53]. An employee-oriented leadership is also preferred in working environments with high demands. According to Wegge et al [54], leader behavior can serve as a buffer between high work demands and critical outcomes, such as stress, by amplifying work-related resources at the workplace. Given the assumption that digitalized workplaces entail high demands, increasing work-related resources through leadership behavior is a particularly important aspect of supporting well-being in the workplace.

Work-related resources play a major role in the relationship between demands and stress [55]. Social resources (social support from colleagues) and task resources (autonomy, the possibility of participation, and the possibility of conducting breaks) are important work-related resources to reduce negative outcomes, such as stress and burnout. A highly digitalized workplace can contain risk factors that might lead to increased demands [46]. In workplaces with high demands, resources could be insufficiently gained, depleted, or even lost, which can cause stress and might increase the risk of getting burnout over time [56].

Maintaining and increasing work-related resources are therefore essential aspects of a health-promoting workplace. Leaders can support their employees in protecting and replenishing their work-related resources to cope with the demands of their work by showing health-promoting leadership behavior [57,58]. Health-promoting leadership is a positive leadership behavior, which enhances the work-related resources of employees. By changing working conditions (such as the health-promoting design of the six areas of work life [59]), it is possible to build up employees’ work-related resources [60]. For example, leaders can ensure that work processes are organized in such a way that employees can cope well with increased workload. Leaders can give their employees opportunities to work autonomously and independently. Rewarding employees is also an essential aspect that can be undertaken by leaders in the form of positive feedback and appreciation. Leaders can strengthen the community in their team by encouraging open communication and mutual support. Acting fairly and paying attention to the values of employees are further aspects of health-promoting leadership [60].

Increasing work-related resources is also essential for a workplace with a high level of digitalization. Atanasoff and Venable [51] assumed that stress due to digitalization is related to lower work-related resources. According to the authors, important resources that should be increased are social support from colleagues, opportunities to participate in the use of technology, and clear information about technology. Therefore, health-promoting leadership could benefit a digitalized workplace as resources are preserved and restored.

The increasing digitalization of workplaces leads to changes in working conditions, which can be risk factors for reduced well-being and performance. Health-promoting leadership can minimize the negative effects of these risk factors by building up enough work-related resources to cope with these risk factors. This way of leadership behavior is described as the “buffer effect,” which means leaders serve as a buffer against high work demands that might be a potential source for stress [54].

**Study Aims and Hypotheses**

In this study, we investigated the following four possible risk factors that digital work could lead to higher stress and lower work-related resources among employees: distributed team work, mobile work, constant availability, and inefficient technical support. First, these four risk factors were examined with regard to their effects on the stress and work-related resources of employees. Second, a possible buffer effect of health-promoting leadership on the relationship of these risk factors with stress and work-related resources was analyzed. This will deepen the understanding of the importance of health-promoting leadership for digitalized workplaces and give an answer to the question of whether leadership behavior can reduce the potential harmful effects of risk factors in digitalized workplaces.

The following four hypotheses are proposed: (1) H1, risk factors in digital work (distributed team work, mobile work, constant availability, and inefficient technical support) are important work-related resources to reduce negative outcomes, such as stress and burnout. A highly digitalized workplace can contain risk factors that might lead to increased demands [46]. In workplaces with high demands, resources could be insufficiently gained, depleted, or even lost, which can cause stress and might increase the risk of getting burnout over time [56].

Maintaining and increasing work-related resources are therefore essential aspects of a health-promoting workplace. Leaders can support their employees in protecting and replenishing their work-related resources to cope with the demands of their work by showing health-promoting leadership behavior [57,58]. Health-promoting leadership is a positive leadership behavior, which enhances the work-related resources of employees. By changing working conditions (such as the health-promoting design of the six areas of work life [59]), it is possible to build up employees’ work-related resources [60]. For example, leaders can ensure that work processes are organized in such a way that employees can cope well with increased workload. Leaders can give their employees opportunities to work autonomously and independently. Rewarding employees is also an essential aspect that can be undertaken by leaders in the form of positive feedback and appreciation. Leaders can strengthen the community in their team by encouraging open communication and mutual support. Acting fairly and paying attention to the values of employees are further aspects of health-promoting leadership [60].

Increasing work-related resources is also essential for a workplace with a high level of digitalization. Atanasoff and Venable [51] assumed that stress due to digitalization is related to lower work-related resources. According to the authors, important resources that should be increased are social support from colleagues, opportunities to participate in the use of technology, and clear information about technology. Therefore, health-promoting leadership could benefit a digitalized workplace as resources are preserved and restored.

The increasing digitalization of workplaces leads to changes in working conditions, which can be risk factors for reduced well-being and performance. Health-promoting leadership can minimize the negative effects of these risk factors by building up enough work-related resources to cope with these risk factors. This way of leadership behavior is described as the “buffer effect,” which means leaders serve as a buffer against high work demands that might be a potential source for stress [54].

**Study Aims and Hypotheses**

In this study, we investigated the following four possible risk factors of digital work that could lead to higher stress and lower work-related resources among employees: distributed team work, mobile work, constant availability, and inefficient technical support. First, these four risk factors were examined with regard to their effects on the stress and work-related resources of employees. Second, a possible buffer effect of health-promoting leadership on the relationship of these risk factors with stress and work-related resources was analyzed. This will deepen the understanding of the importance of health-promoting leadership for digitalized workplaces and give an answer to the question of whether leadership behavior can reduce the potential harmful effects of risk factors in digitalized workplaces.

The following four hypotheses are proposed: (1) H1, risk factors in digital work (distributed team work, mobile work, constant
availability, and inefficient technical support) positively relate to employees’ stress; (2) H2, risk factors in digital work (distributed team work, mobile work, constant availability, and inefficient technical support) negatively relate to employees’ work-related resources; (3) H3, health-promoting leadership moderates the positive relationship between the risk factors in digital work and employees’ stress (the relationship is weaker when health-promoting leadership is high); and (4) H4, health-promoting leadership moderates the negative relationship between the risk factors in digital work and employees’ work-related resources (the relationship is weaker when health-promoting leadership is high). Figure 1 summarizes the overall conceptual model of the study.

Figure 1. Overall conceptual model of the study.

Methods

Participants and Procedures

The study was conducted as an online study with online questionnaires via the online survey platform Questback. The invitation for the online study was sent out in cooperation with a well-known German market research company. The participants of the study were recruited from the company’s online panel. To obtain a heterogeneous sample, we set the target male-to-female ratio at about 50:50. The same ratio was used for age (50% for <40 years and 50% for ≥40 years). As the online survey was in German, only German-speaking people were considered for recruitment (ie, persons from Germany, Austria, and Switzerland). The market research company contacted people in the online panel according to these specifications via email. The only criterion for participation in the study was work for at least 10 hours per week. If individuals stated in the questionnaire that they were working less than 10 hours per week, they were filtered out, and on the next page of the questionnaire, they were told that unfortunately they did not belong to the target group. The survey was then closed for this group.

On the first page of the survey, participants were informed about the purpose of the study, the length of the study, and the contact address of the research group. Participation was voluntary, and a small incentive was offered to people who completed all online questions.

Through this procedure, a representative sample of 1412 German-speaking workers in Austria (n=481, 34.06%), Germany (n=720, 50.99%), and Switzerland (n=211, 14.94%), who filled in all online questionnaires, was obtained. In this sample, 56.94% (804/1412) were women and 43.06% (608/1412) were men. The mean age was 41 years (mean 40.77 years, SD 12.30 years). Additionally, 24.36% (344/1412) had a graduate degree. On average, the participants worked 35 hours per week (mean 35.07 hours, SD 11.58 hours).

The participants worked in different business sectors. The majority worked in the service sector (257/1412, 18.20%), followed by health care (192/1412, 13.60%), commerce (167/1412, 11.83%), manufacturing (136/1412, 9.63%), and the public sector (127/1412, 8.99%).

Measures

Risks in Digital Work Scale

In the risks in digital work scale, 10 items measure different work characteristics in a digitalized workplace that could increase demands at the workplace for the following: (1) distributed team work, (2) mobile work, (3) constant availability, and (4) inefficient technical support. The items are written as statements and refer to the last 4 weeks (“How many times have you experienced the following aspects in the last 4 weeks?”). The 7-point scale ranges from 0 (never) to 6 (always). Example items for the four dimensions are shown in Table 1.
Table 1. Example items for the risks in digital work scale.

<table>
<thead>
<tr>
<th>Construct/scale</th>
<th>Sample item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributed team work</td>
<td>My colleagues at other locations and I support each other (reversed).</td>
</tr>
<tr>
<td>Mobile work</td>
<td>Within a day, my work location changed.</td>
</tr>
<tr>
<td>Constant availability</td>
<td>I was available for work in my free time (eg, by telephone or email).</td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>I received support in case of uncertainties in the technical operation of devices, software, and others (reversed).</td>
</tr>
</tbody>
</table>

**Health-Promoting Leadership**

Health-promoting leadership was measured with the health-promoting leadership conditions questionnaire (HPLC) [9], where employees are able to evaluate the frequency of health-promoting leadership from their direct supervisor during the last 4 weeks. In this study, a short version with seven items was used, where each item can be related to one of the following seven aspects of health-promoting leadership: health awareness, workload, control, reward, community, fairness, and value fit. The items are rated on a 7-point scale ranging from 0 (never) to 6 (always). One example item for the dimension community is “In the last 4 weeks, my leader took care that…work is appreciated.”

**Stress and Resources**

The Recovery-Stress Questionnaire for Work (RESTQ-Work) [61] assesses the stress state and experienced resources in the past 7 days/ nights. In this study, the short version of the RESTQ-Work (RESTQ-Work-27) with 27 items was used. The items can be assigned to a stress or resource score. The stress score consists of 10 items, and the resource score consists of 17 items. The answer scale is a 7-point scale ranging from 0 (never) to 6 (always). One example item for the stress score is “In the past 7 days/ nights…I felt frustrated through my work,” and one example item for the resource score is “In the past 7 days/ nights…I had the chance to make suggestions at work.”

**Statistical Analyses**

The analyses consist of two parts. First, bivariate correlations showed the relationships between all study variables. Second, a hierarchical regression analysis was used to test the hypotheses regarding the moderator effects of health-promoting leadership on the outcomes of stress and work-related resources. To test the moderating effects of health-promoting leadership, interaction terms between health-promoting leadership and all four risks in digital work variables were computed. Before computing the interaction terms, the variables were mean centered (ie, \( z \) standardized). For the analyses, SPSS 26.0 (IBM Corp) was used.

**Results**

**Descriptive Statistics**

Descriptive statistics (means and standard deviations) and reliabilities (Cronbach \( \alpha \)) of the study variables are shown in Table 2. Correlations of all study variables are shown in Table 3.

Table 2. Descriptive statistics and reliabilities of the study variables.

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Score, mean (SD)</th>
<th>( \alpha )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributed team work</td>
<td>2.44 (1.53)</td>
<td>.60</td>
</tr>
<tr>
<td>Mobile work</td>
<td>1.06 (1.19)</td>
<td>.62</td>
</tr>
<tr>
<td>Constant availability</td>
<td>2.19 (1.80)</td>
<td>.71</td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>2.43 (1.66)</td>
<td>.85</td>
</tr>
<tr>
<td>Health-promoting leadership</td>
<td>2.99 (1.59)</td>
<td>.93</td>
</tr>
<tr>
<td>Work-related resources</td>
<td>3.24 (1.04)</td>
<td>.92</td>
</tr>
<tr>
<td>Stress</td>
<td>2.01 (1.30)</td>
<td>.93</td>
</tr>
</tbody>
</table>
Table 3. Correlations between all study variables (N=1412).

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Distributed team work</th>
<th>Mobile work</th>
<th>Constant availability</th>
<th>Inefficient technical support</th>
<th>Health-promoting leadership</th>
<th>Work-related resources</th>
<th>Stress</th>
</tr>
</thead>
<tbody>
<tr>
<td>r</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work-related resources</td>
<td>1</td>
<td>0.10</td>
<td>−0.13</td>
<td>0.58</td>
<td>−0.52</td>
<td>−0.56</td>
<td>0.28</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mobile work</td>
<td>0.10</td>
<td>1</td>
<td>0.29</td>
<td>0.16</td>
<td>−0.09</td>
<td>−0.10</td>
<td>0.22</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
</tr>
<tr>
<td>Constant availability</td>
<td>−0.13</td>
<td>0.29</td>
<td>1</td>
<td>−0.10</td>
<td>0.11</td>
<td>0.12</td>
<td>0.08</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>0.58</td>
<td>0.16</td>
<td>−0.10</td>
<td>1</td>
<td>−0.51</td>
<td>−0.50</td>
<td>0.26</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
</tr>
<tr>
<td>Health-promoting leadership</td>
<td>−0.52</td>
<td>−0.09</td>
<td>0.11</td>
<td>−0.51</td>
<td>1</td>
<td>0.66</td>
<td>−0.38</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
</tr>
<tr>
<td>Work-related resources</td>
<td>−0.56</td>
<td>−0.10</td>
<td>0.12</td>
<td>−0.50</td>
<td>0.66</td>
<td>1</td>
<td>−0.43</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
</tr>
<tr>
<td>Stress</td>
<td>0.28</td>
<td>0.22</td>
<td>0.08</td>
<td>0.26</td>
<td>−0.38</td>
<td>−0.43</td>
<td>1</td>
</tr>
<tr>
<td>P value</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
<td>__a</td>
</tr>
</tbody>
</table>

*Not applicable.

**Regression Analyses**

To test our hypotheses, two step-wise regression analyses were conducted where stress and work-related resources served as the outcomes and the risk factors of digital work and health-promoting leadership served as the predictor variables. In the first step, the risk factors of digital work, including distributed team work, mobile work, constant availability, and inefficient technical support, were entered. In the consecutive second step, health-promoting leadership was entered as the moderator variable. In the third and final step, the interaction terms of the moderating variable health-promoting leadership with the four risk factors were entered. To test if multicollinearity was an issue in our data, we tested the variance inflation factor for all independent variables. All variance inflation factors were below 3 (ranging from 1.02 to 1.70). Thus, multicollinearity was not an issue in our study.

**Regression Analysis With the Outcome Stress**

Table 4 summarizes the regression results for the criterion stress and shows that distributed team work, mobile work, constant availability, and inefficient technical support accounted for 13% of the variance in stress. Distributed team work ($\beta=.19, P<.001$), mobile work ($\beta=.15, P<.001$), constant availability ($\beta=.08, P=.003$), and inefficient technical support ($\beta=.13, P<.001$) showed significant relationships with stress.

In the second step, health-promoting leadership accounted for an additional 6% of the variance in stress. The relationship with stress was negative ($\beta=-.31, P<.001$), indicating that high health-promoting leadership is associated with low stress.

In the third and final step, the interaction terms of the moderating variables were entered. The two interaction terms mobile work*health-promoting leadership ($\beta=.11, P<.001$) and inefficient technical support*health-promoting leadership ($\beta=.07, P=.03$) were significant. The results did not show a moderating effect of health-promoting leadership for the predictors distributed team work and constant availability. This step accounted for an additional 2% of the variance in stress.
Table 4. Results of hierarchical multiple regression analyses for the criterion stress ($R^2=20.7\%$).

<table>
<thead>
<tr>
<th>Step and variable</th>
<th>Stress results$^a$</th>
<th>B</th>
<th>SE B</th>
<th>β</th>
<th>P value</th>
<th>t (df)$^b$</th>
<th>F (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work</td>
<td>0.25</td>
<td>0.04</td>
<td>.19</td>
<td>&lt;.001</td>
<td>6.32 (1407)</td>
<td>50.880 (4,1407)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Mobile work</td>
<td>0.21</td>
<td>0.04</td>
<td>.15</td>
<td>&lt;.001</td>
<td>5.74 (1407)</td>
<td>65.673 (5,1406)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Constant availability</td>
<td>0.11</td>
<td>0.04</td>
<td>.08</td>
<td>&lt;.001</td>
<td>2.94 (1407)</td>
<td>3.01 (1406)</td>
<td>.003</td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>0.17</td>
<td>0.04</td>
<td>.13</td>
<td>&lt;.001</td>
<td>4.17 (1407)</td>
<td>0.03 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work</td>
<td>0.12</td>
<td>0.04</td>
<td>.09</td>
<td>.003</td>
<td>3.01 (1406)</td>
<td>1.03 (1406)</td>
<td>.004</td>
<td></td>
</tr>
<tr>
<td>Mobile work</td>
<td>0.20</td>
<td>0.04</td>
<td>.15</td>
<td>&lt;.001</td>
<td>5.67 (1406)</td>
<td>0.03 (1402)</td>
<td>.001</td>
<td></td>
</tr>
<tr>
<td>Constant availability</td>
<td>0.12</td>
<td>0.03</td>
<td>.09</td>
<td>&lt;.001</td>
<td>3.56 (1406)</td>
<td>0.30 (1402)</td>
<td>.004</td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>0.04</td>
<td>0.04</td>
<td>.03</td>
<td>.30</td>
<td>1.03 (1406)</td>
<td>−0.40 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Health-promoting leadership</td>
<td>0.04</td>
<td>0.04</td>
<td>−.31</td>
<td>&lt;.001</td>
<td>−10.45 (1406)</td>
<td>−0.35 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work</td>
<td>0.12</td>
<td>0.04</td>
<td>.09</td>
<td>.003</td>
<td>3.02 (1402)</td>
<td>1.03 (1402)</td>
<td>.004</td>
<td></td>
</tr>
<tr>
<td>Mobile work</td>
<td>0.21</td>
<td>0.04</td>
<td>.15</td>
<td>&lt;.001</td>
<td>5.87 (1402)</td>
<td>0.03 (1402)</td>
<td>.001</td>
<td></td>
</tr>
<tr>
<td>Constant availability</td>
<td>0.11</td>
<td>0.03</td>
<td>.08</td>
<td>.001</td>
<td>3.23 (1402)</td>
<td>0.30 (1402)</td>
<td>.004</td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>0.04</td>
<td>0.04</td>
<td>.03</td>
<td>.30</td>
<td>1.03 (1402)</td>
<td>−0.05 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Health-promoting leadership</td>
<td>0.04</td>
<td>0.04</td>
<td>−.27</td>
<td>&lt;.001</td>
<td>−8.84 (1402)</td>
<td>−0.35 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Distributed team work*health-promoting leadership</td>
<td>−0.05</td>
<td>0.04</td>
<td>−.27</td>
<td>&lt;.001</td>
<td>−1.19 (1402)</td>
<td>−0.35 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Mobile work*health-promoting leadership</td>
<td>0.15</td>
<td>0.04</td>
<td>.11</td>
<td>&lt;.001</td>
<td>4.21 (1402)</td>
<td>0.15 (1402)</td>
<td>.023</td>
<td></td>
</tr>
<tr>
<td>Constant availability*health-promoting leadership</td>
<td>0.04</td>
<td>0.03</td>
<td>.03</td>
<td>.25</td>
<td>1.15 (1402)</td>
<td>0.04 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support*health-promoting leadership</td>
<td>0.08</td>
<td>0.04</td>
<td>.07</td>
<td>.03</td>
<td>2.19 (1402)</td>
<td>0.08 (1402)</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

$^a$Step 1: $\Delta R^2=12.64 (P<.001)$; Step 2: $\Delta R^2=6.30 (P<.001)$; Step 3: $\Delta R^2=1.72 (P<.001)$.

$^b$df for $t$ values were calculated with the formula N-p-1 (p=number of parameters).

**Regression Analysis With the Outcome Work-Related Resources**

The results for the criterion work-related resources showed that distributed team work, mobile work, constant availability, and inefficient technical support accounted for 37% of the variance in work-related resources (Table 5). Out of these four predictors, distributed team work ($\beta=−.40, P<.001$), constant availability ($\beta=.05, P=.02$), and inefficient technical support ($\beta=−.26, P<.001$) showed significant relationships with work-related resources. Unexpectedly, constant availability showed a low but positive relationship with work-related resources, indicating that being constantly available for work is associated with higher work-related resources. Therefore, only distributed team work and inefficient technical support were negatively related to work-related resources.

In the second step, health-promoting leadership accounted for an additional 15% of the variance in work-related resources. The relationship was positive ($\beta=.47, P<.001$), indicating that high health-promoting leadership is associated with higher employees’ work-related resources.

In the third and final step, the interaction terms of the moderating variables were entered. The one interaction term of mobile work*health-promoting leadership ($\beta=.04, P=.04$) was significant. However, the results did not show a moderating effect of health-promoting leadership for the other three predictors.
**Table 5.** Results of hierarchical multiple regression analyses for the criterion work-related resources (R²=51.3%).

<table>
<thead>
<tr>
<th>Step and variable</th>
<th>Work-related resources(^a)</th>
<th>(P) value</th>
<th>(t) (df)(^b)</th>
<th>(F) (df)</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work</td>
<td>(-0.42) 0.03 (-0.40) (&lt;.001) (-15.43) (1407)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile work</td>
<td>(-0.03) 0.03 (-0.03) .17 (-1.39) (1407)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant availability</td>
<td>0.06 0.02 (0.05) (0.02) 2.39 (1407)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>(-0.27) 0.03 (-0.26) (&lt;.001) (-9.77) (1407)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work</td>
<td>(-0.26) 0.03 (-0.25) (&lt;.001) (-10.39) (1406)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile work</td>
<td>(-0.02) 0.02 (-0.02) .31 (-1.02) (1406)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant availability</td>
<td>0.04 0.02 (0.03) (0.09) 1.72 (1406)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>(-0.11) 0.03 (-0.11) (&lt;.001) (-4.56) (1406)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health-promoting leadership</td>
<td>0.49 0.02 (0.47) (&lt;.001) 20.43 (1406)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work</td>
<td>(-0.26) 0.03 (-0.25) (&lt;.001) (-10.40) (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile work</td>
<td>(-0.01) 0.02 (-0.01) .55 (-0.60) (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant availability</td>
<td>0.04 0.02 (0.03) (0.11) 1.62 (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support</td>
<td>(-0.12) 0.03 (-0.12) (&lt;.001) (-4.79) (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health-promoting leadership</td>
<td>0.48 0.02 (0.47) (&lt;.001) 19.68 (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distributed team work(^*)health-promoting leadership</td>
<td>(-0.03) 0.02 (-0.03) .28 (-1.09) (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile work(^*)health-promoting leadership</td>
<td>0.05 0.02 (0.04) (0.04) 2.04 (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant availability(^*)health-promoting leadership</td>
<td>(-0.03) 0.02 (-0.03) .10 (-1.64) (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inefficient technical support(^*)health-promoting leadership</td>
<td>(-0.04) 0.02 (-0.04) (0.08) (-1.75) (1402)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)Step 1: \(\Delta R^2=36.72\) (\(P<.001\)); Step 2: \(\Delta R^2=14.48\) (\(P<.001\)); Step 3: \(\Delta R^2=0.43\) (\(P=.02\)).

\(^b\)df for \(t\) values were calculated with the formula N-p-1 (p=number of parameters).

**Simple Slope Analyses**

In order to investigate the interaction effects, simple slope analyses were conducted for the significant interaction effects (Figures 2-4). The slopes indicated that employees with high health-promoting leadership experienced less stress than employees with low health-promoting leadership. However, employees with high mobile work did not seem to benefit much from health-promoting leadership, as employees with high mobile work and with high health-promoting leadership seemed to have a similar stress level as that in employees with low health-promoting leadership (Figure 2).

As for the risk factor inefficient technical support, having inefficient technical support was related to higher employee stress. Having high health-promoting leadership could buffer this negative relationship, as the stress level of these employees was lower compared to that in employees with low health-promoting leadership (Figure 3).

As for work-related resources, employees with high health-promoting leadership experienced more resources at the workplace than employees with low health-promoting leadership. In terms of low health-promoting leadership, work-related resources were the lowest in the group of employees with high mobile work (Figure 4).
Figure 2. Effect of a two-way interaction between mobile work and health-promoting leadership on stress. prom.: promoting.

![Graph showing the effect of mobile work and health-promoting leadership on stress.](image1)

Figure 3. Effect of a two-way interaction between inefficient technical support and health-promoting leadership on stress. prom.: promoting.

![Graph showing the effect of inefficient technical support and health-promoting leadership on stress.](image2)
Discussion

Principal Results

Risk Factors of Digital Work

This study explored the relationships between four risk factors of digital work (distributed team work, mobile work, constant availability, and inefficient technical support) and employees’ stress and work-related resources. In addition, the potential role of health-promoting leadership in reducing the critical effects of digital work was investigated.

The results showed that all four risk factors of digital work (distributed team work, mobile work, constant availability, and inefficient technical support) were related to higher employee stress. In addition, distributed team work and inefficient technical support were associated with lower work-related resources.

This is in line with previous literature on digital workplaces. Distributed team work (or in other words, virtual team work) can lead to higher stress, since team collaboration and team support are difficult in teams with low face-to-face contact [20]. This might be the reason for experiencing higher stress and lower resources in this kind of teamwork, such as lower participation and decision possibilities and lower social support. Inefficient technical support, such as receiving low support in learning and using digital tools, is a critical factor as well, which has potential harmful effects on employees’ well-being. Support options, such as training, peer assistance, and efficient support from the technical department if available, are factors that are relatively easy to implement in the organization and can reduce the critical effects on stress and resources.

The results for the risk factor mobile work showed a positive relationship with stress, which is consistent with previous literature. It has been shown that working in multiple locations increases mental demands, such as more interruptions or distractions, increased feeling of “timeless” continuous work, and constant changing of the rhythm of work [15,32]. However, an effect on work-related resources could not be found in this study. This means that mobile work neither increases nor decreases the work-related resources of employees. Important work-related resources, such as autonomy, decision-making, and participation opportunities, as well as social contact with colleagues, do not seem to be affected by mobile work.

We expected that being constantly available for work via telephone or email would be related to higher stress and lower work-related resources. Indeed, constant availability was related to higher employee stress, indicating that the expectation of having to be constantly available for work can lead to difficulties detaching from work, which harms the well-being of employees [35,36]. Unexpectedly, being constantly available for work showed a low but positive relationship with work-related resources. Another study conducted by ten Brummelhuis et al [4] came to a similar conclusion. In their study, constant availability via email or telephone was associated with greater work flexibility, which is perceived as a resource by employees. The simultaneous perception of increased resources and increased stress at the workplace seems implausible at first, but is actually not a contradiction. In the view of Kallus [62], increased stress and increased work-related resources can occur simultaneously. This seems to be the case with our findings in this study. Being constantly available increases stress, as employees might have difficulties detaching from work. At the same time, employees might experience higher flexibility, which is also associated with work-related resources such as higher autonomy.

However, chronic stress might tax the employees’ resources to the extent that resources are damaged and lost to the point where they cannot be activated anymore [56]. Employees and organizations must therefore always pay attention to a balance between stress and resources. The relationships between constant availability and both outcomes were small though. Further
studies are needed to deepen the understanding of the possible critical and beneficial effects of constant availability.

**Health-Promoting Leadership**

Increasing digitalization of the workplace should support employees in their work tasks and not additionally burden them. Leaders play a key role in ensuring that work is designed in a health-promoting way [9]. In this study, we investigated if leaders engaging in health-promoting leadership could act as a buffer between the risks emerging from digital work and critical outcomes of employee well-being.

The results showed interaction effects between mobile work and health-promoting leadership, as well as between inefficient technical support and health-promoting leadership. As for the first interaction effect, the analysis revealed that the combination of low mobile work and high health-promoting leadership was related to low employee stress. This means that having a work location that usually does not change during the week and having a health-promoting leader seems to be the best condition for employee well-being. For employees with high mobile work, the beneficial effect of health-promoting leadership on stress could not be verified. It is possible that the conditions of mobile work make health-promoting leadership behavior more difficult, since the physical distance places special demands on the management and promotion of employees. Therefore, health-promoting leadership cannot buffer the critical effect on stress anymore, as leaders are far away most of the time.

Interestingly, mobile work did not increase or decrease the work-related resources of employees. A potential buffer effect of health-promoting leadership could not be verified. An explanation could be that mobile work itself is perceived as a resource by involving higher autonomy and more decision-making and participation opportunities. Physical distance can also be an obstacle for leaders to build up work-related resources [63].

Further, the results showed an interaction effect between health-promoting leadership and inefficient technical support. Experiencing high support in using digital tools and being led in a health-promoting way seems to be the best combination for employees in regard to stress. With a health-promoting leader and at the same time fewer support opportunities in learning and using digital tools, the stress of employees is high but still below that of employees with low health-promoting leadership.

In other words, in the case of experiencing hindrances in learning and using digital tools, leaders can weaken the potential critical effects on stress. This is in line with previous findings, where high support from supervisors helped employees to cope with using new technology at the workplace, which demands high learning effort [42, 50].

**Theoretical Implications**

Mental risk factors in the workplace that lead to mental stress must be carefully evaluated in each workplace according to international norms like ISO 45001 [64] and especially European laws (eg, the Framework Directive 89/391/EEC [65] and the European Framework for Psychosocial Risk Management, PRIMA-EF [66]). In this study, we were able to show that risk factors in a digitalized work environment must be considered in addition to the commonly evaluated risk factors. Currently, the so-called risk assessment focuses strongly on the following areas: the physical environment, the organizational and social environment, and the task itself (ISO 10075-1 [11]). This study presents the following four possible risk factors that could be included in addition to the aforementioned areas: distributed team work, mobile work, constant availability, and inefficient technical support. We strongly suggest including these risks in current theoretical concepts about risk assessment at the workplace.

In research regarding NWW, possible negative effects of new forms of working are already considered [7]. However, research regarding the positive aspects of NWW still outweighs research regarding the negative effects. Although the advantages of NWW are obvious, such as being flexible regarding working time and location and having higher work-family balance, negative effects are possible if the working conditions are not optimally designed. The results of this study showed that a more critical view of the effects of NWW should be included in research.

In this study, we assumed that leaders who lead in a health-promoting way act as a buffer between work-related demands and employee well-being [54]. The results showed that this buffer effect was visible for one of the four risk factors (inefficient technical support). Although stress among employees increases if they receive little support, explanation, and information when using digital tools, the increase is not as strong if leaders lead in a health-promoting way. For the other three risk factors (distributed team work, mobile work, and constant availability), the results did not indicate a buffer effect.

Employees experience the best working conditions when workplaces have low risks and when health-promoting leadership is high. In a digitalized working world with special risks, such as virtual teamwork, mobile working, and constant availability, it seems that leaders need to show leadership behavior adapted to these working conditions in order to reduce employee stress and increase work-related resources. Research is yet to define such a leadership model that is best suited for digital workplaces. Initial approaches in the field of virtual teams exist, which could serve as a base for such a leadership model [17, 67, 68]. Nevertheless, the goal should be a broader leadership concept that goes beyond research on virtual teams.

**Practical Implications**

In order to remain competitive, many companies are switching to elements of new ways of working, such as home office, mobile work, and increased use of digital media. For successful digitalization of the working process, both the company and individual employees must adapt well to the changed working conditions. Therefore, interventions to support health-promoting digitalization of the workplace have to be developed. In a workplace where digitalization is already well advanced, it is plausible to set digital interventions. For example, the whole process of workplace health promotion can be done digitally, starting with electronic feedback tools to recognize employees’ health states and extending to creating and implementing eHealth tools [69]. The adoption of eHealth tools to promote physical and mental health is an effective way to support
employees [70-72]. Organizations can also benefit from eHealth tools by quickly receiving anonymized feedback about the well-being of their employees. In the event of critical feedback, the organization can act to avoid negative consequences, such as stress and burnout.

Leaders in particular must recognize the needs of their employees in a digitalized work environment even more strongly than in traditional work settings and adapt their leadership behavior accordingly. In addition, in the time of COVID-19, the support of leaders plays a much stronger role in reducing the stress for employees [73]. During the COVID-19 pandemic, many employees are working in home offices, and thus, solutions are needed for leaders on how employees can be optimally supported from a distance. The results of this study provide initial insights into the difficulties of leadership in a digitalized work environment. For example, our results indicate that when employees have high mobile work and therefore are locally distant from their leaders, leaders need more support to be able to lead in a health-promoting way. For this kind of work, certain aspects of digitalization can be an advantage, as digital tools can allow leaders to keep close contact with their employees, for example, by using video calls or chat.

Limitations

This study was a cross-sectional study with the data collected at one measurement point. To determine causality, longitudinal analyses are needed. It seems plausible that risk factors at the organization level affect the well-being of employees and not the other way around. However, it is possible that highly stressed employees perceive certain work characteristics more negatively and thus rate these characteristics as more demanding.

Same-source bias is a possible limitation of the study. As we asked employees to rate risk factors in the organization, we assessed the perceived risk factors from the view of employees. Health-promoting leadership was measured in a similar way.

Although most research in the field of work-related risks and work characteristics has been conducted at the individual level (at the level of employees), a multilevel view of work characteristics (eg, bringing together the rating of teams) is a more accurate measurement of risk factors in the organization.

Since we conducted the study through an online panel organization, we did not have any personal information of the participants, such as names and email addresses. Additionally, participation did not entail any obligation or dependency. As a result, we were able to reduce fears of anonymity, and therefore, we can assume that the responses were honest. Of course, there is always the effect that people want to present themselves better than how they are in reality. We cannot completely rule out the possibility that people answered questions about their work environment more critically or less critically. However, we assume that the way the study was conducted reduced this bias.

Conclusions

The results show that all four risk factors of digital work (distributed team work, mobile work, constant availability, and inefficient technical support) are related to higher stress among employees. As for a possible buffer effect of health-promoting leadership, we found that leaders can mitigate the critical effect of inefficient technical support on stress by showing health-promoting leadership behavior. However, risk factors, such as virtual team work and mobile work, might need a different leadership behavior to reduce the health-impairing effects on employee well-being. The physical distance between leaders and employees in virtual team work and in mobile work might hamper leaders in leading in a health-promoting way. Interestingly, being constantly available for work, including during leisure time, is not as much of a risk as other factors, as employees perceive more work-related resources. More research is needed to identify the conditions under which constant availability has beneficial or impairing effects on the well-being of employees.

Acknowledgments

The authors wish to thank Agnes Diebschlag, Michaela Höfer, Cornelia Hubich-Schmon, Angelika Lepold, and Martin Wefel for their support in the organization of the study “Working World D-A-CH.” This publication has financial support from the University of Graz.

Conflicts of Interest

None declared.

References


44. Weil M, Rosen L. TechnoStress: Coping with Technology @Work @Home @Play. Hoboken, NJ, USA: John Wiley & Sons Inc; 1997.


48. Weil M, Rosen L. TechnoStress: Coping with Technology @Work @Home @Play. Hoboken, NJ, USA: John Wiley & Sons Inc; 1997.


52. Weil M, Rosen L. TechnoStress: Coping with Technology @Work @Home @Play. Hoboken, NJ, USA: John Wiley & Sons Inc; 1997.


56. Weil M, Rosen L. TechnoStress: Coping with Technology @Work @Home @Play. Hoboken, NJ, USA: John Wiley & Sons Inc; 1997.


Abbreviations

ICT: information and communication technology
NWW: new ways of working
An Interactive Web-Based Sexual Health Literacy Program for Safe Sex Practice for Female Chinese University Students: Multicenter Randomized Controlled Trial

Janet Yuen-Ha Wong1*, PhD; Wen Zhang1*, MNurs; Yongda Wu1, PhD; Edmond Pui Hang Choi1, PhD; Herman Hay Ming Lo2, PhD; Wendy Wong3, PhD; Jasmine Hin Man Chio4, PhD; Hau Lin Cherry Tam5, PhD; Fei Wan Ngai6, PhD; Marie Tarrant7, PhD; Man Ping Wang5, PhD; Hextan Yuen-Sheung Ngan8, PhD; Daniel Yee-Tak Fong1, PhD

1 School of Nursing, University of Hong Kong, Hong Kong SAR, Hong Kong
2 Department of Applied Social Sciences, The Hong Kong Polytechnic University, Hong Kong SAR, Hong Kong
3 School of Chinese Medicine, The Chinese University of Hong Kong, Hong Kong SAR, Hong Kong
4 Department of Counselling and Psychology, Hong Kong Shue Yan University, Hong Kong SAR, Hong Kong
5 Department of Social and Behavioural Science, City University of Hong Kong, Hong Kong SAR, Hong Kong
6 School of Nursing, The Hong Kong Polytechnic University, Hong Kong SAR, Hong Kong
7 School of Nursing, The University of British Columbia, Vancouver, BC, Canada
8 Department of Obstetrics and Gynaecology, University of Hong Kong, Hong Kong SAR, Hong Kong

*these authors contributed equally

Corresponding Author:
Daniel Yee-Tak Fong, PhD
School of Nursing
University of Hong Kong
Pokfulam
Hong Kong SAR
Hong Kong
Phone: 852 39176645
Email: dytfong@hku.hk

Abstract

Background: Sexual health concerns among young adults worldwide help to motivate preventative practices against sexually transmitted infections. To foster better sexual health, sexual health literacy must be enhanced. Little research has been conducted on the impact of gender power dynamics on sexual health, such as sexual coercion, even though the prevalence of sexual coercion remains high in China.

Objective: This study describes the development and systematic evaluation of a web-based sexual health literacy intervention called “Smart Girlfriend” for female Chinese university students.

Methods: A multicenter randomized controlled trial was conducted with 781 female university students at 5 universities with dormitories in Hong Kong. Inclusion criteria were used to select unmarried, female, Chinese university students who were ≥18 years old and had not received a sexual health intervention in the past 12 months. Participants were randomly assigned to 2 groups: one group received an interactive web-based sexual health literacy intervention and the other group received a single webpage of online information about condom use. The intervention content was based on the Health Belief Model and the Continuum of Conflict and Control theory. The primary outcome was self-reported consistency of condom use with every partner at 3-month and 6-month follow-up assessments, analyzed using zero/one inflated beta (ZOIB) regression. The secondary outcome was an appraisal of the knowledge, attitudes, norms, and self-efficacy of condom use using the 25-item Multidimensional Condom Attitudes Scale (MCAS). The intention to treat was applied in analyses.

Results: Of 1503 individuals that were screened, 781 (52%) were randomized into 2 groups. The retention rates at the 3-month and 6-month follow-up assessments were 92% and 91%, respectively. Most participants were born locally (536/746, 72%), and 18% (134/746) self-reported as a sexual minority. ZOIB results regarding the consistency of condom use were not significant [model 1: odds ratio (OR) 2.25 with a 95% credible interval (CrI) of 0.84-6.36; model 2: OR 8.03 (95% CrI 0.22-330.31); model 3: OR 1.21 (95% CrI 0.78-1.86)]. Consistency in the intervention group was 5% higher (95% CI 1.90 to 11.63) than the control group at
the 3-month follow-up, and 1% higher (95% CI −5.81 to 8.02) at the 6-month follow-up. MCAS scores at the 3-month follow-up were significantly higher in the intervention group (mean 122.51, SD 15.97) than the control group (mean 119.86, SD 15.85; P=.02).

Conclusions: An interactive web-based sexual health literacy program did not significantly increase the consistency of condom use compared to a single webpage of condom use information; however, it did temporarily improve knowledge, attitudes, norms, and self-efficacy regarding condom use. Future revisions of this intervention should be personalized and delivered with a proactive approach.

Trial Registration: ClinicalTrials.gov NCT03695679; https://clinicaltrials.gov/ct2/show/NCT03695679

(J Med Internet Res 2021;23(3):e22564) doi:10.2196/22564

KEYWORDS
sexual health; eHealth; women's health; sex education; health literacy

Introduction

According to the World Health Organization (WHO), sexual health is a state of physical, mental, and social well-being in relation to sexuality [1]. Sexually healthy individuals have an absence of sexual or reproductive disease and a positive approach to managing respectful sexual relationships free of coercion and violence, thereby exhibiting safe sexual behaviors. Sexual health helps prevent sexually transmitted infections (STIs) and the human papillomavirus (HPV), the second leading cause of cancer deaths among women globally [2], which the WHO proposed as a key global health sector strategy for 2016-2021 [3].

Previous studies have indicated the important role of health literacy in promoting sexual health [4-6]. Health literacy is a form of empowerment to enhance individuals' capacity to access, understand, communicate, and process health information and services to make appropriate health decisions [7]. Sexual health literacy is the ability to understand preventive sexual health information to make informed choices, increase safe sex practices (eg, promoting condom use, limiting the number of sexual partners, avoiding causal sex, and enhancing sexual communication and negotiation skills with regard to sex refusal, condom use, and a partner's STI history), and reduce STI risk [4]. Low sexual health literacy is related to poor sexual health decision-making among university students, including engaging in risky sexual behaviors (such as inconsistent condom use) and delays or difficulties in seeking care [5]. Young adults might generally have good health and thus may not fully understand the importance of sexual health assessment in the absence of obvious symptoms, particularly after engaging in risky sexual behaviors [6]. Due to increasing trends of premarital sex and unsafe sexual behaviors [8], technologically advanced dating apps [9,10], and engagement in compensatory dating and casual sex [11], the risks of STIs and cervical cancer in female university students is high. Therefore, it is paramount that female university students have adequate sexual health literacy to facilitate safe sex practices, which yields better sexual health.

In this study, we operationalize sexual health literacy as individuals' capacity to understand risk information about unsafe sex practices and communicate with sexual partners to make optimal decisions and maintain sexual health. Previous sexual health literacy interventions focused on specific groups of people, such as a 50-minute face-to-face interactive class for HIV-positive people [12] and a 10-hour face-to-face intervention for jailed females to prevent cervical cancer [13]. However, few interventions targeted young females in the general population to prevent common STIs. Moreover, regarding the intervention content, it has been increasingly recognized that interventions should go beyond biophysical content, such as human development and contraception skills, by also including sociocultural content, such as respectful relationships and sexual coercion [14]. Research on effective interventions addressing sexual coercion and safe sex is limited, even though freedom from sexual coercion is a key conceptual component of good sexual health [15].

The internet was the most commonly accessed source for sexual health information in young adults [16]. A web-based sexual health intervention has some potential advantages over a traditional face-to-face intervention, including the capacity to reach a larger number of people in the population with a relatively low cost and facilitating communication with full privacy and confidentiality [16]. Moreover, a web-based intervention's interactive and anonymous delivery is more acceptable and effective [17]; a Cochrane meta-analysis evaluating 15 randomized controlled trials (RCTs) on safe-sex practice interventions found the interactive computer-based interventions to be more effective at improving knowledge about sexual health [18]. In this study, we have developed an interactive web-based sexual health literacy intervention to promote safe sex practices.

The sexual health status of young women in China is generally poor [19], and the level of sexual health knowledge was poorer than what was reported for young women in Western countries [20]. Young women are also vulnerable to risky sexual behaviors [21]. A national survey found that 1.6% of female Chinese university students reported having multiple sexual partners [22], and another study found that only 17.2% of sexually active female Chinese university students consistently used condoms [23]. The prevalence of sexual coercion of female university students in Hong Kong was reported to be approximately 13% in 2015, showing no reduction since 2008 [24,25]. Sexual health interventions in Hong Kong have lagged far behind that of many other places [26]. Moreover, sexual health interventions in Hong Kong often focus primarily on physiological knowledge and the dissemination of STI and STI-prevention information; little attention is paid to the effects of gender-power dynamics on
sexual health, such as sexual coercion, respectful relationships, and sexual communication and negotiation [26]. However, a growing body of literature shows that the more sexual communication and negotiation that occurs before sex, the more likely a condom will be used during sex [27]. Sexual coercion is highly related to unsafe sex practices [28]. Taken together, these facts emphasize a need to revisit, develop, and evaluate comprehensive sexual health literacy interventions in the Chinese context.

In this study, we describe the development and systematic evaluation of a sexual health literacy program called “Smart Girlfriend” using a multicenter RCT. This program is an interactive web-based intervention that aims to disseminate knowledge about STIs and condom use, communication and negotiation about condom use, and sexual coercion in daily life to enhance safe sex practices among female university students in Hong Kong.

**Methods**

**Trial Design**

The design was a multicenter, single-blind, parallel-group RCT, registered with ClinicalTrials.gov (NCT03695679). Ethical approval was obtained from the institutional review board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW-17029) and other universities. We followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

**Sample Size**

Our sample size calculation was based on a primary comparison of behavioral change in the consistency with condom use. A previous study reported that the mean percentage of condom use was 68% (SD 39%) in individuals who underwent a computer-based intervention, compared with 24% (SD 35%) among those in a control condition, corresponding to a moderate to large Cohen effect size of 0.6 [29]. To conservatively detect a small Cohen effect size of 0.3 with 80% power and a maximum 5% false positive error rate using a 2-sided, 2-sample t test, a total of 352 (ie, 2 groups of 176) female university students were required. Assuming a 30% attrition rate based on a previous study using a web-based intervention [30], we calculated a total necessary sample size of 500 participants.

**Participants**

In total, 1503 female university students across various disciplines and years of study were screened from 5 universities with dormitory or residential halls in Hong Kong. Of these, 781 students were recruited. The eligibility criteria were (1) female university students aged 18 years or above who (2) are able to read Chinese or understand Cantonese, (3) are unmarried, (4) have been with intimate partners (ie, current and former dating partners or partners in a relationship) in the past 12 months, and (5) have not received any sexual health information (including formal face-to-face or online education or training courses related to contraceptives and sexually transmitted diseases, from a university, hospital, clinic, or nongovernmental organization) in the past 12 months. The exclusion criteria were (1) an unwillingness to complete the questionnaires at 3 time-points, (2) being pregnant or postnatal, and (3) having a psychiatric illness.

**Recruitment, Randomization, Masking, and Allocation Concealment**

Students were reached via leaflets, campus booths, bulk emails, and posters. All interested participants received an invitation email to log into the Smart Girlfriend webpage (Multimedia Appendix 1-3). Online enrolment was used to screen students for eligibility. For eligible participants, written informed consent was obtained online, followed by a baseline questionnaire. After completing the questionnaire, the recruited participants were randomized to either the intervention group or the control group, according to a list prepared by blocked randomization (with blocks of 4), with a 1:1 randomization ratio. The block size and order of allocation were kept securely in the randomizer to avoid selection bias. The online platform conducted masking and allocation concealment according to the participants’ enrolment sequence. Participants were automatically guided to the webpage associated with their allocation and were not aware of the group allocation in advance. Participants who completed all of the web-based questionnaires were given vouchers with a value of HKD $300 (USD $38.50). The privacy of all participants was ensured. Data collected from all questionnaires were stored in a protected university database.

**Previous Development Efforts of Smart Girlfriend**

Findings from our previous local multisite survey (n=1076) revealed that Chinese university students saw the relationship between unsafe sex practices and sexual coercion as problematic [25]. The results showed that 12% of female university students who were engaged in a dating relationship or had dating partners in the past year experienced sexual coercion within that year [25]. Therefore, we conducted an intervention to help enhance the awareness of sexual coercion among university students. Sexual issues are typically taboo subjects in Chinese culture; therefore, to minimize embarrassing situations for participants, we implemented the Dating Compassion, Assessment, reFerral, and Education (Dating CAFE) Ambassador Programme to help Chinese university students with dating violence. The intervention’s development was based on the theory of planned behaviors and was conducted via 3 face-to-face workshops (totaling 7.5 hours) with 81 university students. Compared to students in the control group, we found that the students trained to be ambassadors had significantly enhanced behavioral intentions and control to help peers who were experiencing dating violence, decreased acceptance of dating violence, and increased subjective norms for helping others [31]. Moreover, we learned that discussions about dating issues were attractive and acceptable among university students. In addition, the face-to-face intervention was labor-intensive, and some students could not be enrolled due to timetable clashes. Thus, a web-based intervention could be a more cost-effective and practical approach for reaching as many eligible young people as possible.

**The Smart Girlfriend Intervention**

The development of Smart Girlfriend was based on the Dating CAFE initiative. Smart Girlfriend is designed to be a sexual
health literacy intervention empowering female university students with enhanced knowledge, attitudes, norms, and self-efficacy around managing sexual health, particularly condom use for safe sex practice. Based on the Health Belief Model (Figure 1) [32], we delivered Smart Girlfriend in 3 phases. In the first phase, participants were able to check their perceived susceptibility and perceived severity for individual STIs. The Harvard Cancer Risk Index [33] was used to ask 8 questions to estimate individual STI and cervical cancer risks. Respondents obtained personalized results from their answers, including factors that may increase or reduce their risk of getting STIs and cervical cancer. In the second phase, participants were given knowledge-based information about STIs and cervical cancer in text format, including relevant statistics, development, possible symptoms, and prevention methods. Some scale-based questions were asked to help the students think about the positive and negative features of condom use. Participants were able to offer personal feedback and were provided with an opportunity to reflect on which benefits or barriers mattered most to them (Figure 2).

Figure 1. Conceptual framework of the Smart Girlfriend program based on the Health Belief Model. STIs: sexually transmitted infections.

Figure 2. An example of a scale-based question asked by Smart Girlfriend to help students think about the positive and negative features of condom use and provide an opportunity for feedback and reflection on what matters most to them. STIs: sexually transmitted infections.

<table>
<thead>
<tr>
<th>Use condom</th>
<th>Not use condom</th>
</tr>
</thead>
<tbody>
<tr>
<td>I want to do everything I can to prevent STIs.</td>
<td>I am the first and only sexual partner for him/her. The chance of getting STIs is very low.</td>
</tr>
</tbody>
</table>

More important | Equally important | More important

In the second phase, participants were also prompted to take action regarding condom use. Therefore, condom use procedures and tips, as well as web links for local STI testing, cervical screening programs, and HPV vaccination programs, were provided. In addition, participants’ self-efficacy in condom use was enhanced by providing information about assertiveness in sexual consent and sexual communication to avoid sexual coercion and casual sex. Three 5-minute videos were created with narrative stories about STIs and HPV infection based on different scenarios relevant to common situations for university students, about the handling of sexual consent in dormitories, engaging in sexual communication at home, and talking to a friend about worries regarding sex without a condom after a Christmas party (Multimedia Appendix 2). The Continuum of Conflict and Control (CCC) theory [34] was used to guide the stories, emphasizing that sexual coercion can occur without

https://www.jmir.org/2021/3/e22564
physical violence and with minimal fear to strengthen participants’ knowledge about sexual coercion, sexual consent pertaining to condom use, and sex refusal. Participants were able to assess their own values and receive feedback on their choices. Textbox 1 shows the perceived benefits of and barriers to condom use featured in the interactive intervention.

Textbox 1. Perceived benefits of condom use and barriers to condom use featured in the interactive intervention.

<table>
<thead>
<tr>
<th>Perceived benefits of condom use:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consistent use of latex condoms before having sex lowers the risk of cervical cancer.</td>
</tr>
<tr>
<td>• Consistent and correct condom use is necessary every time one has sex, from the start of the act to the finish, to effectively lower the risk of sexually transmitted infections (STIs).</td>
</tr>
<tr>
<td>• A condom acts as a barrier against human papillomavirus (HPV) and other STIs.</td>
</tr>
<tr>
<td>• Some types of HPV can cause cells in the cervix to become cancerous; a condom acts as a barrier against HPV and other STIs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Perceived barriers to condom use:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Not knowing the risk of STIs [Link to knowledge about STIs and cervical cancer, including its statistics, development, and possible symptoms]</td>
</tr>
<tr>
<td>• Not knowing how to use a condom [Link to condom use procedures and tips]</td>
</tr>
<tr>
<td>• Low comfort levels with initiating conversations about condom use</td>
</tr>
<tr>
<td>• Feelings of frustration when being rejected due to issues around condom use [Link to video 3 about feelings and provide information to connect condom use and health risks of STIs and cervical cancer]</td>
</tr>
<tr>
<td>• Not knowing what to do after being rejected due to issues around condom use</td>
</tr>
<tr>
<td>• Sexual coercion [Link to definition and statistics of sexual coercion and examples]</td>
</tr>
</tbody>
</table>

In the last phase, a page designed to summarize the participants’ individual factors for facilitating decision-making about consistent condom use in future sexual activities was presented. Participants were asked to rate their level of self-efficacy in terms of knowledge, skills, clarity of information, and perceived support and advice on a scale of 1-5. If the participant’s level of self-efficacy was low (1-3), they were directed to relevant information via hyperlinks.

In the control group, participants received minimal intervention, with only a single webpage of online information about procedures and tips for condom use. The site for the control group had a similar graphic design to the one used for the intervention group, but no self-assessment material or online quiz questions were presented.

An inquiry system was created to handle questions from the participants. This system was designed to help participants in both the intervention and control groups if they needed any support or wanted to seek further clarification.

The time spent engaging with the online information was approximately 30 minutes for the intervention group and 10 minutes for the control group.

Outcomes and Follow-up

All data were collected from the webpage. Participants were sent a reminder email and SMS text message for completing the online questionnaires at 3 time-points: baseline (T1); 3-months postintervention (T2); and 6-months postintervention (T3). The primary outcomes were the consistency of condom use with every partner, in accordance with the recommended guidelines of a systematic review of 56 studies [35], which used the percentage of male condom protected sex with every partner during the past 3 months. Secondary outcomes were (1) knowledge, attitudes, norms, and self-efficacy of condom use, as appraised by the 25-item Multidimensional Condom Attitudes Scale (MCAS) [36]; (2) knowledge, attitudes, norms, and self-efficacy of sexual coercion and sexual consent, as measured by the 39-item Sexual Consent Scale-Revised (SCS-R) [37]; and (3) self-efficacy in sexual communication, estimated by the 20-item Sexual Communication Self-efficacy Scale (SCSES) [38]. The MCAS items were answered using a 7-point Likert scale, and total scores ranged from 7 to 175; a previous study has shown acceptable validity and reliability in the Chinese population [39]. The Cronbach alpha in this study was .84. The SCS-R contained 3 attitudinal subscales (positive attitude toward establishing consent, lack of perceived behavioral control, and sexual consent norms) and 2 behavioral subscales (indirect consent behaviors, and awareness and discussion). The SCS-R items were answered using a 7-point Likert scale, and the Cronbach alpha in this study was .67. The SCSES items were answered using a 4-point Likert scale, and total scores ranged from 20 to 80. With the exception of one of the SCS-R subscales (lack of perceived behavioral control), high scores on the scales indicated a high level of measured outcomes. The Cronbach alpha in this study was .94.

Other outcomes included participant inquiries, participant satisfaction, and participation in the intervention. Participants’ inquiries were collected to understand their further needs. Satisfaction with the intervention was evaluated by recording the overall satisfaction of the intervention on a scale of 0-10. In addition, participants were asked which part of the intervention was most memorable. The higher the score, the higher the overall satisfaction with the intervention. The total recorded views of each website page (recorded via Google Analytics) and the incidence of searching for more information were measured.
Requested demographic information included sexual orientation, birthplace, dating relationship status, and history of childhood sexual coercion. Information regarding individual risk of STIs and cervical cancer (Multimedia Appendix 3) was collected at baseline, including age, age at first sexual intercourse experience, number of sexual partners during one’s lifetime, frequency of condom use, history of being diagnosed with an STI, smoking status, history of giving birth, and history of having a Pap smear test. The experience of sexual coercion was measured using a 7-item subscale of the Revised Conflict Tactic Scale [40], which indicated whether it had happened and how often the behavior had occurred in the past year.

Statistical Analysis

The primary outcome, consistency of condom use, was analyzed using a zero/one inflated beta (ZOIB) regression model because the raw data of the consistency of condom use were not normally distributed, exhibiting excessive zeros and ones (i.e., consistency of condom use = 100%). ZOIB is based on a piecewise distribution, which accounts for the probability mass at 0 or 1 and the probability density within (0,1). Bayesian-based results were obtained using Stan (Stan Development Team; 4 chains, 4000 iterations, 1500 warm-ups) [41]. Odds ratios (ORs) and credible interval (CrI) values were calculated for Bayesian-based analysis.

We adopted the intention-to-treat principle, and all study subjects were included in the analysis. Missing values at the 3- and 6-month follow-ups were replaced by the last observed value. Missing values at baseline were replaced by values from the 3- or 6-month follow-up. If there was no value obtained at any of the 3 time-points, the participant was excluded from the analysis. For other outcomes, the t test was applied for continuous data and the chi-square test was applied for categorical data. All P values were 2-sided, and P < .05 was considered statistically significant. R software (version 3.6.1; R Core Team) with “tidy” and “brms” packages was used to analyze the data. Questions were downloaded from the inquiry system. Content analysis was performed to categorize the collected responses.

Results

CONSORT Flowchart

Figure 3 shows the flow of participants at baseline, grouping randomization, 3-month follow-up, and 6-month follow-up. Of 1503 screened students, 722 were excluded and 781 students were enrolled (enrolment rate: 52%), randomized into the intervention group (384/781, 49%) and the control group (397/781, 51%). Of the 781 included participants, the dropout rate was 8% (60/781) at the 3-month follow-up (intervention: 28/384, 7%; control: 32/397, 8%) and 9% (70/781) at the 6-month follow-up (intervention: 36/384, 9%; control: 34/397, 9%). Finally, 229 participants in the intervention group and 246 participants in the control group were included in the analysis of the primary outcome. A total of 362 participants in the intervention group and 384 participants in the control group were analyzed for other outcomes. Details of the quality check criteria used are provided in Multimedia Appendix 4.
Baseline Characteristics of Participants
The mean age of participants was 21.5 (SD 2.6) years, ranging from 18 to 32 years. Most participants were born locally (536/746, 72%), and 18% (134/746) self-reported as sexual minorities (Table 1). Approximately 10% (78/746) of participants reported child sexual abuse experiences, and 22% (164/746) reported a history of sexual coercion.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total participants (n=746)</th>
<th>Intervention group (n=362)</th>
<th>Control group (n=384)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years, mean (SD)</strong></td>
<td>21.5 (2.6)</td>
<td>21.5 (2.7)</td>
<td>21.5 (2.6)</td>
</tr>
<tr>
<td><strong>Birthplace, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>536 (72)</td>
<td>252 (70)</td>
<td>284 (74)</td>
</tr>
<tr>
<td>Other</td>
<td>210 (28)</td>
<td>110 (30)</td>
<td>100 (26)</td>
</tr>
<tr>
<td><strong>Smoking status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not smoke</td>
<td>674 (90)</td>
<td>329 (91)</td>
<td>345 (90)</td>
</tr>
<tr>
<td>Quit smoking</td>
<td>65 (9)</td>
<td>29 (8)</td>
<td>36 (9)</td>
</tr>
<tr>
<td>Engages in smoking</td>
<td>7 (1)</td>
<td>4 (1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td><strong>Alcohol consumption status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not consume alcohol</td>
<td>309 (42)</td>
<td>150 (41)</td>
<td>159 (42)</td>
</tr>
<tr>
<td>Quit consuming alcohol</td>
<td>129 (17)</td>
<td>58 (16)</td>
<td>71 (19)</td>
</tr>
<tr>
<td>Consumes alcohol</td>
<td>308 (41)</td>
<td>154 (43)</td>
<td>154 (40)</td>
</tr>
<tr>
<td><strong>Sexual orientation, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterosexual&lt;sup&gt;a&lt;/sup&gt;</td>
<td>612 (82)</td>
<td>294 (81)</td>
<td>318 (83)</td>
</tr>
<tr>
<td>Sexual minority&lt;sup&gt;b&lt;/sup&gt;</td>
<td>134 (18)</td>
<td>68 (20)</td>
<td>66 (17)</td>
</tr>
<tr>
<td><strong>History of child sexual abuse, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurred</td>
<td>668 (90)</td>
<td>323 (89)</td>
<td>345 (90)</td>
</tr>
<tr>
<td>Did not occur</td>
<td>78 (10)</td>
<td>39 (11)</td>
<td>39 (10)</td>
</tr>
<tr>
<td><strong>History of sexual coercion, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occurred</td>
<td>164 (22)</td>
<td>77 (21)</td>
<td>87 (23)</td>
</tr>
<tr>
<td>Did not occur</td>
<td>580 (78)</td>
<td>285 (79)</td>
<td>295 (77)</td>
</tr>
<tr>
<td><strong>History of sexually transmitted infections, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>741 (99)</td>
<td>358 (99)</td>
<td>383 (99)</td>
</tr>
<tr>
<td>Yes</td>
<td>5 (1)</td>
<td>4 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td><strong>History of Pap smear test, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has not had a Pap smear test</td>
<td>702 (94)</td>
<td>339 (94)</td>
<td>363 (95)</td>
</tr>
<tr>
<td>Has had a Pap smear test</td>
<td>44 (6)</td>
<td>23 (6)</td>
<td>21 (6)</td>
</tr>
<tr>
<td><strong>Relationship status, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dating/in a relationship</td>
<td>597 (80)</td>
<td>280 (77)</td>
<td>317 (83)</td>
</tr>
<tr>
<td>Broken up/ cohabiting</td>
<td>149 (20)</td>
<td>82 (23)</td>
<td>67 (17)</td>
</tr>
<tr>
<td><strong>Sexual experience, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has not had a sexual experience with a partner</td>
<td>293 (39)</td>
<td>141 (39)</td>
<td>152 (40)</td>
</tr>
<tr>
<td>Has had a sexual experience with a partner</td>
<td>453 (61)</td>
<td>221 (61)</td>
<td>232 (60)</td>
</tr>
<tr>
<td><strong>Age of first sexual intercourse experience, in years (n=463&lt;sup&gt;c&lt;/sup&gt;), mean (SD)</strong></td>
<td>19.6 (2.5)</td>
<td>19.6 (2.5)</td>
<td>19.7 (2.6)</td>
</tr>
<tr>
<td>Number of sexual partners (n=463&lt;sup&gt;c&lt;/sup&gt;), mean (SD)</td>
<td>2.1 (2.8)</td>
<td>2.2 (3.3)</td>
<td>2.0 (2.1)</td>
</tr>
</tbody>
</table>

<sup>a</sup>For the purposes of this study, *heterosexual* was defined as an individual who is exclusively attracted to the opposite sex.

<sup>b</sup>For the purposes of this study, due to small respective sample sizes, the category of *sexual minority* included all respondents who reported that their sexual orientation is “mostly heterosexual,” “bisexual,” “mostly homosexual,” “completely homosexual,” and “not sure.”

<sup>c</sup>This item only includes respondents who reported sexual experience at baseline.
Outcomes

Consistency of Condom Use

ZOIB modeling revealed nonsignificant differences between the intervention and control groups in all models regarding the consistency of condom use (Table 2). The intervention group showed a nonsignificant trend toward being more likely to report 0% or 100% consistency of condom use compared to the control group (OR 2.25, 95% CrI 0.84-6.36), and of those, a nonsignificant trend toward being more likely to report 100% condom use consistency compared to the control group (OR 8.03, 95% CrI 0.22-330.31). At baseline, the consistency of condom use was 78% in the intervention group and 72% in the control group (95% CI −0.97 to 13.04). At the 3-month follow-up, the intervention group exhibited 5% higher consistency (intervention: 80% vs control: 75%, 95% CI −1.90 to 11.63) than the control group, and exhibited 1% higher consistency (intervention: 77% vs control: 76%, 95% CI −5.1 to 8.02) at the 6-month follow-up.

Table 2. Impact of the Smart Girlfriend program on the consistency of condom use at different time points.

<table>
<thead>
<tr>
<th>Model, group, and time-point</th>
<th>Estimate (SE)a</th>
<th>ORb</th>
<th>95% CrIc</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model 1: Report 0% or 100% condom use consistency in all participants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>0.81 (0.52)</td>
<td>2.25</td>
<td>0.84-6.36</td>
</tr>
<tr>
<td>Time3M</td>
<td>0.06 (0.33)</td>
<td>1.06</td>
<td>0.56-2.02</td>
</tr>
<tr>
<td>Time6M</td>
<td>0.17 (0.33)</td>
<td>1.18</td>
<td>0.62-2.25</td>
</tr>
<tr>
<td>Group* Time3M</td>
<td>0.00 (0.48)</td>
<td>1.00</td>
<td>0.39-2.58</td>
</tr>
<tr>
<td>Group* Time6M</td>
<td>−0.04 (0.49)</td>
<td>0.96</td>
<td>0.37-2.48</td>
</tr>
<tr>
<td><strong>Model 2: Report 100% condom use consistency in those reporting 0% or 100%</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>2.08 (1.87)</td>
<td>8.03</td>
<td>0.22-330.31</td>
</tr>
<tr>
<td>Time3M</td>
<td>0.85 (0.73)</td>
<td>2.35</td>
<td>0.58-10.55</td>
</tr>
<tr>
<td>Time6M</td>
<td>1.18 (0.74)</td>
<td>3.26</td>
<td>0.80-14.91</td>
</tr>
<tr>
<td>Group* Time3M</td>
<td>−0.66 (1.12)</td>
<td>0.52</td>
<td>0.06-4.57</td>
</tr>
<tr>
<td>Group* Time6M</td>
<td>−2.66 (1.15)</td>
<td>0.07</td>
<td>0.006-0.62</td>
</tr>
<tr>
<td><strong>Model 3: Report a condom use consistency between 0% and 100% in all participants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td>0.19 (0.22)</td>
<td>1.21</td>
<td>0.78-1.86</td>
</tr>
<tr>
<td>Time3M</td>
<td>−0.00 (0.15)</td>
<td>1.00</td>
<td>0.74-1.34</td>
</tr>
<tr>
<td>Time6M</td>
<td>−0.04 (0.16)</td>
<td>0.96</td>
<td>0.70-1.31</td>
</tr>
<tr>
<td>Group* Time3M</td>
<td>0.07 (0.24)</td>
<td>1.07</td>
<td>0.67-1.71</td>
</tr>
<tr>
<td>Group* Time6M</td>
<td>0.01 (0.25)</td>
<td>1.01</td>
<td>0.63-1.67</td>
</tr>
</tbody>
</table>

aSE: standard error.
bOR: odds ratio.
cCrI: credible interval for a Bayesian-based analysis.
dTime3M: the 3-month follow-up.
eTime6M: the 6-month follow-up.
fGroup*Time3M: the interaction effect between the group and the 3-month follow-up.
gGroup*Time6M: the interaction effect between the group and the 3-month follow-up.

Secondary Outcomes

The MCAS scores of the intervention group significantly increased at the 3-month follow-up compared to the control group (intervention: 122.51, SD 15.97, vs control: 119.86, SD 15.85; P=.02; Table 3). No significant difference was found in other secondary outcomes.
Table 3. The impact of the Smart Girlfriend program on secondary outcomes at different time points.

<table>
<thead>
<tr>
<th>Outcome and time-point</th>
<th>Intervention group (n=362), mean (SD)</th>
<th>Control group (n=384), mean (SD)</th>
<th>t test (df=744)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multidimensional Condom Attitudes Scale (MCAS)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>120.24 (SD 15.39)</td>
<td>118.60 (SD 16.13)</td>
<td>1.42</td>
<td>0.16</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>122.51 (SD 15.97)</td>
<td>119.86 (SD 15.85)</td>
<td>2.27</td>
<td>0.02</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>123.55 (SD 15.76)</td>
<td>121.80 (SD 16.75)</td>
<td>1.47</td>
<td>0.14</td>
</tr>
<tr>
<td><strong>Sexual Consent Scale–Revised (SCS-R) subscale 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>32.76 (SD 12.16)</td>
<td>32.89 (SD 11.93)</td>
<td>–0.15</td>
<td>0.88</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>31.31 (SD 11.77)</td>
<td>32.04 (SD 11.43)</td>
<td>–0.87</td>
<td>0.39</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>30.91 (SD 11.40)</td>
<td>30.68 (SD 11.54)</td>
<td>0.28</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>SCS-R subscale 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>59.43 (SD 10.44)</td>
<td>59.27 (SD 10.43)</td>
<td>0.22</td>
<td>0.83</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>59.18 (SD 9.83)</td>
<td>58.22 (SD 9.93)</td>
<td>1.34</td>
<td>0.18</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>58.82 (SD 9.45)</td>
<td>59.31 (SD 10.75)</td>
<td>–0.67</td>
<td>0.51</td>
</tr>
<tr>
<td><strong>SCS-R subscale 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>28.63 (SD 5.80)</td>
<td>28.03 (SD 5.90)</td>
<td>1.42</td>
<td>0.16</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>27.80 (SD 5.64)</td>
<td>28.01 (SD 5.86)</td>
<td>–0.48</td>
<td>0.63</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>27.92 (SD 5.50)</td>
<td>27.96 (SD 5.77)</td>
<td>–0.09</td>
<td>0.93</td>
</tr>
<tr>
<td><strong>SCS-R subscale 4</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>34.64 (SD 6.25)</td>
<td>34.99 (SD 6.13)</td>
<td>–0.77</td>
<td>0.44</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>34.21 (SD 6.21)</td>
<td>34.37 (SD 6.27)</td>
<td>–0.34</td>
<td>0.73</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>33.88 (SD 6.27)</td>
<td>34.71 (SD 6.27)</td>
<td>–1.81</td>
<td>0.07</td>
</tr>
<tr>
<td><strong>SCS-R subscale 5</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>16.04 (SD 5.31)</td>
<td>16.29 (SD 5.28)</td>
<td>0.65</td>
<td>0.51</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>16.61 (SD 5.32)</td>
<td>16.22 (SD 5.08)</td>
<td>1.02</td>
<td>0.31</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>17.26 (SD 5.02)</td>
<td>16.88 (SD 5.25)</td>
<td>1.02</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>Sexual Communication Self-efficacy Scale (SCSE)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>62.01 (SD 10.94)</td>
<td>60.54 (SD 11.26)</td>
<td>1.81</td>
<td>0.07</td>
</tr>
<tr>
<td>3-month follow-up</td>
<td>63.41 (SD 11.09)</td>
<td>62.08 (SD 10.73)</td>
<td>1.66</td>
<td>0.10</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>63.56 (SD 10.76)</td>
<td>62.80 (SD 10.77)</td>
<td>0.95</td>
<td>0.34</td>
</tr>
</tbody>
</table>

*a*: degrees of freedom.

*b*: SCS-R subscale 1: (lack of) perceived behavioral control.

*c*: SCS-R subscale 2: positive attitude toward establishing consent.

*d*: SCS-R subscale 3: indirect behavioral approach to consent.

*e*: SCS-R subscale 4: sexual consent norms.

*f*: SCS-R subscale 5: awareness and discussion.

Inquiry System

Of the 781 participants, 10% (81/781) sent inquiries via the webpage. Of these, 27% (22/81) of inquiries asked about condoms and other contraceptive methods, 28% (23/81) asked about STIs, 14% (11/81) asked about sexual behaviors, and 31% (25/81) asked about suggestions for intervention, technical issues, or other issues (Table 4). A significant difference was found for condoms and other contraceptive methods ($\chi^2=9.78, \ P=.002$) and STIs ($\chi^2=6.71, \ P=.01$) between the 2 groups. Compared with the control group, participants in the intervention group were more likely to send inquiries about STIs (intervention: 18 vs control: 5), whereas intervention group participants were less likely to send inquiries about condoms and other contraceptive methods (intervention: 6 vs control: 16). In the category of STIs, 3 participants in the intervention group asked whether there is a risk of STIs and how to prevent STIs among women who have sex with women.
### Table 4. Inquiries sent by participants in the intervention and control groups.

<table>
<thead>
<tr>
<th>Inquired issue</th>
<th>Total (n=81), n (%)</th>
<th>Intervention group (n=45), n (%)</th>
<th>Control group (n=36), n (%)</th>
<th>$\chi^2$</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condom and other contraceptive methods</td>
<td>22 (27)</td>
<td>6 (13)</td>
<td>16 (44)</td>
<td>9.78\textsuperscript{a}</td>
<td>.002</td>
</tr>
<tr>
<td>Sexually transmitted infections</td>
<td>23 (28)</td>
<td>18 (40)</td>
<td>5 (14)</td>
<td>6.71\textsuperscript{a}</td>
<td>.01</td>
</tr>
<tr>
<td>Sex life</td>
<td>11 (14)</td>
<td>8 (18)</td>
<td>3 (8)</td>
<td>1.52</td>
<td>.22</td>
</tr>
<tr>
<td>Technical issue</td>
<td>6 (7)</td>
<td>2 (5)</td>
<td>4 (12)</td>
<td>1.30</td>
<td>.25</td>
</tr>
<tr>
<td>Suggestions for the website</td>
<td>8 (10)</td>
<td>5 (11)</td>
<td>3 (8)</td>
<td>0.17</td>
<td>.68</td>
</tr>
<tr>
<td>Others</td>
<td>11 (14)</td>
<td>6 (13)</td>
<td>5 (14)</td>
<td>0.01</td>
<td>.94</td>
</tr>
</tbody>
</table>

\textsuperscript{a}$P<.01$.

### Satisfaction and Participation of Participants

A slight but statistically nonsignificant difference in satisfaction ($t_{677}=0.15; P=.89$) was found between the intervention (n=353) and control (n=326) groups, with average satisfaction scores of 6.19 (SD 2.75) and 6.22 (SD 2.78), respectively. Among participants who reported the type of content they remembered most (Table 5), almost half of the participants in the intervention group (48/118, 41%) and more than half of the participants in the control group (58/107, 54%) reported that content related to condoms was most memorable. In addition, more intervention group participants reported that content about sexual consent was the most memorable (32/118, 27%) than control group participants (21/107, 20%). There was a significant difference between the 2 groups for seeking out more information about safe sex practice at the 3-month follow-up (intervention: 120/334, 36% vs control: 92/353, 26%; $\chi^2=7.83, P=.005$) but not at the 6-month follow-up (intervention: 105/326, 32% vs control: 97/353, 28%; $\chi^2=1.81, P=.18$). Data from Google Analytics revealed that the most visited pages of the intervention were the inquiry page and the page with information about risk factors for cervical cancer.

### Table 5. Content that participants reported to be the most memorable.

<table>
<thead>
<tr>
<th>Most memorable content</th>
<th>Intervention group (n=118), n (%)</th>
<th>Control group (n=107), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical cancer</td>
<td>4 (3.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Sexually transmitted infections</td>
<td>8 (6.8)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Sexual coercion</td>
<td>3 (2.5)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Condoms</td>
<td>48 (40.7)</td>
<td>58 (54.2)</td>
</tr>
<tr>
<td>Sexual consent</td>
<td>32 (27.2)</td>
<td>21 (19.7)</td>
</tr>
<tr>
<td>Other</td>
<td>23 (19.5)</td>
<td>26 (24.3)</td>
</tr>
</tbody>
</table>

### Discussion

#### Principal Findings

This multicenter RCT in Hong Kong is the first study to examine the effects of an interactive web-based sexual health literacy program to promote safe sex practice among female Chinese university students. The consistency of condom use increased over time in both groups. The intervention group exhibited 5% higher consistency at the 3-month follow-up and 1% higher consistency at the 6-month follow-up compared to the control group; however, these differences were not statistically significant. Thus, the results did not reveal an effect from the intervention for increasing the consistency of condom use.

One of the possible explanations for the lack of positive effect may be due to the passive exposure of the intervention to our target audiences. In our intervention, the main components were delivered passively, including the knowledge about STIs, the narrative stories about STIs, and the introduction about sexual coercion. A meta-analysis for HIV-prevention interventions also revealed that participants in active interventions (such as client-tailored counseling and other activities to improve behavioral skills) reported a greater behavioral change improvement compared to passive interventions (such as messages to share procondom information and norms and to verbally model skills); and likewise, passive interventions in the intervention groups did not differ significantly from the control groups [42]. These findings show the positive effect of active interventions and suggest that increasing active components would be necessary for future research in promoting safe sex practice.

Another potential reason for the lack of positive effect could be associated with the nonpersonalized nature of the web-based intervention content. According to the inquiries we received from the participants, some participants asked if women who had sex with women were at risk for STIs, and some intervention content was not applicable to them. Previous studies found that personalized web-based interventions were more effective than nonpersonalized interventions, and the difference between the nonpersonalized intervention group and the blank control group...
was nonsignificant [43]. Thus, behavioral change may be improved if we tailor the intervention content to the participant’s characteristics, such as sexual orientation.

Additionally, the imbalanced ceiling effect for 2 groups might also contribute to the insignificant intervention effect. The proportion of participants reporting 100% condom use at baseline in the intervention group was significantly higher than the control group (68% vs 59%, respectively; \(\chi^2 = 3.90, P = .048\)). Owing to the ceiling effect, the potential capacity of improvement in terms of condom use in the intervention group would be less than the control group, and the effect of intervention might be underestimated [44].

Increased MCAS scores at the 3-month follow-up indicate that the Smart Girlfriend program improved participants’ knowledge, attitudes, norms, and self-efficacy of condom use temporarily; however, there was no significant long-term effect on behavior observed at the 6-month follow-up. These results indicate that the intervention could temporarily improve knowledge, attitudes, norms, and self-efficacy of condom use in young adults but cannot ultimately change their behaviors. These findings were in line with a previous study [45]. Starosta et al [46] found that a web-based intervention improved attitudes toward condoms but could not change condom use at the 3-month follow-up. Thus, it would seem that improvement occurs, but it would decrease over time if there is no further exposure in the intervention [47].

**Strengths and Limitations**

The strengths of the study include the detailed development of the intervention based on theory and previous experience. The low dropout rate in this study indicates that university students welcomed the intervention and that it served the needs of the target population. With the participation of 5 universities in Hong Kong, the study included a diversity of student population characteristics, sexual orientations, and sexual coercion experiences. ZOIB was employed in this study, given the nonnormal distribution data with excessive zeros and ones. In promoting sexual health literacy, self-reported condom use is characterized by a substantial number of zeros or ones and discrete nonzero counts [48]. Excessive numbers of zeros or ones in this dependent variable make it difficult to fit the data using traditional methods, including ordinary least squares models and mixed linear models, which may yield biased estimates of the results. The beta distribution is considered a versatile function that fits a broad range of probability distribution shapes. This study may serve as a promising reference for future studies with similar problems. A high participation rate (91%) was reported in this study, indicating a high acceptability of digital interventions among university students and suggesting that a large number of university students can be reached at a very low cost.

This study has implications for future studies. Temporary improvement was observed in the knowledge, attitudes, norms, and self-efficacy of condom use, but not observed postintervention in behavioral change; this suggests that future research should more thoroughly consider novel methods that maintain the intervention effect and increase the behavioral change effect of web-based sexual health literacy. First, an active approach for intervention delivery may lead to the greatest increase in condom use. For example, virtual reality’s effectiveness for behavioral skills training and practical exercises has been demonstrated in other research fields [49]. Second, the intervention content should be more personalized, especially for our target participants, before the intervention. More specific and advanced information (eg, whether nonpenetrative sex is a risk factor for contracting STIs), more customized content (eg, for women who have sex with women), and personal online counseling through the website might be needed. Third, more attention should be paid to the organization of the external links to other websites. We provided external hyperlinks to other websites to give participants more opportunities to explore other related information. In hindsight, providing external hyperlinks might not have been ideal since they may have distracted the participants from the intervention pathway and led them away from (and discouraged the return to) our website [50]. Recent research tested a web-based basic version alongside a version with added links to external resources, and it was found that the latter version was not effective [51]. The external links could be listed in the last (or a separate) page in future revised interventions.

Our study has several limitations. First, despite our relatively large sample of participants, compared with many other sexual health interventions, our study might lack power concerning the primary outcome for the consistency of condom use. The number of sexually active participants during the 6-month follow-up was relatively lower than expected. We included those who only reported sexual activities in one of 3 questionnaires and used a conservative approach that considered sexually inactive participants as exhibiting no change. This conservative approach might bias our results. Second, there is a potential influence of the Hawthorne effect. A systematic review found that the Hawthorne effect could influence participants’ behavior in RCTs [52]. In our study, self-reported data were collected, and participants knew that the program was designed to increase their consistency of condom use. Third, we did not collect information about the duration of participation. However, due to the digital intervention design, all participants received information about the whole intervention before completing the questionnaires. Finally, our results were vulnerable to differential error because self-reported data were collected. The intervention group may have misreported the consistency of condom use to a greater extent than the control group at baseline (intervention: 78% vs control: 72%), thereby biasing the estimated intervention effect. There is no alternative to self-reporting in web-based trials because collecting biological data via web-based systems is unfeasible. Differential error could not be avoided; however, our trial was conducted under conditions that maximize accurate reporting, using an anonymous web-based questionnaire that assured participants of confidentiality with an absence of investigators.

**Conclusion**

Among university students in Hong Kong, an interactive web-based sexual health literacy program resulted in a small but statistically nonsignificant increase in the consistency of condom use, as well as a significant and temporary increase in
knowledge, attitudes, norms, and self-efficacy of condom use, but not in sexual coercion, sexual consent, or sexual communication, when compared with participants receiving only one webpage of condom use information. The number of participants at enrolment and the high participation rate highlight the need for sexual health literacy programs for young adults. Moreover, a future revision of this intervention should be personalized and delivered with an active approach.

Acknowledgments

We gratefully thank The Food and Health Bureau for granting us the opportunity to conduct this project with the provision of the Health and Medical Research Fund (reference number 14150971). The study's sponsors did not play a role in the study design, data collection, data analysis, data interpretation, or report writing. We also thank all the students who participated in the study, the IT assistants from the School of Nursing at The University of Hong Kong for maintaining the website, and all university administrators for their heartfelt support and assistance in making the data collection successful.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Smart Girlfriend: an interactive web-based sexual health literacy program for safe sex practice in female Chinese university students.

[ PNG File , 351 KB - jmir_v23i3e22564_app1.png ]

Multimedia Appendix 2

Smart Girlfriend Screenshot: 5-minute videos with narrative stories about sexually transmitted infections (STIs) and human papillomavirus (HPV) infection.

[ PNG File , 207 KB - jmir_v23i3e22564_app2.png ]

Multimedia Appendix 3

Smart Girlfriend Screenshot: information collection of individual risk of sexually transmitted infections (STIs) and cervical cancer.

[ PNG File , 167 KB - jmir_v23i3e22564_app3.png ]

Multimedia Appendix 4

Details of the data quality check.

[ DOCX File , 14 KB - jmir_v23i3e22564_app4.docx ]

Multimedia Appendix 5

CONSORT-EHEALTH (V 1.6.1) checklist.

[ PDF File (Adobe PDF File) , 382 KB - jmir_v23i3e22564_app5.pdf ]

References


Health Care Students’ Knowledge of and Attitudes, Beliefs, and Practices Toward the French COVID-19 App: Cross-sectional Questionnaire Study

Ilaria Montagni1, DPhil; Nicolas Roussel2, DPhil; Rodolphe Thiébaut1,2,3*, DPhil, MD; Christophe Tzourio1,3*, DPhil, MD

1Bordeaux Population Health Research Center, U1219, Bordeaux University, INSERM, Bordeaux, France
2Inria, Bordeaux University, Bordeaux, France
3Hospital Center Bordeaux University, Bordeaux, France
* these authors contributed equally

Corresponding Author:
Ilaria Montagni, DPhil
Bordeaux Population Health Research Center, U1219
Bordeaux University, INSERM
146 rue Léo Saignat
Bordeaux, 33000
France
Phone: 33 05 57 57 16 5
Email: ilaria.montagni@u-bordeaux.fr

Abstract

Background: Many countries worldwide have developed mobile phone apps capable of supporting instantaneous contact tracing to control the COVID-19 pandemic. In France, a few people have downloaded and are using the StopCovid contact tracing app. Students in the health domain are of particular concern in terms of app uptake. Exploring their use and opinions about the app can inform improvements and diffusion of StopCovid among young people.

Objective: The aim of this study is to investigate health care students’ knowledge of and attitudes, beliefs, and practices (KABP) toward the StopCovid app.

Methods: A field survey was conducted among 318 students at the health sciences campus of the University of Bordeaux, France, between September 25 and October 16, 2020. A quota sampling method was used, and descriptive statistics and univariate analyses were performed.

Results: Of the 318 respondents, 77.3% (n=246) had heard about the app, but only 11.3% (n=36) had downloaded it, and 4.7% (n=15) were still using it at the time of the survey. Among the 210 participants who had heard about the app but did not download it, the main reasons for not using the app were a belief that it was not effective given its limited diffusion (n=37, 17.6%), a lack of interest (n=37, 17.6%), and distrust in the data security and fear of being geolocated (n=33, 15.7%). Among the 72 students who had not heard of the app and were given a brief description of its functioning and confidentiality policy, 52.7% (n=38) said they would use it. Participants reported that the main solution for increasing the use of the app would be better communication about it (227/318, 71.4%).

Conclusions: Even among health students, the contact tracing app was poorly used. The findings suggest that improved communication about its advantages and simplicity of use as well as clarifying false beliefs about it could help improve uptake.

(J Med Internet Res 2021;23(3):e26399) doi:10.2196/26399

KEYWORDS
contact tracing; COVID-19; mobile app; students; field survey; app; survey; monitoring; knowledge; attitude; belief; practice; communication; use
Introduction

Background Context

Nonpharmaceutical interventions have been used to contain the spread of the SARS-CoV-2 virus [1] while effective treatments and optimal vaccine coverage are made. Besides generalized lockdown and barrier gestures, one of the solutions to limit contagion, locate clusters, and isolate them is the tracing of infected people. Contact tracing is a systematic method used as part of a disease surveillance strategy (predict, observe, and minimize) [2]. In contact tracing, an index case with confirmed infection is asked to provide information about contacted people who were at risk of acquiring infection from the index case within a given time period (between 1 week and 14 days) before the positive test result. These contacts are then alleged to be tracked, advised about their risk, quarantined, and tested [3]. Conventional or manual contact tracing is a long process demanding human resources to contact and follow up with people one by one. It can engender several delays and is potentially biased by imperfect recall of contacts [4]. These limitations can be compensated by digital contact tracing [3,5].

Several smartphone apps have been developed worldwide to automatically and rapidly trace contacts in real time. Across all continents more than 45 apps are currently used [6] and several states are planning to launch such apps [7]. The general functioning of these apps is that each mobile device running the app keeps track of other mobile devices running the app that it comes in to close contact with. When users inform their app that they tested positive, this contact log is used to determine the other mobile devices—and users—that should be notified. Existing apps use different technologies and algorithmic methods to detect contacts between mobile devices (eg, short range Bluetooth Low Energy information exchange or GPS-, WiFi-, or Bluetooth-based geolocation), to keep track of these contacts (eg, using temporary unique identifiers), to evaluate the infection risk (eg, based on a predicted distance and the duration of the contact), and to notify potentially exposed people using a centralized or decentralized network approach [8]. The effectiveness of these apps is based on the fact that individuals are systematically tested, that results of these tests are correct and communicated in the app, that the individuals who are in contact have a smartphone, and that a high proportion of smartphone users download and use the app so as to interrupt the chains of infection transmission [9].

The recrudescence of the virus after the general lockdown from March to May 2020 has especially concerned young people across France and in the Bordeaux region in particular, where incidence of COVID-19 positive cases among young adults aged 20-30 years has increased to about 252/100,000 per week across France and in the Bordeaux region in particular, where March to May 2020 has especially concerned young people [9]. The general functioning of these apps is that each mobile device running the app keeps track of other mobile devices running the app that it comes in to close contact with. When users inform their app that they tested positive, this contact log is used to determine the other mobile devices—and users—that should be notified. Existing apps use different technologies and algorithmic methods to detect contacts between mobile devices (eg, short range Bluetooth Low Energy information exchange or GPS-, WiFi-, or Bluetooth-based geolocation), to keep track of these contacts (eg, using temporary unique identifiers), to evaluate the infection risk (eg, based on a predicted distance and the duration of the contact), and to notify potentially exposed people using a centralized or decentralized network approach [8]. The effectiveness of these apps is based on the fact that individuals are systematically tested, that results of these tests are correct and communicated in the app, that the individuals who are in contact have a smartphone, and that a high proportion of smartphone users download and use the app so as to interrupt the chains of infection transmission [9].

The StopCovid App

The contact tracing app “StopCovid” was launched by the French Government on June 2, 2020 [12]. It was developed by a team of public and private partners lead by the French National Institute for Research in Digital Science and Technology (Inria), and was available in both the Apple and Google Play stores, as it worked on iOS and Android phones. The app was based on Bluetooth signals running in the background of the phone with low-energy wireless transmission [13]. Once the app was activated, the phone logged other phones it came in to contact with, assuming these devices were running StopCovid. These logs did not include any identifying information about the user; they used random ID codes that changed every 15 minutes and were deleted once they were older than 14 days (the incubation period for COVID-19). The app did not locate the user (no GPS-, WiFi-, or Bluetooth-based geolocation); it only knew which random IDs the phone had come in to contact with. Being transparent and anonymous, the app did not collect any personal data nor contact details. If a user declared being positive for COVID-19 using a code delivered with the test results, the app would send that record of the rotating IDs to a centralized server, which in turn would send them out to other devices using the system [14]. Anyone that had the app activated who had been nearby in the last 2 weeks would be pinged with an alert. More precisely, this notification was sent if the person had spent more than 15 minutes within 1 meter of an index case. Users were then recommended to inform their general practitioner, get tested, and self-isolate, thus potentially stopping another line of transmission.

As of October 2020, StopCovid had been installed more than 2.7 million times since the beginning of June (about 4% of the French population, 67 million). Only 7969 users had declared being COVID-19 positive in the app, and only 472 notifications had been sent to potential at-risk contacts. The uptake was less than for apps in Germany (downloaded by 18 million people, about 21% of the German population, 84 million), England and Wales (16 million downloads in a population of 59 million, 27%), and Italy (9 million downloads in a population of 60 million, 26%). All these percentages are low considering that approximately 60% of the adult population would have to adopt the app to contain the pandemic [4,5]. In general, statistics show a limited use of these apps in Europe [15].

The effectiveness of the StopCovid app must be framed in the specific French context: the testing strategy was and is still
unclear with limited testing capacities, tracing was not always possible, and self-quarantining was voluntary and not always followed [16]. Furthermore, three sources of risk have been identified in the StopCovid app in terms of security and data protection: (1) the hacking of the central database, (2) the reporting of fictitious or unverified cases of infection, and (3) the increased vulnerability of the smartphones themselves caused by the activation of Bluetooth [7].

Literature Review on the Uptake of COVID-19–Related Contact Tracing Apps

Recently, several researchers have investigated the acceptability and use of contact tracing apps in the context of the COVID-19 pandemic. Some studies are based on surveys assessing the uptake of these apps among different population samples. These studies mostly refer to a hypothetical app and the intention to use it [16-24], and only a few collect information on the use of an existing tool like StopCovid [25-27]. The majority of documents reporting the real uptake of contact tracing apps are national statistics without a scientific and theoretical background. Other studies are critical viewpoints arguing on the ethical, technical, political, and scientific impact of contact tracing apps on society [2,7,9,28,29].

Concerning surveys, a multicountry cross-sectional study on 1849 adults across France, Germany, Italy, the United Kingdom, and the United States [17] showed that 74.8% of the respondents would install or keep a contact tracing app. Concerns about cybersecurity and privacy, together with a lack of trust in the government, were mentioned as the main barriers to app adoption. Another survey was conducted on 406 German adults [18], and the results showed that trust in the official app providers played an important role in the contact tracing app uptake. However, the threat appraisal of potential infection was not related to the motivation for using the app or for providing one’s own infection status to it. In Belgium [19], 48.7% of 1500 adults declared intending to use a COVID-19 tracing app. The most important predictor was the perceived benefits of the app. Respondents also reported that the clarity on how the app functioned was correlated to the will to use it. Dutch citizens were interviewed in two studies [20,23]: 41.2%-64.1% of the respondents (n=238 [20] and n=900 [23], respectively) were willing to use a contact tracing app. In one study [20], the main reason to use such an app was to control the spread of COVID-19 (30.6%). Concerns about privacy were mentioned as the main reason for not using the app (64.8%). In the other study [23], the rate of potential users strongly varied by age group: the adoption rates of the app ranged from 45.6% to 79.4% for people in the oldest (≥75 years) and youngest (15-34 years) age groups. Educational attainment, the presence of serious underlying health conditions, and the respondents’ stance on COVID-19 infection risks were also correlated with the predicted adoption rate. A national online survey on the Irish population (n=8088 responses) [21] showed that 84% of respondents would probably or definitely download the app. The most common reason for downloading the app was helping family members and friends (79%), and with a sense of responsibility to the wider community (78%). The most common reason for not downloading the app was fear that technology companies or the government might use the app technology for greater surveillance after the pandemic (41%). A longitudinal study was also conducted in Luxembourg on a representative sample of 730 adults [22]. The results showed that 72% would probably or definitely install the app if one was made available. Among motives in favor of contact tracing apps, respondents consistently mentioned responsibility toward the community and loved ones. In contrast, 11% of respondents would definitely not install the app, and their general willingness to use one was hampered by privacy and data security issues.

Acceptance of COVID-19 contact tracing apps has also been explored in France. In the first survey [27], 44% of a representative sample of 2000 French people declared that they would accept being electronically traced to avoid the spread of the virus. However, 23% were definitely against the app, and the majority of them were males and aged 25-34 years. The main reason for opposition was the fear of losing one’s freedom. Another recent survey on 1849 French adults [16] showed that the contact tracing app was rather or totally acceptable by 42.1% of the respondents. A positive correlation was found between the perceived health consequences in case of COVID-19 infection and the willingness to use the contact tracing app. Trust in the government to handle the health crisis was also strongly and positively correlated with the potential use of the app.

Concerning critical viewpoints and opinion papers, they describe the public debate on privacy concerns due to the sensitive nature of the collected data. In particular, several researchers have argued that the adoption of contact tracing apps could lead to the economic exploitation of private data and might create a mass electronic surveillance system [7]. European governments have largely debated on the use of these apps, and ethical guidelines to develop and diffuse them have also been formulated [28]. In France, researchers have particularly investigated within a theoretical framework why the population has not largely adopted the StopCovid app [2,9]. According to an opinion paper [9], there are three main reasons for the low uptake of the app: the belief that the app will not be effective because we cannot reasonably expect that its adoption rate will be sufficient to be protective, the fear of data privacy breaches due to Bluetooth and to the centralized architecture of the app, and concerns on long-term surveillance and informational privacy. According to the author, the app raises a privacy paradox [30] where immediate benefits (eg, the reduction of contacts with infected people) are preferred to the value of privacy. Since the app does not seem to be effective given its limited use, it is not worth risking the breach of one’s privacy. A second study [2] analyzed the political and scientific discourse around the promotion of the StopCovid app. Digital solutions like contact tracing apps might represent a form of alienation including government distrust. By collecting and analyzing media, scientific, and policy articles mentioning StopCovid, the study reported the contradictions of the government in handling the COVID-19 crisis based on partial and imprecise knowledge about the virus. In this context, government officials did not explain in plain language the security, privacy, data collection, processing, storage, and reuse of the StopCovid app. The app was then considered as not efficacious because of its low uptake.
characterized by lack of transparency and based on alienation and coercion.

Study Setting and Aim

This study was conducted at the beginning of the academic year at the University of Bordeaux, France, when face-to-face education was re-established, and students could freely circulate after the first general lockdown. The StopCovid app was available and downloadable for 4 months. The aim of this study is to describe knowledge, attitudes, beliefs, and practices (KABP) about the StopCovid app among students in the health domain in the Bordeaux region. The expected impact is informing on potential improvements as well as public-oriented communication strategies and appropriate political decisions to increase the app diffusion.

Methods

The Field Survey: Recruitment

This study was conducted within the framework of the larger ongoing i-Share (Internet-Based Students Health Research Enterprise [31]) cohort study, a French, nationwide web-based survey on the health and well-being of university students, whose principal investigators and operational staff are based at the University of Bordeaux [32].

The field survey consisted of a paper questionnaire administered face-to-face by five undergraduate students (interviewers) who had been trained to take notes, fill in the questionnaire, and describe the app to respondents. Interviewers approached their peers in the halls, canteen, courtyards, library, and study rooms at the health sciences campus of the University of Bordeaux.

The collection of the data started on September 25, 2020, and ended on October 16, 2020. A sample size of 300 respondents was targeted with quotas set for the sample to be representative of the overall population of students in the health domain at the University of Bordeaux (n=16,566) in terms of sex, age (18-30 years), specific field of health-related study (medicine, dentistry, nursing, pharmacy, public health, etc), and year of study (1 to >6 years). The inclusion criteria were being older than 18 years, being a student in the health domain enrolled at the University of Bordeaux, and providing oral informed consent.

The Questionnaire

The questionnaire was co-designed and tested by a team of 14 public health researchers and operational staff following a structured survey construction method in five steps [33]. The final questionnaire was composed of 36 items, 14 of which were common to all students (sociodemographic characteristics, suggestions for increasing the diffusion of the app, willing to recommend the app to family and friends, and fake news about data collection and sharing within the app). The other items were administered based on four different scenarios: (1) the student has already heard about the app and has downloaded it, (2) the student has already heard about the app and has not downloaded it, (3) the student has never heard about the app but would download it, and (4) the student has never heard about the app and would not download it. Specific questions were then asked depending on the scenario. Before answering further questions, students who had not heard about the app were provided a brief description of it. After responding to fake news about data collection and sharing within the app, all students were given the correct answers. Some questions were multiple choice items. The English version of the questionnaire is available in Multimedia Appendix 1. The time of administration and completion of the questionnaire was about 10 minutes. The field survey was approved by the University of Bordeaux. The oral informed consent reassured students of the anonymous format of the survey and that use of collected data was for research purposes only.

Theoretical Framework

The questionnaire was based on the KABP scheme, which stands for the assessment of knowledge, attitudes, beliefs, and practices of populations about a specific health-related topic. This scheme is extensively used as a quantitative method (predefined questions formatted in a standardized questionnaire) that provides access to quantitative and qualitative information. Thus, items of the questionnaire were developed to capture students’ KABP about the StopCovid app. The results are discussed following the four components of this scheme.

Collected data were interpreted a posteriori through the prism of the technology acceptance model (TAM) [34] and the protection motivation theory (PTM) [35]. The TAM posits that an individual’s intent to use (ie, accept) a technology and use behavior (ie, actual use) is influenced by perceived ease of use and usefulness, which are mediated by external variables such as individual differences, system characteristics and complexity, and social influences. The TAM is especially adaptable to technology-related motivations. The PTM explains why people adopt a preventive behavior and what role fear appeals play in this process. This model comprises the threat appraisal of a potential risk (eg, infection with SARS-CoV-2) and coping appraisal of the recommended preventive behavior (eg, using StopCovid) [18]. Threat appraisal includes the perceived severity of the disease and vulnerability to it. Coping appraisal includes perceived self-efficacy (ie, belief in one’s own competence to perform a behavior even in the face of barriers) and response efficacy (ie, individuals are convinced that a behavior leads to the desired outcome and will be more likely to intend to perform the behavior). The PTM is adaptable to both health-related and technology-related motivations [18].

Data Analysis

All data from the paper questionnaires were entered by the student interviewers in a digital database through the EpiData software version 3.1 [36]. A descriptive analysis was performed, presenting all variables and measures in the form of numbers and percentages for qualitative variables and means and SDs for quantitative variables. Chi-square or exact Fisher frequency comparison tests were used to identify statistically significant differences by age, gender, field, and year of study, modified to binary variables if necessary. Data were normally distributed. Statistical significance was defined with a P value <.05. Statistical powers were calculated for each frequency comparison test, chi-square or Fisher exact test, with the condition of a minimum sample size for the Fisher exact test. In calculating the power, an approximation of the normal distribution for the chi-square tests or an approximation of the
Walters normal distribution for the Fisher exact tests was used. In addition, the size and proportion for each group was specified and the alpha was set at .05. The data were analyzed with SAS version 9.3 (SAS Institute).

**Results**

A total of 590 students were approached to complete the survey after a brief explanation of its objective; 318 completed the survey, while 272 refused to participate, creating a final participation rate of 53.9%. Reasons for not participating were lack of time or no interest in the study topic. Of the 318 participants, 65.7% (n=209) were female students, and the mean age was 20.4 (SD 2.39) years. All fields and years of study were represented. The majority (n=193, 60.7%) of the participants were medical students, which is in line with the total number of medical students at the University of Bordeaux. In accordance with university-related statistics, first-year students were also the most represented (n=129, 40.6%). Figure 1 shows the flowchart of the study population, and Table 1 shows the sociodemographic characteristics with the corresponding data for the total population of health-related students at the University of Bordeaux.

---

**Figure 1.** Flowchart of the study population (n=318).
Table 1. Sociodemographic characteristics of the study population and comparison with all students in the health domain.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Study population (n=318)</th>
<th>Total health care student population at the University of Bordeaux (n=16,566)a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>209 (65.7)</td>
<td>11,713 (70.7)</td>
</tr>
<tr>
<td>Male</td>
<td>109 (34.3)</td>
<td>4853 (29.3)</td>
</tr>
<tr>
<td><strong>Age (years), mean (SD)</strong></td>
<td>20.4 (2.39)</td>
<td>23.8 (—b)</td>
</tr>
<tr>
<td><strong>Year of study, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>129 (40.6)</td>
<td>4445 (31.2)</td>
</tr>
<tr>
<td>2</td>
<td>64 (20.1)</td>
<td>2341 (16.4)</td>
</tr>
<tr>
<td>3</td>
<td>46 (14.5)</td>
<td>2334 (16.4)</td>
</tr>
<tr>
<td>4</td>
<td>23 (7.2)</td>
<td>1200 (8.4)</td>
</tr>
<tr>
<td>5</td>
<td>44 (13.8)</td>
<td>1267 (8.9)</td>
</tr>
<tr>
<td>&gt;5</td>
<td>10 (3.1)</td>
<td>2651 (16.8)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (0.6)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Field of study, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine</td>
<td>193 (60.7)</td>
<td>7104 (49.9)</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>61 (19.2)</td>
<td>1138 (8.0)</td>
</tr>
<tr>
<td>Dentistry</td>
<td>12 (3.8)</td>
<td>521 (3.7)</td>
</tr>
<tr>
<td>Nursing</td>
<td>14 (4.4)</td>
<td>3972 (27.9)</td>
</tr>
<tr>
<td>Public health</td>
<td>15 (4.7)</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>23 (7.2)</td>
<td>1503 (10.6)</td>
</tr>
</tbody>
</table>

aData obtained from internal university documents.

bData not available.

The majority (n=246, 77.3%) of the participants had already heard about the app, mostly through the media (216/246, 87.8%) and secondly through family and friends (39/246, 15.9%).

Concerning these variables, no statistically significant differences were found based on age ($P=.09$), sex ($P=.85$), field ($P=.08$), or year of study ($P=.06$).

Most of the 246 students that knew of the app correctly knew that the app was promoted by the government (n=179, 72.8%), but 25.2% (n=62) answered that they did not know who the promoter was. Male students knew significantly more than female students that the app was promoted by the government (69/85, 81.2% vs 110/161, 68.3%; $P=.03$). Female students were significantly more likely to ignore the promoter of the app compared to male students (47/161, 29.2% vs 15/85, 17.6%; $P=.047$). Students of any health-related discipline other than medicine responded significantly more than medical students that the app was promoted by a research laboratory (4/103, 3.9% vs 0/143, 0.0%; $P=.03$). Medical students were significantly more likely to ignore the promoter of the app (43/143, 30.1% vs 19/103, 18.4%; $P=.04$). No statistically significant differences were found based on age ($P=.06$) or year of study ($P=.17$).

Among the 246 participants who had heard about the app, 14.6% (n=36) had actually downloaded it when it was first released in June 2020 (22/36, 61.1%) or with the new cases of COVID-19 at the beginning of the university year (6/36, 16.7%). Of these 36 students, 41.6% (n=15) were still using the app. Of the total 318 participants, 4.7% (n=15) of students were using the app at the moment of the survey, while those who uninstalled the app had used it from 1 day (6/36, 16.7%) to several weeks (6/36, 16.7%). The main reasons for uninstalling the app were that it was not useful (14/21, 66.7%), the respondent forgot to activate the Bluetooth (5/21, 23.8%), the app drained the phone battery (4/21, 19.0%), and too few people were using it thus making the app ineffective (4/21, 19.0%). Accordingly, students reported that the main fault of the app was that it seemed inefficient given its limited uptake (17/35, 48.6%; 1 missing). For 25.7% (9/35), the app presented technical problems like draining the battery, depending on Bluetooth, or occupying too much storage on the phone. Concerning all previous variables, no statistically significant differences were found based on age ($P$ values ranging from .27 to >.99), sex ($P$ values ranging from .19 to >.99), field ($P$ values ranging from .13 to >.99), or year of study ($P$ values ranging from .26 to >.99).

Some of these students also reported that its qualities were that it was easy to use (18/35, 51.4%) and that it was reassuring (9/35, 25.7%). Male students found the app significantly more user-friendly than female students (12/17, 70.6% vs 6/18, 33.3%; $P=.02$). Concerning this variable on the quality of the app, no statistically significant differences were found based on age ($P=.39$), field ($P=.33$), or year of study ($P=.18$).
Reasons for downloading or not downloading the app are shown in Tables 2 and 3 (multiple answers possible for each individual).

Among the 210 participants who had heard about the app but did not download it, the main reasons for not using the app were lack of interest (n=90, 42.9%), belief that it was neither effective nor useful given its limited diffusion (n=37, 17.6%), not having time to think about it (n=37, 17.6%), and distrust in data security and fear of being geolocated (n=33, 15.7%). The majority of these students might change their mind and use the app if they had more information about it through better communication strategies (n=61, 29.0%) and if more people would use it (n=54, 25.7%). Nonetheless, 26.2% (n=55) would not change their mind and would still not download the app. On the other hand, the main reasons for downloading the app were out of curiosity (13/36, 36.1%) and to protect one’s family, others, and oneself from possible infection (13/36, 36.1%).

### Table 2. Reasons for downloading the StopCovid app.

<table>
<thead>
<tr>
<th>Reasons</th>
<th>Yes, I have downloaded the app (n=36), n (%)</th>
<th>Yes, I would download the app (n=38), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out of curiosity</td>
<td>14 (36.8)</td>
<td>14 (36.8)</td>
</tr>
<tr>
<td>To protect my family, others, and myself from possible infection</td>
<td>13 (36.1)</td>
<td>24 (63.2)</td>
</tr>
<tr>
<td>Because the government advised downloading of the app</td>
<td>5 (13.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>The app could be useful to contain the spread of the virus in general</td>
<td>5 (13.9)</td>
<td>20 (52.6)</td>
</tr>
<tr>
<td>I am afraid of the virus, and all strategies are good to avoid it</td>
<td>1 (2.8)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>I was reassured the app was anonymous</td>
<td>N/A b</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (30.6)</td>
<td>1 (2.6)</td>
</tr>
</tbody>
</table>

*a Multiple answers possible.

b N/A: not applicable.

### Table 3. Reasons for not downloading the StopCovid app.

<table>
<thead>
<tr>
<th>Reasons</th>
<th>No, I have not downloaded the app (n=210), n (%)</th>
<th>No, I would not download the app (n=34), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot see the interest or need</td>
<td>90 (42.9)</td>
<td>17 (50.0)</td>
</tr>
<tr>
<td>Do not like the general idea of this app</td>
<td>10 (4.8)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Do not know how it works, did not get enough information on the app</td>
<td>23 (11.0)</td>
<td>2 (5.9)</td>
</tr>
<tr>
<td>I am suspicious of this type of app</td>
<td>18 (8.6)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Do not trust, because I do not know who is offering this app</td>
<td>11 (5.2)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Not sure about the security of the data, fear of geolocation</td>
<td>33 (15.7)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>My family and friends have discouraged me from downloading it</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>No storage on my phone or it is not powerful enough to have an extra app (battery, Bluetooth)</td>
<td>27 (12.9)</td>
<td>6 (17.6)</td>
</tr>
<tr>
<td>Do not carry my phone with me at all times</td>
<td>2 (1.0)</td>
<td>4 (11.8)</td>
</tr>
<tr>
<td>Do not use public transportation and/or do not go out much in public places (do not come into contact with strangers)</td>
<td>11 (5.2)</td>
<td>4 (11.8)</td>
</tr>
<tr>
<td>It does not seem to be effective (too few people use it)</td>
<td>37 (17.6)</td>
<td>8 (23.5)</td>
</tr>
<tr>
<td>Heard negative feedback on this app</td>
<td>7 (3.3)</td>
<td>1 (20.9)</td>
</tr>
<tr>
<td>Do not really have time to think about it</td>
<td>37 (17.6)</td>
<td>3 (8.8)</td>
</tr>
<tr>
<td>By negligence, not concerned</td>
<td>28 (13.3)</td>
<td>5 (14.7)</td>
</tr>
<tr>
<td>Not sure what it is all about, the principle and/or the functioning</td>
<td>11 (5.2)</td>
<td>N/A b</td>
</tr>
<tr>
<td>Other</td>
<td>15 (7.1)</td>
<td>2 (5.9)</td>
</tr>
</tbody>
</table>

*a Multiple answers possible.

b N/A: not applicable.
The 72 students who had never heard about the app were asked to imagine its content and objective: 41.7% (n=30) reported that it was an app providing advice and information about COVID-19, 29.2% (n=21) reported that it was an app to limit the spread of the virus, 29.2% (n=21) did not know, and 15.3% (n=11) answered “other.” After a short description of the app, 52.7% (n=38) said they would download it. The reasons for downloading or not downloading the app are similar to those provided by the sample who had heard about the app. Among the 34 students who had never heard about the app and were still not willing to download it after a brief description, 32.4% (n=11) would not change their mind, 17.6% (n=6) would download it if more people used it, and 11.8% (n=4) would download it if they had a better mobile phone.

Concerning the functioning of the app, 83.3% (30/36) of the respondents said that they were able to explain it. However, when further asked about geolocation, access to contact information, and how data were transmitted and stocked, their answers were mostly incorrect. As expected, students who had not heard about the app before, but who were presented a quick description of it during the survey, provided correct answers more than their peers. Detailed results are shown in Table 4.

<table>
<thead>
<tr>
<th>Knowledge and beliefs</th>
<th>Yes, I have heard about the app (n=246), n (%)</th>
<th>No, I have not heard about the app (n=72), n (%)</th>
<th>Total (N=318), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>StopCovid geolocates you and tracks your movements</strong></td>
<td>122 (38.4)</td>
<td>44 (61.1)</td>
<td>234 (73.6)</td>
</tr>
<tr>
<td>No (correct answer)</td>
<td>78 (31.7)</td>
<td>44 (61.1)</td>
<td>122 (38.4)</td>
</tr>
<tr>
<td>Yes</td>
<td>138 (56.1)</td>
<td>19 (26.4)</td>
<td>157 (49.4)</td>
</tr>
<tr>
<td>Not sure</td>
<td>30 (12.2)</td>
<td>9 (12.5)</td>
<td>39 (12.3)</td>
</tr>
<tr>
<td><strong>StopCovid collects your contacts and knows their names (on the phone, on social networks, etc)</strong></td>
<td>234 (73.6)</td>
<td>56 (77.8)</td>
<td>330 (105.4)</td>
</tr>
<tr>
<td>No (correct answer)</td>
<td>178 (72.4)</td>
<td>56 (77.8)</td>
<td>234 (73.6)</td>
</tr>
<tr>
<td>Yes</td>
<td>37 (15.0)</td>
<td>5 (6.9)</td>
<td>42 (13.2)</td>
</tr>
<tr>
<td>Not sure</td>
<td>31 (12.6)</td>
<td>11 (15.3)</td>
<td>42 (13.2)</td>
</tr>
<tr>
<td><strong>StopCovid detects people around you and knows their names (physical contacts)</strong></td>
<td>169 (53.1)</td>
<td>62 (85.4)</td>
<td>246 (77.4)</td>
</tr>
<tr>
<td>No (correct answer)</td>
<td>124 (50.4)</td>
<td>45 (62.5)</td>
<td>169 (53.1)</td>
</tr>
<tr>
<td>Yes</td>
<td>82 (33.3)</td>
<td>15 (20.8)</td>
<td>97 (30.5)</td>
</tr>
<tr>
<td>Not sure</td>
<td>40 (15.3)</td>
<td>12 (16.7)</td>
<td>52 (16.4)</td>
</tr>
<tr>
<td><strong>StopCovid has access to your personal data and communicates them</strong></td>
<td>246 (77.4)</td>
<td>55 (76.4)</td>
<td>301 (95.8)</td>
</tr>
<tr>
<td>No (correct answer)</td>
<td>191 (77.6)</td>
<td>55 (76.4)</td>
<td>246 (77.4)</td>
</tr>
<tr>
<td>Yes</td>
<td>28 (11.4)</td>
<td>5 (6.9)</td>
<td>33 (10.4)</td>
</tr>
<tr>
<td>Not sure</td>
<td>27 (11.0)</td>
<td>12 (16.7)</td>
<td>39 (12.3)</td>
</tr>
</tbody>
</table>

Finally, all 318 participants were asked about factors for increasing the use of the app. For the majority (n=227, 71.4%), the solution was a better communication strategy. Other factors were making the app compulsory (n=45, 14.2%), registering more COVID-19 cases (n=30, 9.4%), more information and explanations about the app (n=21, 6.6%), better technical features (n=10, 3.1%), and “other” (n=64, 20.1%).

**Discussion**

**Principal Findings and Interpretation**

As far as knowledge is concerned, 1 out of 5 students had never heard about the StopCovid app; this rate is surprisingly high considering that students in the health domain should be informed of existing tools to limit the spread of COVID-19. Those who knew the app had heard about it mostly through the media (216/246, 87.8%). The majority of students (179/246, 72.8%) correctly knew that the app was promoted by the government. However, concerning the functioning of the app, some students did not know how the contact tracing system worked and how data was managed: percentages of errors in describing the app ranged from 10.4% (33/318) to 49.4% (157/318). For them, the app was not straightforward; in the light of the TAM, reduced ease of app use determines lower acceptance. Furthermore, as an external variable, system complexity might have mediated the perception of ease of use for the app. In general, limited information about a tool, from knowing that it exists to knowing how it works, is associated with poor use of the tool itself. Consistently, when asked how they would improve StopCovid adoption, 71.4% (227/318) of students suggested deploying better communication and information strategies for increasing knowledge about the app.

In terms of attitudes, students reported several reasons for not downloading or uninstalling the app. Their intention not to use the app was mostly due to the fact that they considered the app as neither useful nor effective (14/19, 73.7%), especially because
few people were using it. As suggested by the TAM, perceived usefulness is a key determinant of acceptance of a new technology, which justifies the low adoption of StopCovid by students of our sample. Technical issues like draining the battery, use of Bluetooth, and mobile phone storage were also mentioned (9/19, 31.0%). Once again, according to the TAM, technological components are strictly related to acceptance of a digital tool. On the other hand, reasons to download the app included wanting to protect one’s family and friends: percentages ranging from 36.1% (13/36) to 63.2% (24/38). According to the PMT, the effort or cost (ie, response efficacy) of using the app was worth it to protect others from the virus. A few students (5/36, 13.9%) reported that the promotion of the app by the government motivated them to use it. This result might reflect a certain degree of confidence in political authorities.

As for beliefs, when specifically asked about the functioning and data management of the app, half of the total sample believed that the app was intrusive: it could geolocate them, track their movements, and access phone contacts. For 1 out of 6 students, fear of being tracked and that data could be collected and shared discouraged them from downloading the app. This false belief might have been nourished by the fact that students could have heard in the media that data breaches were possible, directly on their phones through Bluetooth, and that central servers could be violated. According to the PMT model, if beliefs do not support the recommended preventive behavior, probability of adopting such behavior is reduced. Furthermore, if a data breach is felt like a threat, individuals would be motivated not to download the app to protect themselves. Among those who received a clear explanation of the functioning of the app and its confidentiality policy (no geolocation and no access to personal data), 1 out of 2 students felt reassured and would finally download the app. These results confirm that beliefs, either true or false, influence behavioral intention.

Finally, concerning practices, 14.6% (36/246) of participants had actually downloaded the app, and in the whole sample, only about 4.7% (15/318) were still using it at the time of the survey, which is in line with national statistics concerning the general French population (4%). Furthermore, 26.2% (55/210) of respondents would not change their mind and still would not use the app. Possible justifications could include the fact that young people might perceive the pandemic as not dangerous for them. Epidemiological data confirm that COVID-19 is fatal mostly for people older than 60 years or who have a chronic disease [37]. Within the PMT framework, considering the illness as not too severe and perceiving vulnerability as low are related to the limited need to adopt a specific health-related behavior, which corresponds, in our case, to the downloading of the app. Along the same line, students might feel their competences (ie, self-efficacy), such as barrier gestures, are enough to prevent the virus, independent of app use. These are potential explanations for the general lack of interest in the app showed by our sample (90/210, 42.9%).

Comparison With Prior Work

Overall, international and French surveys (eg, [16-18,27]) have showed a higher acceptance of a contact tracing app than the real use we found in our study. Percentages of potential use of the app range from 38.4% [16] to 84% [21], which are substantially higher than the 4.7% (15/318) of respondents in our study who were using StopCovid. However, the lowest rates of acceptance for a contact tracing app were found mostly in France: 38.4% [16] and 44% [27]. Inversely, in our sample, 26.2% (55/210; having heard about the app) to 32.4% (11/34; not having heard about the app) of students would not change their mind and would not use the app at all. This percentage is higher than in the Luxembourg survey (11%) [22] and the Irish survey (7%) [21], but similar to one of the French surveys (23%) [27] and the Belgian survey (20.4%) [19]. Discrepancies between our study and previous surveys might be explained by the fact that the latter asked hypothetical questions about future behavior; high levels of intended installations might not directly translate into actual installation. It might be harder for respondents to visualize how such apps work, thus limiting the reliability of their responses compared to a real-life scenario. Furthermore, optimistic results found in previous surveys might be due to the fact that they had been conducted when the epidemic was on the rise and before digital contact tracing had been widely discussed in the media, especially in relation to data security. This might be the case especially for France [16]; citizens’ opinions might have changed when the StopCovid app was developed and controversies about it were raised in public debate in Spring 2020.

A study exploring the real uptake of an existing app in Singapore, the TraceTogether app, had an uptake of 20% [25]. This higher percentage, compared to our study, might be justified by the fact that Asian countries are often referred to for their decisive and authoritative responses to pandemics. More convincing communication around the app might have increased its uptake. Furthermore, TraceTogether has been a real pioneer in COVID-19–related apps given its high performance, which might have further supported its use. However, the TraceTogether app received criticism for draining mobile phone batteries, which was one of the faults reported in this study about the StopCovid app. In fact, excessive use of battery and data storage were mentioned by some of our students as reasons for not downloading the app (27/210, 12.9%), and 25% (9/36) had uninstalled the app because of these technical problems.

In our study, the three main reasons for not downloading the app were lack of interest (90/210, 42.9%), belief that it was neither effective nor useful given its limited diffusion (37/210, 17.6%), and not having time to think about it (37/210, 17.6%). No previous survey has reported these same reasons, even if in the literature the notion of contact tracing apps’ effectiveness has been widely discussed [5]. Students were aware that if the app is not used by a consistent number of people, it is not efficacious at all. In general, our sample expressed disinterest in the app. The reasons should be further explored, but we might suppose that the app was not considered as useful given the other restrictive measures in place: national lockdown, social distancing, and barrier gestures.
Distrust in data security and fear of being geolocated were mentioned by our sample as the fourth reason for not downloading the app (33/210, 15.7%). Researchers worldwide, from Europe to Asia, have emphasized the privacy controversies of contact tracing apps, presenting them as the main fault of this type of technology [9,17,22,25,38]. Fears of greater surveillance and that the app might be hacked are mentioned in these studies as barriers to app use. In France, the question of data privacy related to the StopCovid app has been particularly explored; the app does not come without short-term and long-term risks of privacy and surveillance. French people face a moral dilemma: the app can prevent the spread of the pandemic, especially protecting older adults, but limit freedom to move, data security, and privacy, which are usually sensitive issues in the French culture and politics [9]. However, this did not seem to be a source of much concern in our study compared to perceived ineffectiveness and inutility of the app. For our sample, uptake of the app might not necessarily be a matter of data security or trust in the government but a question of practicality and usefulness. This result might be explained by the fact that the youth are already used to sharing their information online (eg, in social networks) and are not as concerned by cybersecurity [9]. In line with this, none of our respondents mentioned being reassured that it was anonymous as a reason to download the app. Furthermore, the proportion of students who received an explanation of the functioning of the app were more comfortable about the fact that no private data was collected, users were not geolocated, the app did not access contacts, and that only an anonymous code was transmitted to a centralized server by Bluetooth and deleted after 14 days. For the 15.7% (33/210) of students who were cautious about data security, following the PMT model, severity of and vulnerability to data misuse might have reduced their motivation to use the app, as reported in the German survey [18]. In any case, information should be more accurate on data security since this issue could discourage young people from downloading the app. Exact data management in the contact tracing app needs to be clarified to guarantee the respect of the user’s privacy.

Similarly, trust in the authorities was mentioned in previous research as a factor influencing the uptake of the app: individuals who have less trust in their national government were also less supportive [17]. Despite not exploring the notion of trust in the government, we observed that 13.9% (5/36) of those who downloaded the app were motivated from the advice by the government, we observed that 13.9% (5/36) of those who downloaded the app were motivated from the advice by the government. This response option might be considered as a proxy for trust in the government. Although data from a larger sample is needed to corroborate this result, we might assume that the political discourse has an impact on the diffusion of the app, whether positive or negative.

The main reasons for downloading the app were curiosity (13/36, 36.1% of those who downloaded the app and 14/38, 36.8% of those who would download the app) and wanting to protect family, others, and oneself from possible infection (13/36, 36.1% and 24/38, 63.2%, respectively). The second reason was also reported in the Luxembourg survey [22] and in the Irish study [21]. Students who had received an explanation of the functioning of the app reported twice as much as the other students the fact that the app could prevent them and their beloved ones from the spread of the virus. Similar to half of the Luxembourg study’s sample [22], for some students, a good reason for installing the app was that it may stop the epidemic: percentages ranging from 13.9% (5/36) for those who downloaded the app to 52.6% (20/38) for those who would download the app. In general, when provided with a clear explanation of the app, 1 out of 2 students was convinced to download the app because of our study. In this line, 10.9% (23/210; of those who had heard about the app) and 5.9% (2/34; of those who had not heard about the app) of our respondents said that they would not download the app because they did not have enough information on how it worked. Similarly, participants in the survey conducted in Belgium [19] declared that lack of clarity on its functioning was among the reasons for not downloading the app. This suggests that providing clear information on the objectives of the app might promote its uptake.

Finally, we must consider the specificity of our population compared to previous research. Although studies were conducted on the general population (mostly nationally representative samples), we presented data exclusively from university students in the health domain. Our sample might have felt less concerned by the pandemic or simply less interested in this type of digital solution, or studying in the health domain and potentially working in hospitals might have made a contact tracing app for our respondents superfluous since they could be in contact with patients who were infected. A qualitative study would be useful to analyze the motivation for not using the app in this specific population.

**Strengths and Limitations**

This was one of the first studies reporting data on students’ KABP about a contact tracing app in a pandemic context. Previous studies have explored the intention of downloading this type of app as a general idea but were not based on a developed and currently diffused app [17-19,23]. Reasons for downloading and using the app were presented to inform future steps to increase its diffusion. The specific focus on students was another strong point of this study: young people were especially concerned by the transmission of the virus in subsequent COVID-19 waves. Mobilizing this population to adopt the app is pivotal in this particular epidemiological context.

Limitations of this study include the relatively small sample. More than 300 students in the health domain were interviewed among a total population of 18,000 students. Findings cannot be generalized, but the sample was recruited according to quota sampling to be, as much as possible, representative of sex, age, specific field of study (from medicine to pharmacy), and year of study. This might increase the representativeness of the interviewed population group. However, it is possible that students interested in the topic were more willing to participate so that the final sample might be biased (self-selection bias). The small sample also justifies the few significant differences that were identified. This is confirmed by the low statistical powers that were obtained following performed statistical tests (<0.50).

https://www.jmir.org/2021/3/e26399
The New Version of the StopCovid App: TousAntiCovid

StopCovid received several criticisms and even the French Prime Minister Jean Castex officially declared not having downloaded the app. The government considered the low uptake of the app as the main issue of StopCovid. Some weeks after the implementation of this study, on October 22, 2020, the French President Emmanuel Macron announced the launch of a new contact tracing app, TousAntiCovid. There are two main differences between the two versions of the app: embedded functionalities and promoting strategy. Concerning functionalities, they include provision of information on new cases (effectice R, incidence rate, hospitalizations, etc), advice and news about COVID-19, geolocation of testing centers, and generation of the mandatory certificates for permission to be outdoors during the lockdown. This last functionality, in particular, might have increased the download and use of the app. As for promoting strategy, it was more intense but less coercive and more transparent about the app compared to StopCovid. The French President and Prime Minister were strongly engaged in the communication campaign from the beginning, whereas StopCovid had mainly been promoted by the Minister of Health and by the Digital Secretary of State [2], who have less influence on the general population. In light of this, a new survey on the TousAntiCovid app might provide different results to compare with our study.

Implications

This survey was conducted as the preliminary phase of a complex intervention aimed at promoting the uptake of the StopCovid app among students in the health domain at the University of Bordeaux. After this first appraisal of KABP about StopCovid, the next steps are to implement a series of actions at the university. Professors and lecturers have been mobilized and trained to present the contact tracing app to their students during classes. Furthermore, students will also be informed by more communication such as short videos on the university website and intranet, flyers, posts on social networks, and posters. Student ambassadors and associations will also be involved in the diffusion of the app. This complex intervention will be evaluated through a second series of random field surveys aimed at observing an increase in the number of app downloads. Depending on the results of the evaluation, the intervention will be extended to students in other fields of study at the University of Bordeaux and other universities across France.

Conclusion

Overall, we found broad support for app-based contact tracing, notwithstanding the low uptake of StopCovid among French students in the health domain. The results suggest that the functioning and purpose of the app were not well known and appraised among participants, especially because of the lack of factual communication. Efforts are to be taken in these terms to increase knowledge about the new TousAntiCovid app, diffuse its adoption, and consequently improve preventive behaviors among young people who represent an important target audience in the strategies to limit the transmission of COVID-19. The way the app traces contacts should be better explained so as to maximize its download and consequential use by eliminating any potential false belief. The French government should be particularly involved in providing quality, clear, appropriate, and straightforward information about TousAntiCovid.

Acknowledgments

The project is led by the University of Bordeaux in close collaboration with the University Hospital of Bordeaux, the Regional Health Authority, and the National Institute for Research in Digital Science and Technology (Inria).

The authors wish to thank the i-Share team [31] for managing and conducting the study and for revising the questionnaire: Julie Arsandaux, Fadi El Khoury, Shérazade Kinouani, Mélissa Macalli, Elena Milesi, Marie Mougin, Garance Perret, and Clothilde Pollet. Within the i-Share team, the authors wish to thank especially Edwige Pereira and Aude Pouymayou for their support in statistical analysis. The authors are also indebted to the student ambassadors that carried out the field survey: Idriss Boukili, Justine Char, Jade Giacosa, Oleg Hounkpatin, Jeanne Langlois, and Marie Lanneluc.

All data generated or analyzed during this study are included in this manuscript. The full data set is available on reasonable request.

The i-Share team is currently supported by an unrestricted grant of the Nouvelle-Aquitaine Regional Council (Conseil Régional Nouvelle-Aquitaine; grant no. 4370420) and by the Bordeaux Initiatives d’excellence program of the University of Bordeaux (ANR-10-IDEX-03-02). The team has also received grants from Public Health France (Santé Publique France, contract no. 19DPPP023-0) and the Nouvelle-Aquitaine Regional Health Agency (Agence Régionale de Santé Nouvelle-Aquitaine). The funding bodies were not involved in the study design or in the collection, analysis, or interpretation of the data.

Authors’ Contributions

IM was responsible for writing the manuscript, conducting the literature search, data collection, and interpretation. CT, RT, and NR were responsible for the study design and revision of the manuscript.

Conflicts of Interest

None declared.
Multimedia Appendix 1

English version of the StopCovid field survey questionnaire.

[PDF File (Adobe PDF File), 63 KB - jmir_v23i3e26399_app1.pdf ]

References


21. Montagni et alJOURNAL OF MEDICAL INTERNET RESEARCH


https://www.jmir.org/2021/3/e26399

J Med Internet Res 2021 | vol. 23 | iss. 3 | e26399 | p.192 (page number not for citation purposes)
31. i-Share. URL: https://www.i-share.fr/ [accessed 2021-02-26]
36. EpiData Entry 3.1. URL: https://www.epidata.dk/index.htm [accessed 2021-03-02]

Abbreviations

i-Share: Internet-Based Students Health Research Enterprise
KABP: knowledge, attitudes, beliefs, and practices
PTM: protection motivation theory
TAM: technology acceptance model
Investigating Associations Between Screen Time and Symptomatology in Individuals With Serious Mental Illness: Longitudinal Observational Study

Philip Henson¹, MS; Elena Rodriguez-Villa², BA; John Torous², MD

¹Mt Sinai School of Medicine, New York, NY, United States
²Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, United States

Corresponding Author:
John Torous, MD
Beth Israel Deaconess Medical Center
Harvard Medical School
75 Fenwood Rd
Office 618
Boston, MA, 02115
United States
Phone: 1 6177541213
Email: jtorous@bidmc.harvard.edu

Abstract

Background: Increasing screen time exposure from digital devices like smartphones has shown a variety of mixed associations with cognition, behavior, and well-being in adults and children but little is known about its associations with symptomatology in individuals with serious mental illness.

Objective: To determine the range of associations between screen time and symptoms of individuals with mental illness, we utilized a method called specification curve analysis.

Methods: In this observational study, we recruited smartphone-owning adults (≥18 years old) with schizophrenia and healthy controls. We installed 2 research-source smartphone apps, mindLAMP and Beiwe, to collect survey results, cognitive test results, and screen time metrics over a period of 3 months. Surveys were scheduled for twice a week, but participants were instructed to take the surveys naturally as much or as little as they wanted. Screen time was collected continuously in the background. A total of 140 participants was recruited from the outpatient clinic population as well as through general public advertising. Age-matched, smartphone-owning healthy controls were also part of the recruitment pool. A specification curve analysis was a priori designed to explore the relationship between every combination of independent variable and dependent variable in order to demonstrate to what degree screen time relates to symptoms in individuals with serious mental illness.

Results: The sample consisted of 88 participants (54 with schizophrenia and 34 healthy controls) who completed both the initial and follow-up visits, completed at least one self-reported survey, and had a minimum passive data cutoff of 5 consecutive days. While we found an association between smartphone screen time metrics and cognition (adjusted $R^2=0.107$, $P<.001$), specification curve analysis revealed a wide range of heterogenous associations with screen time from very negative to very positive. The effects differed based on diagnostic group, age bracket, type of regression model used, and the specific independent and dependent variables selected for analysis.

Conclusions: The associations between screen time and mental health in patients with schizophrenia are heterogenous when examined with methods that reduce analytical bias. The heterogeneity in associations suggests that complex and personalized potential effects must be understood in the greater context of an individual. This analysis of longitudinally collected screen time data shows potential for future research that could benefit from high resolution metrics on smartphone use.

(J Med Internet Res 2021;23(3):e23144) doi:10.2196/23144

KEYWORDS
mHealth; schizophrenia; apps; mobile; screen time
Introduction

Technology pervades many, if not most, facets of daily life. Advances in functionality, speed, customization, and smart programming offer opportunities to access, communicate, and share resources with unprecedented efficiency. But this same connectivity has also raised issues around mental health impact. Digital devices are a mode for connectivity, explaining why 74% of Americans use a computer for their work [1] and 81% of Americans own a smartphone [2]. Screen time is thus a byproduct of productivity and sociability for many people. Resulting fears around increasing time spent looking at a screen and mental health concerns—whether it is for work or for leisure—have emerged.

Concerns, for youth especially, focus on how screen time may hinder physical activity, attention, cognition, and emotional well-being. Despite the vast increases in screen time, often across multiple devices and above recommended limits [3], data to validate or obviate concerns are limited. Studies to date show contradictory evidence on short-term and long-term effects of screen time on youth and adults [4]. Small sample sizes, self-report measures, and a deficit of longitudinal research have yielded inconclusive results. A recent paper used specification curve analysis (SCA) to highlight the degree to which study results measuring the impact of screen time on youth varied based on analytical choices [5]. The analysis enumerated the associations between screen time and emotional well-being among young people but also illustrated that the effect is smaller than other influences such as bullying.

Studies involving screen time among individuals with severe mental illness are even more scarce. On one hand, screen time may be of benefit for patients with serious mental illness as it may facilitate beneficial social connections that may be lacking offline and offer patients a sense of community and connection [6]. On the other hand, screen time may distract patients with serious mental illness from real-world obligations or expose them to harmful and stigmatizing content. One study in individuals with schizophrenia showed a positive correlation between phone use and functional capacity and cognition [7], but overall research on the topic is lacking. The need for understanding on this subject is critical, as research from a 2016 study suggests that nearly 50% of people with serious mental illness may spend up to 3 hours per day in front of their phone screen and nearly 20% may spend up to 10 hours per day on a computer screen [8], potentially making screen time a key exposure in their routine and daily life.

Screen time and exposure have likely only increased for all people, including those with serious mental illness, in the last 4 years since that 2016 study. Understanding how screen time has a positive or negative effect—or any effect at all—on the well-being of individuals with serious mental illness like schizophrenia is thus critical for ensuring today’s care remains responsive to the exposure and realities faced by patients. The data needed to identify problematic screen time involve total screen time, session time, and number of checks from smartphones. A recent study found that typical smartphone usage is relatively consistent and can be inferred with just 5 days of data [9]. On the other hand, habitual checking behaviors (sessions lasting less than 15 seconds) that may be indicative of preoccupation with mobile phones, can be inferred with just 2 days of data. These results, along with the finding that self-reported smartphone usage did not correlate with the objective measurements, suggest an important opportunity to use smartphone-derived screen time metrics in studying its effects.

Our research aimed to address a gap in the literature and understanding by investigating the effect of screen time on individuals with schizophrenia. Our unique dataset, with longitudinal objective screen time measures, self-report surveys, and both baseline and longitudinal cognition tests, offers an opportunity to begin to appreciate the impact of screen time on a subset of patients with serious mental illness. In relying on objective metrics of screen time derived from longitudinal phone screen on/off sensor data instead of single time-point, self-reported screen time, we hoped to avoid biases that have made prior works on screen time and mental health difficult to generalize. In this paper, we aimed to (1) investigate the association between screen time and baseline cognition in individuals with schizophrenia, (2) determine the impact of screen time on symptomatology in both people with schizophrenia and healthy controls via SCA to determine if effects hold across all possible analytical combinations, and (3) identify the association between screen time and symptomatology on an individual basis in both people with schizophrenia and healthy controls. We sought to determine the extent of screen time’s effect on symptoms in individuals with schizophrenia at both group and individual levels and expected to find complicated and heterogeneous associations between screen time metrics and symptomatology.

Methods

Longitudinal Data Collection Platforms

Two types of longitudinal data were collected: (1) active data in the form of participant self-reported surveys and cognitive tests and (2) passive data that included GPS, accelerometer, and screen time. Two research applications, mindLAMP and Beiwe, were installed on participants’ smartphones after receiving institutional review board approval at the Beth Israel Deaconess Medical Center [10,11].

Participants

For both studies, smartphone-owning adults (≥18 years old) were recruited from the greater Boston area starting August 2018 through the Massachusetts Mental Health Center in Boston, MA and general public advertising for convenience sampling of controls. A total of 140 participants enrolled after signing written informed consent, 6 dropped out, and 46 were excluded for not providing at least one self-reported survey or having inadequate screen time data (a minimum of 5 days of smartphone usage was used as a passive data cutoff). Of the 88 remaining participants, 54 had a clinical diagnosis of schizophrenia (SZ), and 34 were healthy controls (HC). All participants owned a smartphone and were given a smartwatch for the duration of the study to assist in data collection. Demographic information can be found in Table 1.
Table 1. Demographic characteristics of 88 smartphone-owning participants from the greater Boston area.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HC(^a) (n=34)</th>
<th>SZ(^b) (n=54)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>39.62 (14.56)</td>
<td>33.02 (11.71)</td>
<td>.250</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td>.681</td>
</tr>
<tr>
<td>Male</td>
<td>19 (56)</td>
<td>25 (46)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>13 (38)</td>
<td>25 (46)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2 (6)</td>
<td>4 (7)</td>
<td></td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>American Indian or Alaskan Native</td>
<td>0 (0)</td>
<td>4 (7)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>27 (79)</td>
<td>3 (6)</td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>2 (6)</td>
<td>19 (35)</td>
<td></td>
</tr>
<tr>
<td>Multiracial or other</td>
<td>1 (3)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>White Caucasian</td>
<td>4 (12)</td>
<td>20 (37)</td>
<td></td>
</tr>
<tr>
<td>Not reported</td>
<td>0 (0)</td>
<td>6 (11)</td>
<td></td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Some high school</td>
<td>0 (0)</td>
<td>2 (4)</td>
<td></td>
</tr>
<tr>
<td>High school graduate or GED(^c)</td>
<td>3 (9)</td>
<td>15 (28)</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>2 (6)</td>
<td>20 (37)</td>
<td></td>
</tr>
<tr>
<td>4-year college graduate or higher</td>
<td>29 (85)</td>
<td>17 (32)</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)HC: healthy control.
\(^b\)SZ: clinical diagnosis of schizophrenia.
\(^c\)GED: General Educational Development test.

Data Collection Protocol

After signing informed consent, participants completed paper-and-pencil symptom surveys, completed a cognitive assessment with a validated iPad version of the Brief Assessment of Cognition in Schizophrenia (BACS, SZ group only) [12], and installed mindLAMP and Beiwe on their smartphones. BACS was not administered for the HC group due to the lack of a psychiatric diagnosis as well as the assessment’s specificity for individuals with schizophrenia. For 3 months, participants were notified on their smartphones to take 10 surveys per week: 2 each of mood (PHQ-9 [Patient Health Questionnaire-9]) [13], anxiety (GAD-7 [7-item Generalized Anxiety Disorder assessment]) [14], sleep, and sociability. Each survey ended with a cognitive test: Jewels A or Jewels B, which are smartphone-adapted versions of the classic Trails-A and Trails-B tasks to assess a wide variety of cognitive domains including attention, visual search, task switching, and psychomotor speed [15]. Jewels B was used for the analysis as it is a more complex task and has shown better separation between individuals with psychosis and healthy controls [16]. A single score, or “beta value,” was used to represent performance on a Jewels task and takes into account both accuracy and error rate. Meanwhile, the Beiwe app collected multiple passive data streams (GPS, accelerometer, screen on/off, and call and text logs) simultaneously and uploaded the data to a Health Insurance Portability and Accountability Act–compliant server every hour. Raw screen time (in seconds) was calculated by summing the intervals between “Screen On” and “Screen Off” data points. While participants were paid for their clinical visits and in-person surveys, no study compensation was provided for app engagement or survey completion.

Data Analysis

All analyses were performed using the R programming language (version 3.6.2 [17]). Raw screen time data were aggregated by day and processed into 3 main screen time metrics: (1) screen time (seconds), (2) session time (seconds), and (3) number of checks (unitless). Session time was calculated by dividing screen time by the number of sessions and checks (ie, “habitual checking behaviors” were sessions lasting less than 15 seconds) [9]. Smartphone surveys were also aggregated by day, and survey scores were averaged if more than one of the same survey was taken that day (eg, separate PHQ-9 results of 10 and 11 on the same day would be converted to 10.5).

Correlations between the first month of screen time and baseline cognition were conducted using the Spearman rank correlation coefficient, and P values were adjusted using the false discovery rate method. Multivariate multiple linear regression was performed on longitudinal screen time and Jewels B cognition beta values.

SCA was inspired by Orben and Przybylski [5] and aided by the “specr” package in R [18]. Gender (male or female) was added as a covariate, and 2 models were used: linear model and generalized linear model. Groups were separated for SCA based...
on age (<30 years old or ≥30 years old) and diagnostic group (SZ or HC).

Linear model regression was performed at the individual level between screen time and symptoms, and regression estimates were arranged from high to low. Only individuals with survey results in each of the 4 survey categories of interest (mood, anxiety, sleep, social) were included in this portion of the analysis.

Results

Cognition
Participants with schizophrenia (n=54) were assessed at baseline for cognition via BACS, and all 88 participants (54 SZ and 34 HC) were assessed longitudinally via the Jewels B assessment within the mindLAMP smartphone app.

Baseline
Among the 6 subdomains of the BACS (Verbal Memory, Verbal Fluency, Digit Sequencing, Symbol Coding, Token Motor, and Tower of London), Spearman correlations between screen time metrics and SZ baseline BACS subdomains ranged from –0.17 to 0.29, but there were no significant correlations (P values ranged from .25 to .98).

Longitudinal
Multivariate multiple linear regression revealed a significant regression equation in SZ for the association of the screen time metrics (number of sessions, number of checks, screen time, and session time) with longitudinal beta values for cognition (Jewels B assessment [16]): $F_{4,144}=5.43, P<.001$ with an adjusted $R^2$ of 0.107. The beta values used to represent cognition take into account accuracy and error rate, and the greater the beta value, the better the performance. The regression equation for HC was not significant (adjusted $R^2=0.035, P=.068$).

Specification Curve Analysis
SCA on data for all 88 participants (54 SZ and 34 HC) revealed estimates (regression coefficient $\beta$) for over 600 combinations, or specifications, ranging from –1.19 to 1.05 (Figure 1). The figure is meant to be a high-level representation of the heterogeneity of associations between screen time metrics and symptoms, displayed in order of most negative on the left to most positive on the right. If we were to zoom in, we could see, for example, that an individual column within the red area might involve screen time, sociability, linear model, covarying for gender, and including participants with schizophrenia over the age of 30 years. For that group, the model found a significant negative association between self-reported sociability behavior and smartphone screen time. Individual analyses can be read as a vertical column, with each column (ie, specification) representing a unique combination of variables that was tested in this analysis. For example, the leftmost column of results involves checks, social, linear model, no covariates, and the control group of participants aged ≥30 years. In other words, this is the most negative association ($\beta=1.19$) and suggests that more checking behavior was associated with worse reported sociability for an older control group while not adjusting for gender using a linear model. On the right side of the plot, the most positive association ($\beta=1.05$) was between checks and sleep (ie, more checking behavior was associated with better reported sleep) in SZ, but not HC, for individuals over 30 years old using a generalized linear model and adjusting for gender.

Figure 1. Specification curve analysis of screen time and symptoms, as a visual representation of the >600 combinations of regression analyses between screen time metrics and self-reported mood, anxiety, sleep, and sociability: (A) regression coefficient, (B) variables.
Individual Participant Regression

As shown in Figure 2, linear model estimates at the participant level revealed differences in screen time’s effect on symptoms among individuals as well as between groups, with lower and more negative values identified in the SZ group (mean –0.136, SD 4.3) than in the HC group (mean 0.51, SD 1.6). Individual estimates ranged in SZ from –28.9 for sociability to 12.6 for anxiety (mean 0.51, SD 1.6) and in HC from –3.4 to 5.8 in HC (mean –0.136, SD 4.3). Note that only participants with results in all 4 survey domains were included in this analysis (18 SZ and 13 HC), and completion of surveys was optional in the study.

Figure 2. Individual effects of screen time on symptoms measured using the mindLAMP mobile phone app, plotted from low to high for (A) participants with a clinical diagnosis of schizophrenia (n=18) and (B) healthy controls (n=13), with self-reported survey scores in all categories.
Discussion

Principal Findings

Using longitudinal and objective measurements related to screen time, we found a range of positive and negative associations with mental health symptoms at both population and individual levels in patients with schizophrenia. We found no significant associations between screen time and baseline cognition but did find associations in schizophrenia between cognition as measured by the Jewels B cognitive task and screen time metrics (adjusted $R^2=0.107, P<.001$). The low $R^2$ indicates that, despite the significant trend, much of the variability cannot be explained by the model. Nonetheless, patterns of smartphone use may be related to underlying cognitive functioning—presenting opportunities for capturing novel data and designing more engaging apps.

However, it is important to consider the multitude of factors in addition to screen time that may contribute to well-being, symptomatology, and cognition. An SCA on 3 large data sets of over 350,000 people found that many other personal and behavioral factors can have as much, if not more, of an effect on well-being than technology use [5]. For example, bullying and marijuana use had a greater negative effect on well-being than technology use, whereas proper sleep and nutrition had a greater positive effect. The authors even drew attention to neutral factors like eating potatoes as having nearly as negative of an effect on technology use. Our dataset is much smaller but does rely on objective metrics of screen time and also suggests that at a population level, screen time itself is not highly associated with symptomology.

As with previous screen time analysis studies, our results show a wide range of regression results based on the chosen analysis isolated components. However, the SCA did bring to light some interesting results around group differences in the study. For example, both screen time and checking behavior had greater positive associations with symptoms of older controls than younger controls (x2.1 and x3.69, respectively) and checking time across all ages in the SZ group had a more positive association with symptoms than in the HC group (x3.48). While there are many potential reasons for these associations beyond the scope of this study, they highlight potential beneficial associations contrary to some perceptions that older adults or those with schizophrenia may not want to engage or even use technology. Results that screen time and checking behaviors were associated with improved sleep outcomes in those with schizophrenia but not controls also highlights that results in healthy controls do not always mirror those in patients, and that caution is necessary if seeking to apply the broader research base of screen time in the general population to those with serious mental illness.

On an individual basis, our results suggest that simple rules or guidance around screen time and mental health for individuals with schizophrenia, or controls, may not be practical. The individual participant analysis revealed heterogeneity in the effect of screen time on symptoms, with individual screen time effect estimates ranging in the SZ group from −28.9 for sociability to 12.6 for anxiety (mean 0.51, SD 1.6) and from −3.4 to 5.8 in the HC group (mean −0.136, SD 4.3). In this sample, the effects on the HC group were more positive but less variable than in the SZ group. This could be because the controls in this smartphone study may be naturally more interested in technology and thus more technology-literate and use their smartphones more regularly in ways that improve symptoms, for example playing a game to reduce stress. In addition, the greater variability in the SZ group may be due to inherent variability in symptoms and behavior associated with serious mental illness that is not present in healthy controls.

There are very few studies investigating neurocognitive effects of screen time in schizophrenia, and our results do not yet suggest conclusive evidence to fill this literature gap. Our baseline assessment of cognition was not associated with any screen time metrics, but this analysis was performed at a population level, and results may be washing out due to individual variance. There is, however, evidence that past mobile phone use in older (>40 years old) individuals with schizophrenia is associated with higher global cognitive performance [7]. Despite the mean age difference, this is in line with our longitudinal assessment finding of an association between phone checking behavior and higher performance on the Jewels B cognitive task.

While several individual studies have found associations between screen time and symptoms of depression or anxiety in both adults and children [19–21], our SCA results are in agreement with a recent large dataset analysis (n=355,358) suggesting a complex relationship between screen time and symptoms [5]. We did not have data on other personal and behavioral factors (eg, bullying, nutrition) for comparison, but the range of estimates produced by the SCA analysis demonstrates that the effect of screen time is still heterogenous and difficult to parse given all the variables.

Limitations

As with all studies, there are several limitations that need to be addressed. First, with longitudinal behavioral data, it is important to note that behavior and symptomatology can change throughout the day, so while daily aggregation employed in our study represents a high resolution for longitudinal analysis, it could be higher to capture fluctuations within the day. Still, compared to survey studies where patients estimate their mental health and screen time over weeks or even months, our methods offer improvement. Second, individual analysis only included participants with data in all survey categories. We are likely missing information from those less engaged with the app or who elected to take only a subset of surveys due to the naturalistic study design. Third, there may be a time lag between screen time and symptom change that is not accounted for as independent and dependent variables are paired for a given day, although such an effect has not yet been well characterized in the research to date. Finally, while controls were matched on age, they differed in education and race, potentially due to convenience sampling, which may have had a confounding effect.
Conclusion
Increasing screen time is a growing concern, and despite recent research efforts, there are very few studies reporting the effect of screen time on individuals with schizophrenia. The importance of a priori analysis and transparent methods around digital mental health is also highlighted in our results, which show how divergent conclusions can be supported if using more limited analysis. Our results show that variance at the individual and population levels can account for drastically different reporting of screen time’s associations with symptoms, from very negative to very positive, demonstrating a complex relationship that requires further exploration.

Conflicts of Interest
None declared.

References
Abbreviations

BACS: Brief Assessment of Cognition in Schizophrenia
GAD-7: 7-item Generalized Anxiety Disorder assessment
HC: healthy control
PHQ-9: Patient Health Questionnaire-9
SCA: specification curve analysis
SZ: clinical diagnosis of schizophrenia

©Philip Henson, Elena Rodriguez-Villa, John Torous. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 10.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Cost-effectiveness of a Telemonitoring Program for Patients With Heart Failure During the COVID-19 Pandemic in Hong Kong: Model Development and Data Analysis

Xinchuan Jiang, BSc, MPhil; Jiaqi Yao, BSc, MPhil; Joyce Hoi-Sze You, PharmD
School of Pharmacy, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China (Hong Kong)

Corresponding Author:
Joyce Hoi-Sze You, PharmD
School of Pharmacy
Faculty of Medicine
The Chinese University of Hong Kong
8th Floor, Lo Kwee-Seong Integrated Biomedical Sciences Building
Shatin, NT
Hong Kong
China (Hong Kong)
Phone: 852 39436830
Email: joyceyou@cuhk.edu.hk

Abstract

Background: The COVID-19 pandemic has caused patients to avoid seeking medical care. Provision of telemonitoring programs in addition to usual care has demonstrated improved effectiveness in managing patients with heart failure (HF).

Objective: We aimed to examine the potential clinical and health economic outcomes of a telemonitoring program for management of patients with HF during the COVID-19 pandemic from the perspective of health care providers in Hong Kong.

Methods: A Markov model was designed to compare the outcomes of a care under COVID-19 (CUC) group and a telemonitoring plus CUC group (telemonitoring group) in a hypothetical cohort of older patients with HF in Hong Kong. The model outcome measures were direct medical cost, quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratio. Sensitivity analyses were performed to examine the model assumptions and the robustness of the base-case results.

Results: In the base-case analysis, the telemonitoring group showed a higher QALY gain (1.9007) at a higher cost (US $15,888) compared to the CUC group (1.8345 QALYs at US $15,603). Adopting US $48,937/QALY (1 × the gross domestic product per capita of Hong Kong) as the willingness-to-pay threshold, telemonitoring was accepted as a highly cost-effective strategy, with an incremental cost-effective ratio of US $4292/QALY. No threshold value was identified in the deterministic sensitivity analysis.

In the probabilistic sensitivity analysis, telemonitoring was accepted as cost-effective in 99.22% of 10,000 Monte Carlo simulations.

Conclusions: Compared to the current outpatient care alone under the COVID-19 pandemic, the addition of telemonitoring-mediated management to the current care for patients with HF appears to be a highly cost-effective strategy from the perspective of health care providers in Hong Kong.

(J Med Internet Res 2021;23(3):e26516) doi:10.2196/26516

KEYWORDS
telemonitoring; mobile health; smartphone; heart failure; COVID-19; health care avoidance; cost-effectiveness

Introduction

Heart failure (HF) is a chronic disease affecting 38 million patients worldwide, with high in-hospital mortality (6.4%), 1-year readmission rate (24%-30%), and 1-year postdischarge mortality (20%) [1-5]. This chronic cardiac disease imposes a substantial global economic burden of US $108 billion per annum (approximated in 2012) [6], which is expected to increase considerably with the aging of the population [7]. Hong Kong is a developed city with an aging population, and the local epidemiological findings on outcomes of patients with HF were consistent with those of western countries [8,9].

The COVID-19 pandemic has imposed major burdens and barriers on the operation of health care systems worldwide. COVID-19 has not only disrupted the provision of routine
medical care but has also caused patients to delay and avoid seeking medical care [10]. COVID-19 was reported to be a factor associated with avoiding medical consultation in Hong Kong [11]. Patients with chronic conditions such as HF are therefore at risk of suboptimal care during the COVID-19 pandemic as a result of disruption or avoidance of routine medical care. The treatment outcomes of HF under current care during the COVID-19 pandemic are expected to be compromised.

Telehealth is a potential timely alternative to minimize the risk of COVID-19 transmission by reducing direct physical contact and to sustain continuous medical care to patients with HF during the COVID-19 pandemic [12]. The benefits of telemonitoring programs have been examined in clinical studies for the management of patients with HF. A meta-analysis reported that the application of telemonitoring program was associated with reduced risk of all-cause mortality and HF-related mortality [13].

The Markov model is a well-established decision-analytic model for simulation of expected treatment costs and health-related outcomes by incorporating relevant clinical probabilities, costs, and utility inputs. In a Markov model, hypothetical subjects proceed through health states (Markov states) in the next model cycle according to transition probabilities. Markov modeling is recommended for evaluating the outcomes of diseases that might progress, improve, or relapse through transition over a series of health states [14]. The cost-effective application of telemonitoring for the management of HF was demonstrated by Markov model–based analyses prior to the era of COVID-19 [15,16], and the patients’ medical avoidance was therefore not evaluated as an influential factor. In this study, COVID-related medical avoidance was considered in the model-based analysis. The aim of our study was to examine the potential clinical and health economic outcomes of adding telemonitoring programs to current medical care during the COVID-19 pandemic for the management of patients with HF from the perspective of health care providers in Hong Kong.

Methods

Model Design

A Markov decision-analytic model was designed to estimate the potential outcomes of current care under COVID-19 (CUC) with and without telemonitoring in a hypothetical cohort of older patients with HF (age 65 years or above) in Hong Kong (Figure 1). The outcomes were simulated from the entry of the model for a time frame of 10 years or until death, whichever occurred first. The two strategies examined in this study were (1) CUC plus telemonitoring (telemonitoring group) and (2) CUC alone (CUC group). The hypothetical cohort entered the model at one of the New York Heart Association (NYHA) classes I-IV and proceeded to another health status by the corresponding probability in each monthly cycle. The model outcome measures were direct medical cost, quality-adjusted life-years (QALYs), and incremental cost-effectiveness ratio (ICER).

Figure 1. Simplified Markov model of telemonitoring for patients with HF. CUC: care under COVID-19; HF: heart failure.

Multidisciplinary care is the standard management approach in usual care for patients with HF in Hong Kong, as recommended by the American College of Cardiology Foundation/American Health Association Guideline for the Management of Heart Failure [17]. Patients in the CUC and telemonitoring groups therefore all received multidisciplinary care, while patients in telemonitoring group received telemonitoring-mediated HF management in addition to multidisciplinary care. The telemonitoring-mediated management approach evaluated in a clinical outcome study was adopted in this model [18]. The patients in the telemonitoring group transmitted cardiac measures (heart rate, blood pressure, and weight) daily to the HF management team and answered a short series of questions pertinent to their HF symptoms via an app downloaded to a smartphone. A clinically validated algorithm that was embedded in the app stratified patients into different states and further identified patients with urgent needs. The patients with urgent needs would receive an alert message and an automated call suggesting emergent services. The on-call clinician would also be alerted to provide timely intervention at the onset of symptom exacerbations. Patients who were classified as nonurgent cases would receive self-instruction on administration of medications and when to contact a care provider.

Because of patients’ concerns about the risk of acquiring COVID-19 at health care facilities during the pandemic, patients in both arms might or might not have avoided attending the in-person medical care clinic. The telemonitoring-mediated care also required daily transmission of cardiac measures via a smartphone app, and patients in the telemonitoring group might or might not have achieved adherence to the telemonitoring requirements. Patients in both arms might have experienced...
HF-related hospitalization. For the patients who survived (with or without hospitalization) in each cycle, they might have remained in the same NYHA classification or improved/progressed to another NYHA classification.

**Model Inputs**

All the model inputs are shown in Table 1. The clinical inputs were retrieved from published reports written in English, identified from a literature search on MEDLINE over the period of 2000-2020. Epidemiology or disease burden studies in the Chinese population, randomized clinical trials, and meta-analyses were the preferred sources for clinical model inputs.
Table 1. Model parameters.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Base case value</th>
<th>Range of sensitivity analysis</th>
<th>Distribution</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical inputs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of NYHA(^a) classification (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>9</td>
<td>8.1-9.9</td>
<td>Dirichlet</td>
<td>[19]</td>
</tr>
<tr>
<td>Class II</td>
<td>44</td>
<td>39.6-48.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>34</td>
<td>30.6-37.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class IV</td>
<td>13</td>
<td>8.6-17.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transition probability (monthly)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I to I</td>
<td>0.9597</td>
<td>0.9538-0.9678</td>
<td>Dirichlet</td>
<td>[20]</td>
</tr>
<tr>
<td>I to II</td>
<td>0.0394</td>
<td>0.0315-0.0473</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I to III</td>
<td>0.0009</td>
<td>0.0007-0.0011</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I to IV</td>
<td>0</td>
<td>0-0.0011</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II to I</td>
<td>0.0073</td>
<td>0.0058-0.0088</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II to II</td>
<td>0.9877</td>
<td>0.9852-0.9902</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II to III</td>
<td>0.0039</td>
<td>0.0031-0.0047</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II to IV</td>
<td>0.0011</td>
<td>0.0009-0.0013</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III to I</td>
<td>0.001</td>
<td>0.0008-0.0012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III to II</td>
<td>0.0443</td>
<td>0.0354-0.0532</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III to III</td>
<td>0.8843</td>
<td>0.8612-0.9074</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III to IV</td>
<td>0.0704</td>
<td>0.0563-0.0845</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI to I</td>
<td>0.0010</td>
<td>0.0008-0.0012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI to II</td>
<td>0.0443</td>
<td>0.0354-0.0532</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI to III</td>
<td>0.8515</td>
<td>0.8612-0.9074</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VI to IV</td>
<td>0.1032</td>
<td>0.0563-0.0845</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probability of HF(^b)-related hospitalization in multidisciplinary care (monthly)</td>
<td>0.0296</td>
<td>0.0237-0.15</td>
<td>Beta</td>
<td>[9]</td>
</tr>
<tr>
<td>Probability of all-cause mortality in multidisciplinary care (monthly)</td>
<td>0.0279</td>
<td>0.0076-0.0383</td>
<td>Beta</td>
<td>[9]</td>
</tr>
<tr>
<td><strong>Risk ratio of event with versus without multidisciplinary care</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HF-related hospitalization</td>
<td>0.74</td>
<td>0.64-0.87</td>
<td>Lognormal</td>
<td>[21]</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>0.75</td>
<td>0.59-0.96</td>
<td>Lognormal</td>
<td>[21]</td>
</tr>
<tr>
<td><strong>Risk ratio of event with versus without telemonitoring</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HF-related hospitalization</td>
<td>0.5</td>
<td>0.36-0.64</td>
<td>Lognormal</td>
<td>[18]</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>0.81</td>
<td>0.70-0.94</td>
<td>Lognormal</td>
<td>[13]</td>
</tr>
<tr>
<td>Adherence to telemonitoring-guided management (%)</td>
<td>80</td>
<td>64-96</td>
<td>Triangular</td>
<td>[22]</td>
</tr>
<tr>
<td>Duration of COVID 19–related health care avoidance (years)</td>
<td>1.5</td>
<td>0.5-2</td>
<td>Triangular</td>
<td>[23]</td>
</tr>
<tr>
<td><strong>Utility inputs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Utilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NYHA class I</td>
<td>0.82</td>
<td>0.78-0.85</td>
<td>Uniform</td>
<td>[24]</td>
</tr>
<tr>
<td>NYHA class II</td>
<td>0.74</td>
<td>0.69-0.75</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
At the entry of the model, the distribution of patients among the four statuses (NYHA class I: 9%, NYHA class II: 44%, NYHA class III: 34%, and NYHA class IV: 13%) adopted the baseline characteristics of patients with HF in Northeast Asia [19]. The yearly transition rates between NYHA classes were retrieved from the Eplerenone in Mild Patients Hospitalization And Survival Study in Heart Failure [20], and MATLAB (MathWorks) was used to generate the monthly transition matrix. HF-related hospitalization (2.96%) and all-cause mortality for patients aged ≥65 years (2.79%) with multidisciplinary care were approximated from the Hong Kong Heart Failure Registry. In this study, a total of 1940 new-onset HF cases were identified in the Hong Kong Chinese population between 2005 and 2012. Both of the above estimates were retrieved from patients followed in the outpatient setting, with a prior history of hospitalization for decompensated HF [9]. The clinical impacts of multidisciplinary care (vs without multidisciplinary care) on HF-related admission (risk ratio [RR] 0.74; 95% CI 0.63-0.87) and all-cause mortality (RR 0.75; 95% CI 0.59-0.96) were retrieved from a systematic review of 29 trials (5039 patients) on multidisciplinary strategies for management of patients with HF [21]. The probabilities of HF-related hospitalization and all-cause mortality in patients who avoided medical care during the COVID-19 pandemic were approximated using the risks of events without multidisciplinary care. The relative change of hospitalization rate associated with telemonitoring-mediated care (RR 0.5, 95% CI 0.36-0.64) was obtained from an outcome study of a smartphone-based telemonitoring system in 315 patients with HF [18]. The relative impact of telemonitoring on all-cause mortality (RR 0.81, 95% CI 0.70-0.94) was estimated from a meta-analysis of 37 trials that evaluated the comparative effectiveness of telemonitoring versus no telemonitoring for HF management [13]. The adherence of telemonitoring was defined as achieving 70% of scheduled daily data transmission and HF symptom reporting. The percentage of achieved adherence was assumed to be 80% based on a study investigating the patient adherence of a smartphone-based telemonitoring system for HF [22]. The percentage of medical avoidance among patients with HF (26.1%) was approximated from a public survey of 765 subjects on the use of health services during the COVID-19 pandemic in Hong Kong [11]. The base-case value of health care avoidance duration was estimated to be 1.5 years with a range of 0.5-2 years, based upon the epidemiologic projections of the COVID-19 pandemic [23].

Both the utility scores of the NYHA classes and disutilities due to hospitalization were retrieved from the predicted utilities of patients with HF in the Systolic Heart Failure Treatment with the I, Inhibitor Ivabradine Trial (n=5313) [24]. The expected QALY gain in each group was calculated by the time spent in the health statuses and the corresponding utility scores. The QALY gain was discounted at an annual rate of 3%.

The cost analysis in this model was conducted using direct medical costs in the year 2020 from the perspective of public health care providers in Hong Kong. The costs of telemonitoring-mediated care (in the telemonitoring group) and the costs of HF-related inpatient and outpatient care (in both groups) were included. The cost of HF-related hospitalization was estimated by the daily cost of inpatient care and the length of stay of the patients. The daily cost of inpatient care was approximated from the fees and charges of public hospital services provided by the Hospital Authority in Hong Kong [25]. The length of hospital stay was estimated from a review on the burden of HF in 9 countries or regions (including Hong Kong) in Asia [26]. The monthly outpatient cost was estimated from the findings of a retrospective observational study on the total management cost (including hospitalization cost and ambulatory care cost) of patients with HF (n=73) recruited from a public hospital in Hong Kong [27]. The implementation cost of telemonitoring per capita (US $80) and

### Table 1: Parameters and Base Case Values

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Base case value</th>
<th>Range of sensitivity analysis</th>
<th>Distribution</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA class III</td>
<td>0.64</td>
<td>0.55-0.77</td>
<td>Uniform</td>
<td>[24]</td>
</tr>
<tr>
<td>NYHA class IV</td>
<td>0.46</td>
<td>0.41-0.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disutilities of hospitalization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NYHA class I</td>
<td>0.04</td>
<td>0.03-0.05</td>
<td>Uniform</td>
<td>[24]</td>
</tr>
<tr>
<td>NYHA class II</td>
<td>0.07</td>
<td>0.06-0.08</td>
<td>Uniform</td>
<td>[24]</td>
</tr>
<tr>
<td>NYHA class III</td>
<td>0.10</td>
<td>0.08-0.12</td>
<td>Uniform</td>
<td>[24]</td>
</tr>
<tr>
<td>NYHA class IV</td>
<td>0.29</td>
<td>0.23-0.35</td>
<td>Uniform</td>
<td>[24]</td>
</tr>
<tr>
<td>Cost inputs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily cost of hospitalization (US $)</td>
<td>654</td>
<td>523-785</td>
<td>Gamma</td>
<td>[25]</td>
</tr>
<tr>
<td>Length of hospitalization for HF (days)</td>
<td>8</td>
<td>6-10</td>
<td>Triangular</td>
<td>[26]</td>
</tr>
<tr>
<td>Monthly outpatient cost for HF (US $)</td>
<td>197</td>
<td>158-236</td>
<td>Gamma</td>
<td>[27]</td>
</tr>
<tr>
<td>Telemonitoring-mediated care (US $)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site implementation cost per patient</td>
<td>80</td>
<td>64-96</td>
<td>Gamma</td>
<td>[16]</td>
</tr>
<tr>
<td>Monthly cost of telemonitoring</td>
<td>50</td>
<td>40-60</td>
<td>Gamma</td>
<td>[16]</td>
</tr>
</tbody>
</table>

*aNYHA: New York Heart Association.

bHF: heart failure.
monthly cost of telemonitoring (US $50) were approximated from the reported costs of a smartphone-based telemonitoring system [16], including a smartphone, blood pressure monitor, weight scale, and licensing fee. The implementation cost was a one-time charge, while the monthly cost of telemonitoring was a recurrent cost for maintenance of the app. Hong Kong is a developed city with a high smartphone penetration rate of 85.5% in the overall population [28]. In this study, the monthly cost of telemonitoring was estimated at US $50 (US $1=HK $7.8), assuming the patients used their smartphones and installed the telemonitoring app. All costs were discounted annually by 3%.

Cost-effectiveness Analysis and Sensitivity Analysis

Expected costs and QALY gains were simulated for the two strategies in the base-case analysis. The ICERs were calculated using the equation \(\text{ICER} = \frac{(\text{total cost}_{	ext{telemonitoring group}} - \text{total cost}_{	ext{CUC group}})}{(\text{QALY}_{	ext{telemonitoring group}} - \text{QALY}_{	ext{CUC group}})}\). As recommended by the World Health Organization in 2002, an ICER less than 1 × the gross domestic product per capita was considered to be highly cost-effective [29]. The gross domestic product per capita of Hong Kong was US $48,937 in 2019 and was adopted as the willingness-to-pay (WTP) threshold [30]. A treatment alternative was preferred if (1) it was effective in saving QALYs at lower cost or (2) it was effective in saving QALYs at a higher cost with an acceptable ICER (< the WTP threshold).

Deterministic and probabilistic sensitivity analyses using Monte Carlo simulations were performed to examine the robustness of the base-case results. In the deterministic sensitivity analysis, each model input was evaluated over the range reported in the retrieved studies. If no range was specified, the parameter was examined over a range of ±20% of the base-case value. In the probabilistic analysis, 10,000 Monte Carlo simulations of each model outcome measure were generated by randomly drawing the value of all model inputs simultaneously from the distribution specified in Table 1. The probabilities of each strategy to be accepted as cost-effective in the 10,000 Monte Carlo simulations were determined against the variation of the WTP threshold (from US $0-100,000/QALY) in the acceptability curve. All analyses were performed using TreeAge Pro 2020 (TreeAge Software, Inc).

Results

Changes of Outcomes With Versus Without COVID-19–Related Health Care Avoidance

Over a time frame of 1.5 years (base-case value of health care avoidance duration), the expected direct medical cost and QALYs of the CUC group (with COVID-19–related health care avoidance) were US $7114 and 0.7960 QALYs, respectively. The expected cost and QALYs of usual care (without COVID-19–related health care avoidance) over a period of 1.5 years were US $6888 and 0.8135 QALYs, correspondingly. Compared with usual care (without COVID-19–related health care avoidance), CUC (with COVID-19–related health care avoidance) increased the cost by US $226 with a loss of 0.0175 QALYs.

Base-Case Analysis

The expected QALY gains and total costs of the telemonitoring group and the CUC group were compared. The direct medical cost for the CUC group was US $15,603 and the QALYs were 1.8345, while these values for the telemonitoring group were US $15,888 and 1.9007, respectively. The incremental QALYs saved by the telemonitoring group (versus the CUC group) were 0.0662, with an additional cost of US $284. The ICER for the telemonitoring group versus the CUC group was US $4292/QALY, which is below the WTP threshold of 48,937 USD/QALY (1× gross domestic product per capita in Hong Kong). Telemonitoring was therefore a highly cost-effective strategy in the base-case analysis.

Sensitivity Analyses

One-way deterministic sensitivity analyses were conducted for all model inputs. The ICERs of the telemonitoring group remained below the WTP threshold in the one-way variation of all parameters. No influential factor with the threshold value was found. For eight critical parameters, the ICERs varied by more than 20% (Figure 2): probability of HF-related hospitalization in multidisciplinary care, risk ratio of hospitalization with telemonitoring versus without telemonitoring, percentage of patients achieving telemonitoring adherence, probability of all-cause mortality in multidisciplinary care, risk ratio of mortality with telemonitoring versus without telemonitoring, length of stay of hospitalization, daily cost of hospitalization, and monthly cost of telemonitoring. Of these eight critical parameters, the probability of HF-related hospitalization in multidisciplinary care had the highest impact on the total cost. When the monthly probability of HF-related hospitalization in multidisciplinary care increased from the base-case value of 0.0296 to >0.0515, the telemonitoring group gained higher QALYs at a lower cost than the CUC group.
The risk ratios of telemonitoring versus no telemonitoring for HF-related hospitalization and all-cause mortality were two parameters representing the relative effectiveness of the telemonitoring-mediated care. To further investigate the interaction of these two parameters with the cost-effective acceptance of telemonitoring, a two-way deterministic sensitivity analysis was conducted with the risk ratios of telemonitoring versus without telemonitoring for HF-related hospitalization (range 0.5-1) and all-cause mortality (range: 0.81-1). The gray area in Figure 3 indicates the combinations of these two variables for telemonitoring to be acceptable as the preferred option (higher QALY gained at lower cost or at higher cost with an ICER < the WTP threshold).

**Figure 2.** One-way sensitivity analysis of the ICER of the telemonitoring group versus the CUC group. CUC: care under COVID-19; ICER: incremental cost-effectiveness ratio.

**Figure 3.** Two-way variation of the risk ratios with telemonitoring versus without telemonitoring on HF-related hospitalization and all-cause mortality. CUC: care under COVID-19; HF: heart failure.
The incremental costs versus incremental QALYs gained by telemonitoring (when compared with the CUC group) in 10,000 Monte Carlo simulations are shown in a scatter plot in Figure 4. The telemonitoring group gained an average QALY of 0.0688 (95% CI 0.0681-0.0695, \(P<.001\)), with a mean additional cost of US $319 (95% CI US $306-US $333, \(P<.001\)). In 10,000 Monte Carlo simulations, the probability of the telemonitoring group to be more effective in QALY gain and cost-saving was 23.5%. The telemonitoring group gained a higher QALY at a higher cost, with ICER< WTP (US $48,937/QALY) 75.7% of the time.

The probabilities of each strategy to be accepted as cost-effective are shown in the acceptability curve over a wide WTP range of US $0-100,000/QALY (Figure 5). The probabilities of the telemonitoring and CUC groups were the same (50%) at a WTP threshold of US $4700/QALY. The telemonitoring group was accepted to be cost-effective 99.2% of the time at the WTP threshold of US $48,937/QALY.

Figure 4. Scatter plot of the incremental cost-effectiveness ratios for the telemonitoring group versus the care under COVID-19 group. QALY: quality-adjusted life-year; WTP: willingness-to-pay.
Discussion

Principal Results

This is the first analysis of the potential cost-effectiveness of smartphone-based telemonitoring systems for HF management during the COVID-19 pandemic. Our model results indicated that adding telemonitoring to current CUC for the management of patients with HF is a cost-effective strategy in the base-case analysis, with an ICER (US $4292/QALY) 10-fold below the WTP threshold (US $48,937/QALY). One-way sensitivity analysis supported the robustness of the base-case findings in that no influential parameter with a threshold value was identified. The high probability of the telemonitoring group to be accepted as the preferred strategy throughout a wide WTP range in the probabilistic sensitivity analysis further supported that adding telemonitoring to HF management is a highly cost-effective strategy.

The implementation cost is a modifiable factor when introducing a new technology in a health care system. In this study, telemonitoring was assumed to have a monthly cost of US $50 based on the estimated cost of a currently available smartphone-based telemonitoring system in Canada [16,18]. We further examined the impact of the monthly cost of the telemonitoring system in an extended one-way sensitivity analysis, and we found that telemonitoring-mediated care remained highly cost-effective if the monthly cost of telemonitoring was below US $467. Our findings were consistent with a cost-utility study of a telemonitoring-mediated HF care system in Canada in that the telemonitoring strategy was highly acceptable to be cost-effective, with an ICER of US $6701/QALY (WTP threshold=US $37,718/QALY) [16]. Our study further evaluated the interacting impact of two key parameters (risk ratios of events with telemonitoring vs without telemonitoring), which represented the relative effectiveness of telemonitoring in lowering HF-related hospitalization and all-cause mortality, on the cost-effective acceptance of the telemonitoring strategy. The combinations of these two parameters, as indicated in the two-way sensitivity analysis (Figure 3), provided the effectiveness thresholds required for the telemonitoring program to be accepted as cost-effective.

Health care systems in many countries worldwide are facing unprecedented challenges to maintaining routine medical care. This is particularly difficult when the target patients are older people with chronic cardiac diseases, who also belong to the high-risk group for life-threatening complications if they acquire COVID-19. In Hong Kong, the public health care system has struggled to provide care to patients with COVID-19 and protection against the disease to staff and other patients. Under these circumstances, public health care providers deferred some nonurgent care, and older patients also avoided attending their scheduled routine care appointments. As a result of fewer in-person clinic follow-ups, the risks of unplanned HF-related hospitalization and subsequently mortality inevitably increased. The benefits of providing telemonitoring programs for HF management were recognized long before the COVID-19 pandemic. The pandemic has highlighted the urgency of adding telemonitoring-mediated care to in-person routine care for patients with HF [31]. Hong Kong is a developed city with a...
high smartphone penetration rate [28]. An effective smartphone-based telemonitoring system with a clinician-approved algorithm is a feasible and practical option for patients with HF in Hong Kong. In light of social distancing measures in the landscape of the COVID-19 pandemic, the acceptance of applying telemonitoring-mediated care is expected to highly increase at the levels of policy decision-makers, health care providers, and patients. The COVID-19 pandemic will surely catalyze the application of telemonitoring-mediated health care services in the very near future. Cost-effectiveness evaluation of telemonitoring-based medical care is therefore highly warranted to assist policy makers in the decision-making process of resource allocation.

Limitations

There are limitations to this analysis. The cohort-based Markov model simplified real-life HF events with a limited number of health states. Other factors can impact the cost-effectiveness of HF management. For instance, influenza infection is associated with increased morbidity and mortality of patients with HF [32], and the influenza infection rate has dramatically decreased since the COVID-19 outbreak in Hong Kong [33]. Further evaluation of the impact of reduced influenza infections on HF outcome measures is highly warranted. The impact of telemonitoring on HF hospitalization and all-cause mortality varied among different types of telemonitoring, as indicated by the findings of a comprehensive network meta-analysis [13]. The cost-effectiveness of telemonitoring may therefore vary subject to the specific type of telemonitoring. Some model inputs were retrieved from overseas trials, which may affect the applicability of the model results for patients with HF in Hong Kong. Vigorous sensitivity analysis was therefore conducted on all model inputs over a broad range. The base-case results were found to be robust over the variation of all model inputs in both the deterministic and probabilistic sensitivity analyses. Additionally, the adherence of telemonitoring is not a parameter ready to be transferred between different health care systems. Health care practitioners should therefore examine the adherence of local patients when implementing a telemonitoring program for patients with HF.

Conclusion

Compared to the current CUC during the pandemic alone, the addition of telemonitoring-mediated management to current care for patients with HF appears to be a highly cost-effective strategy from the perspective of health care providers in Hong Kong. Our findings provide evidence to inform decision makers on the application of telemonitoring amid the COVID-19 pandemic. Telemonitoring has long been considered as a future model of care, and the COVID-19 pandemic has fast-forwarded the application timeline of telemonitoring in clinical settings worldwide. It is expected that a mixed mode of disease management with in-person and telemonitoring-mediated care is likely to be sustained beyond the pandemic era. Further cost-effectiveness evaluations of mixed modes of care for the management of high-burden chronic diseases, such as diabetes mellitus, are highly warranted.

Conflicts of Interest

None declared.

References


Abbreviations

CUC: care under COVID-19
HF: heart failure
ICER: incremental cost-effective ratio
NYHA: New York Heart Association
QALY: quality-adjusted life-year
RR: risk ratio
WTP: willingness-to-pay
Opportunities and Challenges for Digital Social Prescribing in Mental Health: Questionnaire Study

Shivani Patel¹, MRCPsych; Gerry Craigen², MD; Mariana Pinto da Costa³,4, MD; Becky Inkster⁵,6, DPhil

¹South London and Maudsley NHS Trust, London, United Kingdom
²Department of Psychiatry, Faculty of Medicine, University of Toronto, Toronto, ON, Canada
³Institute of Psychiatry, Psychology and Neuroscience, King’s College London, London, United Kingdom
⁴Institute of Biomedical Sciences Abel Salazar, University of Porto, Porto, Portugal
⁵Department of Psychiatry, University of Cambridge, Cambridge, United Kingdom
⁶Finance and Economics Programme, The Alan Turing Institute, London, United Kingdom

Corresponding Author:
Shivani Patel, MRCPsych
South London and Maudsley NHS Trust
Denmark Hill
London
United Kingdom
Phone: 44 3228 6000 ext 1234
Email: shivaninpatel1183@gmail.com

Abstract

Background: The concept of digital social prescription usually refers to social prescriptions that are facilitated by using technology. Tools that enable such digital social prescriptions may be beneficial in recommending nonmedical activities to people with mental illness. As these tools are still somewhat novel and emerging, little is known about their potential advantages and disadvantages.

Objective: The objective of this study is to identify the potential opportunities and challenges that may arise from digital social prescriptions.

Methods: We developed a qualitative questionnaire that was disseminated through social media (Facebook and Twitter). A purposive sample targeting digital mental health experts and nonexperts was approached. The questionnaire asked participants’ views about digital social prescription; the core elements linked with a definition of digital social prescription; and the strengths, weaknesses, opportunities, and threats associated with digital social prescription.

Results: Four core elements were recommended to define the concept of digital social prescription: digital, facilitate, user, and social. The main strength identified was the possibility to rapidly start using digital social prescription tools, which were perceived as cost-effective. The main weaknesses were their poor adherence and difficulties with using such tools. The main opportunities were an increased access to social prescription services and the prevention of serious mental illness. The main threats were certain groups being disadvantaged, patients being subject to unintended negative consequences, and issues relating to confidentiality and data protection.

Conclusions: Although digital social prescriptions may be able to effectively augment the social prescriptions, a careful consideration of practical challenges and data ethics is imperative in the design and implementation of such technologies.

(J Med Internet Res 2021;23(3):e17438) doi:10.2196/17438

KEYWORDS
mental health; technology; psychiatry; mobile phone
Introduction

Background

The idea of health care professionals prescribing activities to their patients has been around since the 1990s when contemporary exercise referral schemes were first created [1]. The term social prescription has since been defined as “a means of enabling general practitioners (GPs) and other frontline health care professionals to refer people to ‘services’ in the community instead of offering only medical solutions” [2]. Social prescribing services are typically offered by voluntary and community sector organizations and usually involve a person who supports people to access local activities [3]. Examples of activities may range from traditional formalized programs such as smoking cessation programs to exercise, cooking classes, and befriending services [4-6]. The benefits of social prescribing have previously been explored, with studies suggesting a reduction in GP consultations and accident and emergency department attendance when social prescribing services are working well [7] and a reduced requirement for psychiatrists and mental health nurse consultations [8]. The term digital social prescription has previously been described as “any digital solution, technology, information or electronic system that enables social prescribing” [9].

Digital technologies have become increasingly pervasive within the society [10], and our dependence on interactive technologies for the delivery of health care has been particularly important during the global COVID-19 pandemic [11]. Interactive technologies have successfully enabled changes in human attitudes and behaviors [12,13], and the use of this technology for social prescription could offer a health benefit to our modern society. Currently, digital social prescription tools (DSPTs) used in the United Kingdom are used for patients with physical health comorbidities. DSPTs, such as those developed by Evergreen Life [14] and Elemental [15], use electronic patient records and community directory software to match nonmedical activities that have been shown to benefit a patient’s medical condition. The matching process involves using an algorithm designed to match activities to a patient based on their preferences, comorbidities, and locality. This process aims to tailor nonmedical interventions to the needs and preferences of the patient in a sophisticated and efficient manner.

Objective

The objective of this study is to collect the views of both experts and the general public on digital social prescription while focusing on the core elements that should base the concept of digital social prescription and identify the potential benefits and challenges that may arise from digital social prescriptions.

Methods

Study Design

This study includes a qualitative questionnaire (Multimedia Appendix 1) with views of both experts and nonexperts on the potential use of digital social prescriptions.

Instrument

The questionnaire started with a short introduction of digital social prescriptions, including a diagram on how it might work in practice. The questionnaire asked participants’ views of digital social prescription; the core elements linked with a definition of digital social prescription; and the strengths, weaknesses, opportunities, and threats (SWOT) associated with digital social prescription.

Data Sampling and Collection

The instrument targeted digital mental health experts and nonexperts. Experts were selected from a purposive sample of researchers who had published in the Journal of Medical Internet Research on a topic relating to digital mental health in the last 5 years and were contacted by email. Nonexperts were approached through social media platforms (Facebook and Twitter).

Data Analysis

We used content analysis [16] and the SWOT framework to analyze responses from participants. SWOT frameworks are commonly used in strategic analysis to analyze the internal (strengths and weaknesses) and external (opportunities and threats) factors relating to a project concept or idea [17]. The first author (SP) coded all the material, and the second author (MP) reviewed all the data to ensure the consistency and credibility of the coding and grouping [18].

Results

Sociodemographic Data of Participants

Our sample consisted of 22 nonexpert participants and 22 expert participants (Table 1).
Table 1. Demographics of the sample.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Expert, n (%)</th>
<th>Nonexpert, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-20</td>
<td>0 (0)</td>
<td>2 (9)</td>
</tr>
<tr>
<td>20-30</td>
<td>12 (55)</td>
<td>14 (64)</td>
</tr>
<tr>
<td>30-40</td>
<td>8 (36)</td>
<td>4 (18)</td>
</tr>
<tr>
<td>40-50</td>
<td>2 (9)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>50+</td>
<td>0 (0)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8 (36)</td>
<td>10 (45.5)</td>
</tr>
<tr>
<td>Female</td>
<td>69 (59)</td>
<td>12 (54.5)</td>
</tr>
<tr>
<td>Nonbinary</td>
<td>23 (5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Nationality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>British</td>
<td>6 (27)</td>
<td>19 (86.5)</td>
</tr>
<tr>
<td>Canadian</td>
<td>4 (18)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Indian</td>
<td>0 (0)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Greek</td>
<td>0 (0)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Dutch</td>
<td>2 (9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>American</td>
<td>8 (41.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Australian</td>
<td>1 (4.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental health professional (doctor, psychologist, or mental health worker)</td>
<td>0 (0)</td>
<td>8 (36)</td>
</tr>
<tr>
<td>Student</td>
<td>1 (4.5)</td>
<td>12 (54.5)</td>
</tr>
<tr>
<td>Researcher</td>
<td>21 (95.5)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>0 (0)</td>
<td>1 (4.5)</td>
</tr>
</tbody>
</table>

Definition of Digital Social Prescription

Expert and nonexpert participants were asked to provide a definition of digital social prescriptions. For both groups, the responses gathered identified four core elements: (1) digital, (2) facilitate, (3) user, and (4) social (Table 2).

As a result, the following definition is proposed: digital social prescription refers to social prescriptions that have been facilitated through the use of technology, such as mobile phone apps or online platforms intended to benefit its users.

We used the terms digital social prescription tools and digital platforms interchangeably to reflect the views of our participants.

The findings from our SWOT analysis are reported in Textbox 1 and Textbox 2.

Table 2. Expert participants’ (N=22) and nonexpert participants’ (N=22) responses to the question “How would you define digital social prescription?” grouped by core element.

<table>
<thead>
<tr>
<th>Participant type</th>
<th>Words from participants’ responses</th>
<th>User</th>
<th>Social</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Digital</td>
<td>Facilitate</td>
<td>Recommended as a part of health care</td>
</tr>
<tr>
<td>Expert</td>
<td>• Digital</td>
<td>• Use</td>
<td>• Prescribed by a clinician</td>
</tr>
<tr>
<td></td>
<td>• Technology</td>
<td>• Facilitate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Web-based platforms</td>
<td></td>
<td>• Recommended to patients</td>
</tr>
<tr>
<td>Nonexpert</td>
<td>• Technology</td>
<td>• Facilitate</td>
<td>• Self</td>
</tr>
<tr>
<td></td>
<td>• App</td>
<td>• Link</td>
<td>• Patients</td>
</tr>
<tr>
<td></td>
<td>• Digital platform</td>
<td>• Allow</td>
<td>• Doctors</td>
</tr>
</tbody>
</table>
**Textbox 1.** Strengths, weaknesses, opportunities, and threats analysis of responses from expert participants (n=22).

<table>
<thead>
<tr>
<th>Strengths</th>
<th>n=13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Quick to start</td>
</tr>
<tr>
<td></td>
<td>Quick to download</td>
</tr>
<tr>
<td>Easy to use</td>
<td>Intuitive for users</td>
</tr>
<tr>
<td></td>
<td>Easy to use</td>
</tr>
<tr>
<td>Social connection</td>
<td>Social connection in local area</td>
</tr>
<tr>
<td></td>
<td>Social connection in area</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weaknesses</th>
<th>n=15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of interest</td>
<td>Fatigue</td>
</tr>
<tr>
<td></td>
<td>High drop-off rate</td>
</tr>
<tr>
<td></td>
<td>Lack of continuity</td>
</tr>
<tr>
<td>Hard to use</td>
<td>Technical difficulties to use</td>
</tr>
<tr>
<td></td>
<td>Not acceptable to disadvantaged groups—lower socioeconomic groups, older people, and people with physical health comorbidities</td>
</tr>
<tr>
<td>Authenticity of participation</td>
<td>Interference from bots and trolls</td>
</tr>
<tr>
<td>Difficulty in remaining updated</td>
<td>Difficult to keep up with new technologies</td>
</tr>
<tr>
<td></td>
<td>Difficulties with maintaining lists</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>n=15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved access</td>
<td>Access for more people</td>
</tr>
<tr>
<td></td>
<td>Greater access if done equitably</td>
</tr>
<tr>
<td></td>
<td>Access to care for poorer groups in the society</td>
</tr>
<tr>
<td></td>
<td>Access for hard-to-reach groups—poor mobility and poor socioeconomic groups</td>
</tr>
<tr>
<td>Loneliness</td>
<td>Help to combat isolation</td>
</tr>
<tr>
<td></td>
<td>Target loneliness</td>
</tr>
<tr>
<td>Resource efficiency</td>
<td>Help to free up resources that can be redirected toward significant mental illness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Threats</th>
<th>n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Privacy and confidentiality relating to data</td>
<td>Privacy of data</td>
</tr>
<tr>
<td></td>
<td>Use and storage of data</td>
</tr>
<tr>
<td>Issue</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Widening the health gap (n=5)</td>
<td></td>
</tr>
<tr>
<td>- Widen the gap between those who can afford technologies and those who cannot</td>
<td></td>
</tr>
<tr>
<td>- Digital divide exacerbating health inequalities</td>
<td></td>
</tr>
<tr>
<td>Not accepted by establishment (n=1)</td>
<td></td>
</tr>
<tr>
<td>- Seen as a fad by traditional clinicians</td>
<td></td>
</tr>
</tbody>
</table>
Textbox 2. Strengths, weaknesses, opportunities, and threats analysis of responses from nonexpert participants (n=22).

**Strengths**

- **Cost (n=17)**
  - Cheap or cost-effective
  - Requires fewer human resources to be involved in the process as it uses an algorithm for matching

- **Time (n=10)**
  - Quick
  - Reduce the waiting time between patient expressing an interest and being able to start an activity

- **User experience (n=9)**
  - System more transparent for patients as they can track their social prescribing referral throughout the process
  - “On-demand” service
  - Younger generations might find it easier to engage
  - All that there is to offer in one place

- **Local (n=8)**
  - Able to easily identify activities close to patient’s location
  - Digital social prescribing will match patient with local activities, allowing patients to feel more connected to their community
  - Easy to find available activities (n=5)
  - Update activities quickly
  - Greater variety of activities and easier to keep a register

- **Efficiency (n=3)**
  - Less paperwork

**Weaknesses**

- **Difficulty in using the tool (n=19)**
  - Difficulties in using it
  - Older generation and very ill patients might find it difficult to use such tools
  - Language barriers

- **Poor engagement (n=14)**
  - People not turning up to activities
  - People not using it over longer periods
  - Not everyone understands the intended goal
  - May not be culturally appropriate

- **Lack of human connection (n=13)**
  - Patients feel they are not being listened to
  - Patients might be distrustful, lack of link worker to help with building trust
  - No function for support workers to provide guidance
  - Patient expectations for the management of problem (n=10)
  - “Tech solution” might put people off
  - People may feel this is not an appropriate response
  - Mismatch between patients’ expectations of an activity and the reality
  - People might be offended that they are asked to use a digital app instead of being able to talk to a health care professional in the first instance
- Delay in appropriate management (n=1)
  - Delay in treatment
- Problems with maintaining lists of activities (n=3)
- Problems with social prescription—directories with activities are not free of errors or comprehensive
- Community centers are paper based
- Activities do not get listed
- Cost of keeping this system updated

**Opportunities**

- Greater access (n=20)
  - Greater access to activities
  - Allow for a more widespread uptake of social prescription
- Address loneliness and social connection (n=10)
  - Improve social connections for those who are isolated
- Role in prevention (n=11)
  - Potential role in prevention of mental health disorders through strengthening social connections
  - Cheaper cost might mean rolled out earlier to help in prevention

**Threats**

- Patient protection from adverse unintended consequences (n=5)
  - Those providing activities may not have the patients’ best interests
  - No clear way that patients are being protected from outsiders
- Confidentiality and data protection (n=10)
  - Data may be sold for profit
  - Data may not be kept safe
  - Hackers may access data
- Bias (n=10)
  - Educated middle-class groups more likely to use technology to their advantage than those who need services
  - Some groups may be favored over other either through the algorithm being inherently biased or access only being available in neighborhoods who can afford to invest in a digital solution
- Not helpful for some groups (n=5)
  - Not helpful for all mental health conditions
  - Many people are not online and do not wish to be, some of the groups who need social prescribing the most are among these

**Strengths**

The expert group identified the main strength of DSPTs as being quick to start, whereas the nonexpert group perceived the main strength as their potential cost-effectiveness.

Both experts and nonexperts suggested that DSPTs would be faster to use; the nonexpert group suggested that using a digital platform would make the process of social prescription faster partly through a reduction in paperwork for those prescribing the activity. Both the expert and nonexpert groups commented on DSPTs being easy to use and having an improved user experience. Nonexpert participants suggested that reasons for these included users being able to clearly track their referral through the platforms, the platforms providing an on-demand service, and that all activity information would be consolidated in one place. They further suggested that younger people would find this way of accessing services easier to navigate than traditional methods. Both expert and nonexpert groups also suggested that DSPTs could be used to help individuals feel more connected to their local community.

The nonexpert group suggested that cost-effectiveness would be a significant advantage of DSPTs, whereas none of the expert
participants commented on their cost-effectiveness. The nonexpert group suggested that although digital social prescription would use an algorithm for matching patients, there would be fewer people who would need to be involved in the social prescription process, which may result in the process being less costly.

**Weaknesses**

Experts identified the main weakness of DSPTs as having a high dropout rate, whereas nonexpert groups were concerned that certain groups would find technology particularly difficult to use.

Both experts and nonexperts commented on the loss of interest and high dropout rates of patients using DSPTs. One expert suggested that patients may be fatigued with technology solving problems, and nonexperts additionally suggested that patients may not understand the point of DSPTs and may therefore not be motivated to continue using it. Both experts and nonexperts identified that DSPTs may be difficult for certain groups to use. These groups included older people, people with physical health disabilities, people from lower socioeconomic groups, and people with cultural or language barriers. Both experts and nonexperts also commented on the difficulty of maintaining the updated lists of local activities.

Experts commented on specific issues related to the technology used in facilitating digital social prescriptions. Experts commented on the difficulty in health care services being able to keep up with new developments in technology. They also commented on the potential interference on platforms by bots and trolls, which may affect the authenticity of participation.

Nonexperts raised concerns about DSPTs being inappropriate for those experiencing serious mental illness or where activities on offer may not be culturally appropriate. Several participants commented on digital social prescriptions resulting in a possible loss of human connection, perceived as inappropriate by patients and their families. A delay in appropriate treatment has also been cited as a potential weakness.

**Opportunities**

Both experts and nonexperts felt that the main opportunity relating to digital social prescription was an increased access to mental health care. Experts particularly felt that this may be of particular benefit to hard-to-reach groups, including those from poorer socioeconomic backgrounds or those with other physical health comorbidities. Both experts and nonexperts perceived DSPTs as a potential help to prevent loneliness and improve social connection.

One expert commented on digital social prescription helping with resource efficiency by freeing up resources that could be directed to those experiencing significant mental illness. Nonexperts considered DSPTs to play a role in the prevention of mental health disorders.

**Threats**

Both experts and nonexperts were concerned with data protection, confidentiality, and the potential monetization of data. Both experts and nonexperts also commented on the potential of bias resulting in a widening of health outcomes among different groups of individuals. This may be due to affluent middle-class individuals being the early adopters of new technology or due to the algorithms used in the DSPTs being inherently biased against certain groups. Nonexpert participants also commented that digital social prescriptions may be funded in certain areas, but this may not be the case in other areas.

Nonexperts considered that some individuals who would benefit from social prescription may not want to use new digital technologies to access activities. They also note that digital social prescriptions may not be beneficial for all mental health conditions. Some participants expressed concern regarding unintended consequences of digital social prescription; for example, if the activity involved patients volunteering at a coffee shop, then these patients may be exploited as free labor.

Experts additionally suggested that digital social prescriptions may be seen as a fad by clinicians and rejected.

**Discussion**

**Principal Findings**

From the consultation of the various participants, our study proposes a definition for digital social prescription: “Digital social prescription refers to social prescription that has been facilitated through the use of technology, such as mobile phone apps and online platforms intended to benefit users.”

The main perceived benefits of DSPTs were improved access to mental health care, fast adoption by users, and cost-effectiveness. Other perceived benefits included improved user experience, helping users feel more connected to their local communities, and potential prevention of loneliness and serious mental illness. There appeared to be significant crossover with regard to the perceived benefits of DSPTs from both experts and nonexperts. The main exception to this was cost-effectiveness, which was considered a significant benefit from nonexperts but was not commented on by the expert group.

The main challenge of DSPTs identified from our questionnaire was a poor engagement with such tools and certain groups finding the technology difficult to use. Other challenges include the DSPT being viewed as inappropriate by both patients and clinicians, certain groups being effectively excluded from using these tools, unintended negative consequences for patients, and concerns with confidentiality and data protection. Experts also commented on the difficulty faced by health care providers in keeping up with developments in technology and security, which may include issues relating to data hacking and interference from artificial intelligence–powered bots or trolls. The responses to the potential challenges from DSPT were broadly similar; however, experts emphasized the challenges of technology more than nonexperts. Interestingly, almost all the expert respondents also commented on the high dropout rates of DSPTs, which may reflect their own experiences from working in the field and their concerns with user engagement.
Strengths and Limitations

To our knowledge, this is the first qualitative study to explore the potential benefits and challenges of digital social prescription and suggests a definition of digital social prescribing that originated from such views. Our study compared the responses of a purposively selected sample of experts in digital mental health with those of nonexperts. The overall sample included a range of different ages, genders, nationalities, and occupations. By comparing the views of experts with nonexperts, we were able to identify key similarities and differences in their perspectives and views on digital social prescription, which, for the most part, were largely similar.

The main limitation of this study was that it had a small sample size. In addition, while focusing on incorporating views of experts and nonexperts (ie, the general public), there might have been other stakeholders, such as clinicians, patients, and caregivers, who we have not particularly targeted in this study. This would be an important area of further research, particularly as the use of digital tools in health care has become more prevalent. It is also worth noting that none of the expert cohort were older than 50 years, which may skew the views provided.

Comparison With the Literature

The discussion of these findings was organized to reflect the themes that emerged in our study. The themes that were mentioned most frequently are discussed first.

It is important to note that as the majority of studies relating to social prescription refer to nonpharmacological prescription of exercise (exercise groups, gym programs, etc), most of the available literature concerns nonmental health–specific social prescription programs. Nevertheless, they provide a basis for understanding some of the core discussions regarding implementation and barriers to social prescription, which may also be relevant to digital social prescribing for mental health.

A key benefit of DSPTs identified by both experts and nonexperts was improved access to mental health care. Access to mental health care is a significant issue worldwide. The Five Year Forward View of Mental Health published in 2016 identified that approximately 15% of those with anxiety and depression were being seen by Improving Access to Psychological Therapy services [19]. The provision of services in low- and middle-income countries is even more sparse, with estimates suggesting that up to 90% of individuals living with mental health disorders are receiving no mental health care [20]. Access to smartphones has been a global phenomenon, and there has been considerable interest in delivering mental health care through mobile phone technology [21]. Young people have been shown to adopt new technologies quickly and to use mobile phone technology in the event of sickness, personal health crises, or in response to health concerns of others [22]. In the United Kingdom, a majority of mental health conditions are managed through primary care, and it has been suggested that the use of technology may allow for more options of self-referral with automated or semiautomated interventions, thereby improving access [23].

Cost-effectiveness was perceived as one of the main benefits of digital social prescriptions by nonexpert participants in this study. Cost-effectiveness and social prescriptions have been a hotly debated topic over the past decade. Some studies have indicated that social prescription may result in fewer hospital and GP appointments, thereby translating into reduced costs for the National Health Service [7]. However, critics have suggested that there is a poor evidence for sustained improved health care outcomes [24,25] and that social prescription programs that have demonstrated positive health outcomes incur a higher cost than traditional care [26]. A systematic review of physical activity interventions in primary care showed that interventions ranged from £304 (US $425) to £75,982 (US $106,346) per quality-adjusted life year depending on the scheme intensity [27]. Digital social prescription may provide a greater efficiency in some respects to matching individuals with activities, but if the bulk of the cost depends on how individual programs are run, then the use of a digital platform may only have a marginal effect on costs for social prescription programs.

One of the main barriers in assessing social prescription programs is that the programs delivered by third-sector organizations often have limited funding, and it is therefore difficult to gather data on outcomes over a sustained period [28]. It is likely that this same problem will exist with digital social prescribing programs, as the activities that are matched with patients would also be largely provided through third-sector organizations.

Interestingly, the study participants did not comment on the intrinsic benefits and functionality that technology may have beyond being quick and easy to use. A review conducted by Husk et al [29] did not identify speed and efficiency as important factors leading to the successful use of social prescription programs, and human factors such as support from their link worker or practical support, such as free travel for activities, mattered much more to participants. There may, however, be opportunities provided by using digital means to access social prescriptions. Hollis et al [30] described the potential of mobile phone apps having embedded validated measures such as the Patient Health Questionnaire-9 depression scale as well as the option for patients to track their symptoms over time. With respect to DSPTs, this may also mean that large amounts of user data that can be used to evaluate the effectiveness of these tools can be collected quickly and accurately.

Adherence to DSPTs was identified as the main challenge by both experts and nonexperts. Indeed, adherence to traditional social prescription programs has also been shown to be challenging. Pavey et al [31] conducted a systematic review of the uptake and adherence to exercise referral schemes, which are the most common social prescription in the United Kingdom. They identified that the pooled level of adherence to exercise referral schemes was only 49% in observational studies and 43% in randomized controlled trials. In studies examining factors that improve adherence to social prescription programs, the relationship between navigators and patients has been shown to be one of the most important factors facilitating social prescription [32,33]. The skill of those conducting the activity also appears to be an important factor for adherence [34,35] as well as patients being able to see positive results from undertaking activities [36]. Given the existing literature, one can assume that a purely digital social prescription platform, in
which there is no direct human contact, may result in even poorer adherence. However, a digital platform may allow participants to record key data, such as sleep and mood, and improvements in these parameters may improve adherence.

Several barriers to using digital social prescriptions were also described. Cultural and religious factors are likely to play an important role in determining whether a social prescription will be effective. In several cultures, seeking help for mental health conditions can often be stigmatizing [37], and some activities such as mixed-sex swimming may be seen as inappropriate in the context of an individual’s culture. Language may also be a significant barrier in allowing individuals to participate in a prescribed activity if the DSPT is only available in English. In addition, digital barriers were also described by participants. Older people in the United Kingdom have been shown to experience high rates of loneliness as compared with other groups in the society [38]; however, official Office for National Statistics data in 2019 showed that from those aged ≥75 years who participated in the survey, less than half used the internet [39]. Ethnicity has also been shown to contribute to the digital divide, with studies showing that Black, minority, and ethnic backgrounds are more likely to access computers outside their own homes as compared with White individuals [40]. This brings with it the challenge of ensuring adequate privacy in engaging with internet-based content related to an individual’s mental health.

Data protection and information sharing are important factors to consider in digital social prescriptions. It also appears to be a concern for consumers. In a 2017 survey, confidence in the data security of technology companies declined from 31% in 2016 to 24% in 2017 [41]. Confidentiality is an important tenet of medicine; however, in practice, there are many scenarios in which information sharing between parties is necessary to provide the best care for a patient. Guidelines relating to social prescription have indicated that it is the responsibility of the referrer to transfer any relevant information to the person conducting the nonmedical activity [42]. Despite this, survey data [41] have indicated that patients are much more averse to sharing their data with nonphysicians, even if these parties are integral to the delivery of patient care. Clear guidelines explaining how data are used and stored would be required to ensure that the consent from patients is valid. It would also be necessary to consider how these security rules would be enforced and what remedies should be offered to those affected by security breaches.

Algorithmic programming is central to the apps that we use today and is likely to be used in the development of a DSPT. These algorithms might result in potential race discrimination, gender discrimination, and ageism [43, 44]. This may also be an important consideration with regard to a DSPT. Existing psychiatric risk assessment tools that have been shown to have poor accuracy [45] may be integrated into digital social prescribing software, further resulting in an effective discrimination against certain groups. Furthermore, clinicians who may be involved in designing these tools may introduce their own biases, which could include greater patient restrictions, particularly for those of certain ethnic backgrounds [46]. Organizations, including the Open Data Institute, are considering the potential ethical implications arising from the use of digital tools and have suggested the use of ethical frameworks such as the Data Ethics Canvas [47] to address these issues.

Although there have been no known studies directly looking at the unintended consequences of digital social prescription, bridging the online and offline worlds can create risks, and in cases where things might go wrong, liability may be an issue for both clinicians and software developers. There has been some discussion of the potential negative consequences relating to social prescription [48], which includes patients becoming stressed by the commitment required or becoming so consumed in an activity that they neglect other key aspects of their life and well-being.

Implications for Practice, Research, and Policies

DSPTs may be a helpful method for delivering nonmedical activities to those with mental illness. There are various types of DSPTs with their differences, although with a commonality of providing patients with nonmedical activities that are available in a patient’s local area. The use of such DSPTs may result in greater accessibility of activities for patients and may be more cost-effective than traditional social prescription methods.

There are several challenges associated with digital social prescriptions. First, digital social prescriptions may not be appropriate for all patients. A careful consideration of symptomatology and patient expectations must be considered before making any universal recommendations. Barriers to using digital social prescriptions are likely to exist. This may include cultural and language barriers, difficulty with using the technology due to unfamiliarity, or difficulty with using the platform due to physical impairment. Cost may also be a prohibitive factor. These barriers need to be studied in more detail, and steps should be taken to improve access to digital social prescriptions. Issues relating to patient confidentiality and data protection are likely to arise in the development of DSPTs. These issues should be considered at every stage of the development and implementation of digital social prescription programs.

Although digital social prescriptions may be of benefit to patients, there is not enough evidence to substantiate this. Research looking at short-term and long-term outcome measures, such as clinical impact and cost-effectiveness, is required to identify the true benefit. Given that adherence to DSPTs was identified as the main perceived challenge, research into how adherence may be improved would also be important. On the basis of the data collected from this research, decisions can be made as to whether DSPTs should be used more widely in mental health care.

Conclusions

Digital social prescriptions may be able to provide important opportunities and help to reduce the burden of distress in patients. Important patient considerations ranging from the appropriateness of an activity to patient discrimination will need to be carefully considered in the design and implementation of this technology. More evidence is needed to further support the advancement of digital social prescribing, but with more
risperous research and respect for data ethics, this may be a significant advancement in 21st century medicine.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Digital social prescribing questionnaire used in the study.

References
15. Elemental. URL: https://elementalsoftware.co [accessed 2019-04-04]


### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSPT</td>
<td>digital social prescription tool</td>
</tr>
<tr>
<td>GP</td>
<td>general practitioner</td>
</tr>
<tr>
<td>SWOT</td>
<td>strengths, weaknesses, opportunities, and threats</td>
</tr>
</tbody>
</table>

©Shivani Patel, Gerry Craigen, Mariana Pinto da Costa, Becky Inkster. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 09.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Informatics Methodology Used in the Web-Based Portal of the NASCITA Cohort Study: Development and Implementation Study

Michele Zanetti1, BEng; Antonio Clavenna1, MD; Chiara Pandolfini1, PhD; Claudia Pansieri1, PharmD; Maria Grazia Calati1, HS; Massimo Cartabia1, StatSc; Daniela Miglio1, HS; Maurizio Bonati1, MD
Laboratory for Mother and Child Health, Department of Public Health, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy

Corresponding Author:
Chiara Pandolfini, PhD
Laboratory for Mother and Child Health
Department of Public Health
Istituto di Ricerche Farmacologiche Mario Negri IRCCS
Via Mario Negri 2
Milan, 20156
Italy
Phone: 39 02 3901 4478
Email: chiara.pandolfini@marionegri.it

Abstract

Background: Many diseases occurring in adults can be pinned down to early childhood and birth cohorts are the optimal means to study this connection. Birth cohorts have contributed to the understanding of many diseases and their risk factors.

Objective: To improve the knowledge of the health status of Italian children early on and how it is affected by social and health determinants, we set up a longitudinal, prospective, national-level, population-based birth cohort, the NASCITA study (NAscere creScere in ITAlia). The main aim of this cohort is to evaluate physical, cognitive, and psychological development; health status; and health resource use in the first 6 years of life in newborns, and potential associated factors. A web-based system was set up with the aim to host the cohort; provide ongoing information to pediatricians and to families; and facilitate accurate data input, monitoring, and analysis. This article describes the informatics methodology used to set up and maintain the NASCITA cohort with its web-based platform, and provides a general description of the data on children aged over 7 months.

Methods: Family pediatricians were contacted for participation in the cohort and enrolled newborns from April 2019 to July 2020 at their first well-child visit. Information collected included basic data that are part of those routinely collected by the family pediatricians, but also parental data, such as medical history, characteristics and lifestyle, and indoor and outdoor environment. A specific web portal for the NASCITA cohort study was developed and an electronic case report form for data input was created and tested. Interactive data charts, including growth curves, are being made available to pediatricians with their patients’ data. Newsletters covering the current biomedical literature on child cohorts are periodically being put up for pediatricians, and, for parents, evidence-based information on common illnesses and problems in children.

Results: The entire cohort population consists of 5166 children, with 139 participating pediatricians, distributed throughout Italy. The number of children enrolled per pediatrician ranged from 1 to 100. The 5166 enrolled children represent 66.55% (5166/7763) of the children born in all of 2018 covered by the same pediatricians participating in the cohort. The number of children aged over 7 months at the time of these analyses, and for whom the most complete data were available upon initial analyses, was 4386 (2226/4381 males [50.81%] and 142/4370 twins [3.25%]). The age of the mothers at birth of the 4386 children ranged from 16 to 54 years. Most newborns’ mothers (3758/4367, 86.05%) were born in Italy, followed by mothers born in Romania (101/4367, 2.31%), Albania (75/4367, 1.72%), and Morocco (60/4367, 1.37%). Concerning the newborns, 138/4386 (3.15%) were born with malformations and 352/4386 (8.03%) had a disease, most commonly neonatal respiratory distress syndrome (n=52), neonatal jaundice (n=46), and neonatal hypoglycemia (n=45).

Conclusions: The NASCITA cohort is well underway and the population size will permit significant conclusions to be drawn. The key role of pediatricians in obtaining clinical data directly, along with the national-level representativity, will make the findings even more solid. In addition to promoting accurate data input, the multiple functions of the web portal, with its interactive platform, help maintain a solid relationship with the pediatricians and keep parents informed and interested in participating.

Trial Registration: ClinicalTrials.gov NCT03894566; https://clinicaltrials.gov/ct2/show/NCT03894566

https://www.jmir.org/2021/3/e23087
Introduction

It is well known that many diseases occurring in adults can be traced back to early childhood [1,2]. In fact, nearly all domains of later health experience, including cardiovascular and respiratory disease, cognitive decline, and psychological health, have been associated with early life exposures [3]. Many different factors in childhood play a role in future health inequalities between individuals, from socioeconomic status to parental care, to lifestyle factors, but the way they are related is uncertain.

Birth cohort studies are studies that follow a group of newborns for an extended period in order to assess possible associations between exposures in early life and later health. Northern Europe has a long-lasting tradition in birth cohorts [4,5], starting from as far back as 1921 [6]. Findings from these studies have led to important knowledge in different fields, contributing to the understanding of multiple diseases and their risk factors [7,8]. These studies have also set the basis of our positive daily health behaviors. The Avon Longitudinal Study of Parents and Children (ALSPAC), for example, showed that eating oily fish during pregnancy was associated with better eye and cognitive development in children [9].

Numerous large- and small-scale birth cohorts have been set up, also in the past decade, not only in Europe but all around the world [10]. Characteristics vary greatly from one cohort to another in terms of design, objectives, size, and duration of follow-up.

Since 2003, several cohorts have also been carried out in Italy. Most of them have general aims, with data collection limited in time or to specific geographical contexts [11-19]. Italy is a special country with a public, universal health care system that should be equally accessible to all, but considerable health inequalities exist [20,21]. Up to now, no national-level birth cohort has been set up that included a large sample of the pediatric population independent of socioeconomic status or other types of limitation, such as gestational age. The Piccoliπ cohort [17], for example, recruited newborns from northern and central Italy; the NINFEA cohort [16] population was limited to women who had enough knowledge of the internet to complete online questionnaires; and the ICON cohort [19] selected preterm newborns and enrolled additional newborns of later gestational age.

In order to improve the knowledge of the health status of Italian children early on and how it is affected by social and health determinants, we set up a longitudinal, prospective, national-level, population-based birth cohort, the NASCITA study (NAscere e creSCere in ITAlia) [22]. Like many other cohorts, it addresses multiple research questions [16,17]. NASCITA is unique, however, in terms of characteristics, methodology, and population size. The findings will add important evidence, in terms of epidemiological data, for the development of specific prevention measures and interventions to improve the health status of children.

The main aim of the NASCITA cohort is to evaluate physical, cognitive, and psychological development, and health status and health resource use during the first 6 years of life in a group of newborns, and to evaluate potential associated factors.

The peculiarity of NASCITA is that data collection is designated to the general pediatricians, fitting itself into the Italian public health care system, as data reported in NASCITA are part of those routinely collected by the family pediatricians at the well-child visits. Furthermore, the data are equally distributed throughout the Italian territory.

A website and web-based system [23] were set up in order to host the cohort, provide ongoing information to pediatricians and to families, and facilitate data input on the part of the pediatricians. The system was also designed to optimize data accuracy, minimize missing data, and permit data monitoring, analysis, and reporting throughout the duration of the cohort.

This article describes the informatics methodology used to set up and maintain the NASCITA cohort with its web-based platform, and provides a general description of the participant characteristics.

Methods

Cohort Organization

NASCITA is embedded in Italian pediatric primary care practice. Data collection for the NASCITA cohort occurs for the most part during the 7 well-child visits planned for each child. The majority of the participating pediatricians are part of the national Pediatric Cultural Association (ACP), an association with about 2000 members consisting mainly of family pediatricians and with which the coordinating center has collaborated over the years. Participation was proposed to the ACP and forms the basis of pediatrician participation in the study. Pediatrician participation was voluntary and for free. Collaboration was also expanded through contact with other pediatric scientific societies and associations. Meetings were held during 2018 to present the study to a group of pediatricians acting as local representatives. Each representative then asked other pediatricians working in their area (at the local health unit or regional levels) to participate. Pediatrician enrollment was monitored and discussed with the local representatives. A scientific committee was set up to supervise the project, and includes professionals and lay people from different fields of expertise.

At the start of the study, there were 7960 cities/towns in Italy. These were classified into 21 geographic clusters (Figure 1), identified based on geographic and administrative criteria used by the Italian National Statistics Institute (ISTAT) [24]. More specifically, these take into consideration geographic area (north, center, south), setting (urban, rural), and land characteristics.
(plain, mountain, sea). Four cities were also selected (Milan, Rome, Bari, and Palermo), covering the different geographic areas and the islands.

Enrollment of newborns began in April 2019 and ended in July 2020. Recruitment of the newborns (and their parents) took place during the first routine well-child visit scheduled for all newborns in Italy within their first 45 days of life. All newborns assigned to the participating pediatricians were enrolled if parental consent was given. Pediatricians chose when to begin enrolling their newborns and continued to enroll for (at least) a 1-year period. Follow-up of the children will continue until at least the age of 6 years.

A minimum recruitment of 5000 newborns was calculated in order to have enough power to study common childhood exposures and outcomes.

In this article we present the characteristics of the children aged over 7 months at the time of analyses in order to provide more complete data, as pediatricians would have had time to fill in most missing data for these participants.

Figure 1. The 21 geographic clusters, identified based on ISTAT geographic and administrative criteria. ISTAT: Italian National Statistics Institute.

Ethics
Parents were given oral and written information about the study and a consent form to sign if interested in participating. Pediatricians signed a consent form before participation as well. Withdrawal from the study was guaranteed at any time to both pediatricians and parents.

Data Collection
Italian health care is provided free or at a nominal charge through a network of 148 local health units. The local health units assign children to a family pediatrician until they are 6 years old, after which the children can be registered with a general practitioner or remain with that pediatrician until they are 14 years old. In Italy there are about 7500 family pediatricians, for an average of 450,000 births/year [25], so about 60 newborns/year are assigned to each pediatrician. All children are scheduled 7 well-child visits at the pediatrician’s office during their first 6 years of life to ensure necessary preventive care and monitor a child’s growth and development.

Basic data are being collected and consist of data that are part of those routinely collected by the family pediatricians at the well-child visits. Some data will also be collected during each extra contact with the enrolled children. Data collection also involves parental data, such as medical history, characteristics and lifestyle, indoor and outdoor environment, and circumstances during pregnancy and around birth. Follow-up data on children will cover different fields, including physical and mental/cognitive development, nutrition and allergies, environmental exposures, and preventable infectious diseases. See Table 1 for a description of the main parts of the questionnaire. Questions were added to allow the project, in a second phase, to address specific areas such as nutrition, environment, and nurturing care.
### Table 1. Main sections of the online questionnaires and description of the general data collected.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal data</td>
<td>Name, place of birth, family data such as number of family members, sibling health, parental place of birth, allergies</td>
</tr>
<tr>
<td>Medical history</td>
<td>Mother’s pregnancy data (including medicines, smoking and alcohol consumption, and reading out loud and listening to music), birth data (eg, newborn height, weight), perinatal medical history (eg, malformations, diseases, transfer to an intensive care unit), breastfeeding status at discharge</td>
</tr>
<tr>
<td>Visits 1-7</td>
<td>Medicines taken, anthropometric measures; breastfeeding status/weaning/nutrition; sleep data; age-appropriate physical examination; vitamin D + K prophylaxis; psychomotor, neurologic, and cognitive development; general health; paternal depression; language development; family habits (eg, smoking, reading out loud, listening to music, nursery school, indoor and open-air activities); home proximity to traffic or to areas of intensive farming; screen time</td>
</tr>
<tr>
<td>Extra visits</td>
<td>Type of contact (office, phone, home visit), diagnosis, medicines/specialist visits/examinations prescribed</td>
</tr>
<tr>
<td>Vaccination compliance</td>
<td>Vaccines received and adverse reactions</td>
</tr>
<tr>
<td>Exiting the cohort</td>
<td>Reason for exit (transfer, pulled out of study, death)</td>
</tr>
</tbody>
</table>

### Statistical Analysis

The analyses of the cohort data will evaluate specific research questions related to the overall aims of the study, such as the relationship between child development and the domains that affect nurturing care during the preschool period including health, nutrition, and caregiving routine; the association between the well-being of children and parental adherence to the recommendations for better child care and development; and the differences between geographical settings in educational and socialization opportunities available and in the care provided by the family pediatricians.

Data are presented as frequencies, percentages, and mean (SD) or median values. Percentages are based on denominators for which missing values have been excluded. All data management and analyses have been performed using SAS version 9.4 (SAS Institute) and ArcMap version 10.5 (ESRI). More detailed analyses will be performed, as specified in the protocol [22], and reported in future articles.

### Web Portal

A specific web portal for the NASCITA cohort study was developed [23] with reserved sections for the coordinating center, registered users, and participating pediatricians. The web portal serves to assist pediatricians with data collection and to provide findings and other information during the study period to parents and pediatricians, also with the use of graphics for the analyses and data collected, based on a successful approach already reported by the coordinating center [26]. Selected sections of the portal have been translated into English. See Figure 2 for the functions of the web portal and its architecture.

Newsletters focused on child cohorts are periodically provided in the pediatrician’s general area and contain bibliographic information of the current biomedical literature. In the private area, each participating pediatrician can access information including cohort documents; frequently asked questions; the study protocol; and pdf versions of the case report forms (CRFs); as well as patient data for input/modification; interactive data charts of his/her patients or of those of the entire cohort, including growth curves (Figure 3); and data concerning subsections of the cohort addressing areas such as nutrition and environment in which he/she participates. The pediatrician’s section on the web portal, together with individual telephone calls with the pediatricians and online and in-person meetings on the study’s progress and possible problems, serves to keep pediatricians engaged in the study.

The information for the parents section contains a growing series of cards, created in collaboration between health professionals and parents, that provide evidence-based information on the more common illnesses and problems in young children as well as answers to common questions that parents have on child care. This section also contains links to useful emergency telephone numbers and information pages.
Electronic Case Report Form

The CRF was created and tested together with a group of pediatricians. An electronic CRF (eCRF) was then set up and tested, again with the help of the pediatricians, before enrollment began. More specifically, the pediatricians were asked to register themselves and access the portal starting from January 2019 to test it. The eCRF (Figure 4) was set up in such a way as to facilitate the pediatricians’ input of data for the study and to provide fast and efficient support for any problems or doubts about data input. A “chat” section was consequently included through which pediatricians can ask for support. The eCRF

Figure 2. Functions of the platform and its architecture.

Figure 3. Individual child’s data plotted on growth curve, as seen by the pediatrician.
includes consistency and range checks to prevent internal inconsistencies (e.g., value ranges, fields with limited values, and time ranges). Data are, in any case, monitored continuously and irregularities resolved through email, chat, or phone contact with the pediatricians.

The eCRF has been structured in a way that will permit data collection to be expanded to cover the additional areas (e.g., nutrition) more thoroughly in a second phase; the different data collection sections are, in fact, based on an XML definition that can easily be implemented and modified [27].

The development engine of the eCRF has been made available on Gitlab [28].

A test was performed with a group of pediatricians (including those with less experience in using the computer) to assess the additional amount of time it would take each pediatrician to enter data for a patient throughout the duration of the study. Entering data for the first follow-up visit took about 15 minutes. Multiplying this by the average number of newborns per pediatricians and, considering that after 3 months of the start of the study the subsequent regular check-ups would begin, an average of 3 hours a month in the first year was calculated, after which the amount of time necessary would decrease.

**Figure 4.** eCRF screenshots: input for second visit.

---

**Data Quality Control**

A dashboard is dedicated to checking the completeness, or lack, of the visits and displays a table listing the children for whom data have been included by that pediatrician. Each column in the table represents a specific visit and shows a series of colored bells (green, yellow, or red) that indicate the completeness status of the visit (Figure 5). When a pediatrician opens the data on a specific visit, the system displays a list of the variables with missing information in order to facilitate data completion.

Frequent reports will automatically be created to monitor recruitment of pediatricians and children and the data inputted. Individual and group reports will also be created for the pediatricians and for the study’s scientific committee.
Data Security

The private area is accessible only through authentication by pediatricians, who have been previously approved and enabled. A specific role is assigned to them, for example, compiler. Passwords must have at least eight characters and contain special and uppercase characters. Each pediatrician with a compiler role can insert their patients’ data. Sensitive data, such as name and last name, are encoded and visible only to the compiler. Once the data are saved, they are transmitted via secure HTTPS protocol, and are stored in databases that can be accessed only by authorized project staff (IT, statisticians). Back-ups are kept for security and disaster recovery.

Results

Enrollment in the NASCITA cohort began on April 1, 2019, and ended on July 31, 2020. The number of participating pediatricians is 139 and the total number of children enrolled is 5166. The pediatricians are distributed throughout Italy, with 68 in the north, 29 in the center, and 42 in the south. The 5166 children enrolled represent 66.55% (5166/7763) of the children born in all of 2018 covered by these same pediatricians. The total number of children aged over 7 months at the time of these analyses was 4386. Of these children, excluding those with missing data, 2226/4381 (50.81%) were male and 142/4370 (3.25%) were twins. The children were distributed throughout Italy, with 2025/4386 (46.17%) in the north, 882/4386 (20.11%) in the center, and 1479/4386 (33.72%) in the south. Table 2 reports the distribution of the number of these 4386 children enrolled and the percentage of children born, by cluster and geographic area, based on ISTAT data [24], and shows that there are minimal differences. The number of children enrolled per pediatrician ranged from 1 to 100 (mean 32 [SD 18.5]; median 30).

The age of the mothers at birth of the 4386 children ranged from 16 to 54 (mean 33 [SD 5.4] years; median 33 years, excluding 133 missing values), while the age of the fathers ranged from 17 to 69 (mean 36 [SD 6.3]; median 36, excluding 154 missing values). Most of the newborn’s mothers (3758/4367, 86.05%) were born in Italy; the 3 next most common countries were Romania (101/4367, 2.31%), Albania (75/4367, 1.72%), and Morocco (60/4367, 1.37%). For two-thirds of children (2892/4320, 66.94%), the mothers were married or living in civil union; for 1233/4320 children (28.54%), the mother was living with the father; and for 167/4320 (3.87%), mothers were single. Most of the children’s mothers had a university (1813/4320, 41.96%) or high-school degree (1800/4320, 41.66%), followed by a middle-school diploma (675/4320, 15.63%) and an elementary (30/4320, 0.69%) level of education. Family size (including the enrolled child) was grouped into 2, 3, 4, or >4 people, with half (2189/4311, 50.78%) of the families being made up of 3 people, followed by 1567/4311 (36.35%) made up of 4 people. Two-member families represented 1.43% (62/4311) of the total. Concerning the pregnancies, 3741/4363 (85.74%) were physiologic pregnancies, while in the remaining pregnancies gestational diabetes (203/622 mothers, 32.64%), gestational hypertension (90/622, 14.47%), and preeclampsia (41/622, 6.59%) were the most common diseases. Concerning the newborns, 139/4340 (3.20%) were born with malformations and 352/4335 (8.12%) had a disease, the 3 most common of which were neonatal respiratory distress syndrome (n=52), neonatal jaundice (n=46), and neonatal hypoglycemia (n=45).
### Table 2. Distribution of the number of children and the number of children born in each cluster and geographic area.

<table>
<thead>
<tr>
<th>Distribution/Location</th>
<th>Children enrolled, n (N=4386)</th>
<th>Population enrolled, n (%)</th>
<th>Births per year in Italya, n (%)</th>
<th>Difference between the third and fourth columns, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metropolis: Milan</td>
<td>184</td>
<td>184/4386 (4.20)</td>
<td>11,267/467,640 (2.41)</td>
<td>1.79</td>
</tr>
<tr>
<td>Metropolis: Rome</td>
<td>428</td>
<td>428/4386 (9.76)</td>
<td>21,497/467,640 (4.60)</td>
<td>5.16</td>
</tr>
<tr>
<td>Metropolis: Bari</td>
<td>70</td>
<td>70/4386 (1.60)</td>
<td>2214/467,640 (0.47)</td>
<td>1.13</td>
</tr>
<tr>
<td>Metropolis: Palermo</td>
<td>62</td>
<td>62/4386 (1.41)</td>
<td>5578/467,640 (1.19)</td>
<td>0.22</td>
</tr>
<tr>
<td>North: urban mountain</td>
<td>b</td>
<td>—</td>
<td>2243/467,640 (0.48)</td>
<td>-0.48</td>
</tr>
<tr>
<td>North: urban plain</td>
<td>304</td>
<td>304/4386 (6.93)</td>
<td>45,595/467,640 (9.75)</td>
<td>2.82</td>
</tr>
<tr>
<td>North: urban sea</td>
<td>93</td>
<td>93/4386 (2.12)</td>
<td>10,258/467,640 (2.19)</td>
<td>0.07</td>
</tr>
<tr>
<td>North: rural mountain</td>
<td>228</td>
<td>228/4386 (5.20)</td>
<td>25,274/467,640 (5.40)</td>
<td>-0.20</td>
</tr>
<tr>
<td>North: rural plain</td>
<td>1151</td>
<td>1151/4386 (26.24)</td>
<td>112,824/467,640 (24.13)</td>
<td>2.11</td>
</tr>
<tr>
<td>North: rural sea</td>
<td>60</td>
<td>60/4386 (1.37)</td>
<td>5882/467,640 (1.26)</td>
<td>0.11</td>
</tr>
<tr>
<td>Center: urban plain</td>
<td>61</td>
<td>61/4386 (1.39)</td>
<td>6330/467,640 (1.35)</td>
<td>-0.04</td>
</tr>
<tr>
<td>Center: urban sea</td>
<td>1</td>
<td>1/4386 (0.02)</td>
<td>5339/467,640 (1.14)</td>
<td>-1.12</td>
</tr>
<tr>
<td>Center: rural mountain</td>
<td>90</td>
<td>90/4386 (2.05)</td>
<td>13,887/467,640 (2.97)</td>
<td>-0.92</td>
</tr>
<tr>
<td>Center: rural plain</td>
<td>233</td>
<td>233/4386 (5.31)</td>
<td>31,997/467,640 (6.84)</td>
<td>-1.53</td>
</tr>
<tr>
<td>Center: rural sea</td>
<td>68</td>
<td>68/4386 (1.55)</td>
<td>11,118/467,640 (2.38)</td>
<td>-0.83</td>
</tr>
<tr>
<td>South: urban mountain</td>
<td>8</td>
<td>8/4386 (0.18)</td>
<td>4010/467,640 (0.86)</td>
<td>-0.68</td>
</tr>
<tr>
<td>South: urban plain</td>
<td>136</td>
<td>136/4386 (3.10)</td>
<td>15,826/467,640 (3.38)</td>
<td>-0.28</td>
</tr>
<tr>
<td>South: urban sea</td>
<td>421</td>
<td>421/4386 (9.60)</td>
<td>27,281/467,640 (5.83)</td>
<td>3.77</td>
</tr>
<tr>
<td>South: rural mountain</td>
<td>98</td>
<td>98/4386 (2.23)</td>
<td>21,932/467,640 (4.69)</td>
<td>-2.46</td>
</tr>
<tr>
<td>South: rural plain</td>
<td>421</td>
<td>421/4386 (9.60)</td>
<td>47,026/467,640 (10.06)</td>
<td>-0.46</td>
</tr>
<tr>
<td>South: rural sea</td>
<td>255</td>
<td>255/4386 (5.81)</td>
<td>40,262/467,640 (8.61)</td>
<td>-2.80</td>
</tr>
<tr>
<td>Missing</td>
<td>14</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

aBased on data on the newborn population residing in the cluster on January 1, 2017. ISTAT demographic statistics data [24] referring to December 31, 2016, were used for clusters with missing data.

b—: not available.

### Discussion

#### Considerations

The NASCITA cohort is based on community-level pediatric practice, involving the family pediatricians directly, as very few European cohorts do [29]. With their clinical practice, pediatricians are most in contact with patients and can promote study and action. Their involvement in child cohorts permits the collection of prospective, community-level data and allows them to contribute to optimizing both the quality of the data collected and its re-investment back into the community as health promotion interventions. In fact, pediatricians play a key role both in educating families and in implementing curative and disease prevention interventions through their routine clinical practice. They are in the optimal position to influence public health in general because adult health also depends on habits embraced when young, and pediatricians can undoubtedly influence children and their parents to adopt healthy lifestyles.

In order to give something back to the pediatricians participating in the cohort, we have attempted to provide the pediatricians with useful information and interesting data, such as the interactive data charts of their patients. The system set up through which pediatricians can easily and quickly contact the cohort team for any questions or problems, and the periodic meetings organized to update pediatricians on the cohort’s status and to discuss any current issues or suggestions are additional ways to show our appreciation for all their continuing efforts. During the latest meeting we had with the participating pediatricians, online in November 2020, we described the enrolled population as it was just after enrollment closure and the next steps. On this occasion several pediatricians provided additional suggestions for improving input, resulting in the message to all that their participation and efforts are ongoing and continue to be acknowledged by the research team.

Recruitment of newborns took place over a period of 1 year for each pediatrician. This time span permitted us to avoid introducing bias related to the period of recruitment, for example, by recruiting newborns born during one season as opposed to another. The sample of children aged over 7 months reflects the distribution of births in Italy in terms of both geographic area (north, center, and south) and 21 clusters, based on the ISTAT data. Collection of data at the national level will
permit the identification of differences in health care quality, such as those caused by socioeconomic inequalities present between the north and south of Italy [30], and of differences in family behaviors that influence child health status (eg, smoking or reading out loud to children). Better identifying health care–related inequalities will permit the channeling of resources where they are most needed [31]. If funding is obtained, the population enrolled could be expanded further.

As explained previously, the web portal has multiple functions and is fundamental for several reasons. The innovative aspects involve permitting the accurate input and monitoring of data through the use of a tool that creates data collection based on an xml definition, and providing pediatricians with interactive charts of current data to share with the children’s parents. This xml-based system allows a continuous and simple updating of the CRF, saving a lot of time in the development and testing phase. In addition, saving the data in the JavaScript Object Notation (JSON) format allows greater flexibility in the database structure which, therefore, does not need to be remodeled at each CRF update [32].

Furthermore, our idea for the future is to interconnect the portal with apps for parents to use to access data and to provide additional information.

**Strengths and Limitations**

This is one of a very limited number of child cohorts based on the participation of family pediatricians, permitting the collection of data by those directly involved with the children and the implementation of findings to inform and help those directly involved (the children and their families). Furthermore, the large, representative population sample of newborns throughout the country, which allows stratified trends based on socioeconomic and geographic characteristics to be performed, and the use of standard measurements for anthropometric and neurocognitive parameters are among the strengths of this study.

A limit of the NASCITA cohort is that it does not collect biological samples due to the costs of data collection and storage, so it will not be able to evaluate genetic or immunological factors, for example. Resources and efforts were utilized, however, to achieve the largest population size possible in order to have enough power to study relatively common child exposures and outcomes. Another limitation is the potential bias in the pediatrician population because participation was voluntary and this may have led more motivated pediatricians to participate than others.

**Conclusions**

The NASCITA cohort is well underway and its population size will permit significant conclusions to be drawn. The key role of pediatricians in obtaining clinical data directly, along with the national-level representativity, will make the findings even more solid. In addition to promoting accurate data, the multiple functions of the web portal, with its expanding, interactive platform, will help maintain a solid relationship with the pediatricians and keep parents informed and interested in participating.

**Acknowledgments**

The authors thank all the participating pediatricians and committee members for their work and dedication. We also thank Davide Bazzi and Massimo Vitali for assistance in creating and in the support of servers, databases, and back-up system. No direct funding was received. The costs were covered by resources from the Laboratory for Mother and Child Health and by an economic contribution by the Associazione Amici del Mario Negri and by 2 anonymous donors, all of whom we wish to thank.

**Authors’ Contributions**

MB, AC, and C Pansieri conceptualized the study, designed the web portal, and designed the CRF. AC, C Pandolfini, C Pansieri, and DM tested the CRF. MZ created the web portal, the eCRFs, and the interactive charts system. AC, MC, and C Pansieri coordinated and monitored data collection. MGC collaborated in assisting the pediatricians with data input problems and managed email and phone communication with pediatricians and with the technical and scientific committees. MC carried out the analyses. DM and C Pansieri were responsible for merging requests for modifications and corrections to the CRFs during testing, for re-testing them, and for creating the layout with data check and limit specifications for transformation into the electronic version. DM was responsible for website content and created the information cards for parents and the newsletters for the pediatricians. C Pandolfini wrote the first draft of the manuscript. All authors interpreted data and critically reviewed and revised the final manuscript as submitted. All authors agree to be accountable for aspects of their contribution to the work. MB is the guarantor.

**Conflicts of Interest**

None declared.

**References**


7. Framingham Heart Study. URL: https://framinghamheartstudy.org/ [accessed 2021-02-16]

8. Nurses’ Health Study. URL: https://www.nurseshealthstudy.org/ [accessed 2021-02-16]


10. BirthcoHORTs.net. URL: https://www.birthcohorts.net/ [accessed 2021-02-16]


23. Nascere e crescere in Italia (Coorte NASCITA). URL: http://nascita.marionegrioni.it/ [accessed 2021-02-16]


32. JavaScript Object Notation. URL: https://www.w3.org/TR/html-json-forms/#the-application-json-encoding-algorithm [accessed 2021-02-16]

Abbreviations

ACP: Pediatric Cultural Association
CRF: case report form
eCRF: electronic case report form
ISTAT: National Statistics Institute
JSON: JavaScript Object Notation
NASCITA cohort: NAscere e creSCere in ITAlia cohort

©Michele Zanetti, Antonio Clavenna, Chiara Pandolfini, Claudia Pansieri, Maria Grazia Calati, Massimo Cartabia, Daniela Miglio, Maurizio Bonati. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 12.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Effects of Information Architecture on the Effectiveness and User Experience of Web-Based Patient Education in Middle-Aged and Older Adults: Online Randomized Experiment

Tessa Dekkers1,2, PhD; Marijke Melles1, PhD; Stephan B W Vehmeijer1, PhD, MD; Huib de Ridder1, PhD

1Faculty of Industrial Design Engineering, Delft University of Technology, Delft, Netherlands
2Faculty of Behavioural, Management and Social sciences, University of Twente, Enschede, Netherlands
3Department of Orthopaedic Surgery, Reinier de Graaf Hospital, Delft, Netherlands

Corresponding Author:
Tessa Dekkers, PhD
Faculty of Behavioural, Management and Social sciences
University of Twente
Drienerlolaan 5
Enschede, 7522 NB
Netherlands
Phone: 31 534899741
Email: t.dekkers@utwente.nl

Abstract

Background: Web-based patient education is increasingly offered to improve patients’ ability to learn, remember, and apply health information. Efficient organization, display, and structural design, that is, information architecture (IA), can support patients’ ability to independently use web-based patient education. However, the role of IA in the context of web-based patient education has not been examined systematically.

Objective: To support intervention designers in making informed choices that enhance patients’ learning, this paper describes a randomized experiment on the effects of IA on the effectiveness, use, and user experience of a patient education website and examines the theoretical mechanisms that explain these effects.

Methods: Middle-aged and older adults with self-reported hip or knee joint complaints were recruited to use and evaluate 1 of 3 patient education websites containing information on total joint replacement surgery. Each website contained the same textual content based on an existing leaflet but differed in the employed IA design (tunnel, hierarchical, or matrix design). Participants rated the websites on satisfaction, engagement, control, relevance, trust, and novelty and completed an objective knowledge test. Analyses of variance and structural equation modeling were used to examine the effects of IA and construct a theoretical model.

Results: We included 215 participants in our analysis. IA did not affect knowledge gain (P=.36) or overall satisfaction (P=.07) directly. However, tunnel (mean 3.22, SD 0.67) and matrix (mean 3.17, SD 0.69) architectures were found to provide more emotional support compared with hierarchical architectures (mean 2.86, SD 0.60; P=.002). Furthermore, increased perceptions of personal relevance in the tunnel IA (β=.18) were found to improve satisfaction (β=.17) indirectly. Increased perceptions of active control in the matrix IA (β=.11) also improved satisfaction (β=.27) indirectly. The final model of the IA effects explained 74.3% of the variance in satisfaction and 6.8% of the variance in knowledge and achieved excellent fit ($\chi^2_{17,215}=14.7; P=.62$; root mean square error of approximation=0.000; 95% CI [0.000-0.053]; comparative fit index=1.00; standardized root mean square residual=0.044).

Conclusions: IA has small but notable effects on users’ experiences with web-based health education interventions. Web-based patient education designers can employ tunnel IA designs to guide users through sequentially ordered content or matrix IA to offer users more control over navigation. Both improve user satisfaction by increasing user perceptions of relevance (tunnel) and active control (matrix). Although additional research is needed, hierarchical IA designs are currently not recommended, as hierarchical content is perceived as less supportive, engaging, and relevant, which may diminish the use and, in turn, the effect of the educational intervention.

(J Med Internet Res 2021;23(3):e15846) doi:10.2196/15846
Introduction

Background

Verbal and written patient education methods are often supplemented with web-based education to improve patients’ ability to learn, remember, and apply health information. Such improvements are needed because patients’ recall of traditional education is generally poor [1-3], which negatively affects their satisfaction with care, ability to self-manage, and emotional well-being [4,5].

There are many options to engage patients with web-based education, ranging from animations and interactive exercises to tailored health advice [6]. However, for education to be the most effective, patients must be able to use such functions independently. An efficient information architecture (IA) supports independent use [7,8], yet few studies have systematically examined IA in the context of web-based health education. To support intervention designers in making informed choices that enhance patients’ learning, this paper describes a randomized experiment concerning the effect of IA on the effectiveness, use, and user experience of a patient education website and the theoretical mechanisms that explain these effects. In addition, the study explores the benefit of tailoring IA to specific user profiles.

IA

IA concerns “the structural design of a shared information environment” [9]. It describes “the way in which digital content is organized and displayed, which strongly impacts users’ ability to find and use content” [10]. IA has a pervasive role in website design because it affects the user’s ability to find information with no or very limited training and helps save long-term costs. Web-based environments with effective IAs are typically more scalable, easier to maintain and update, and require fewer redesigns [9]. Yet, despite the importance of IA, there is a lack of primary research that examines IA specifically in the context of web-based health education. A recent review on this subject revealed that to date, only 1 study has empirically manipulated IA in isolation from other design features [10]. This study, conducted in 2012 by Crutzen et al [11] to examine web-based hepatitis information, investigated whether providing users with the opportunity to skip pages (or not) affected website use and user perceptions of efficiency, effectiveness, and enjoyment. It was found that an architecture that provided users with less control over navigation increased both website use and knowledge gain [11]. Although this study demonstrated that IA influences web-based learning experiences, it examined only one particular IA design (the tunnel). Therefore, we argue that a more comprehensive examination of IA is required. For this purpose, we used the taxonomy of 4 archetypes of IA by Danaher et al [12,13]: tunnel, hierarchical, matrix, and hybrid architectures. Hybrid architectures mix design elements of tunnel, hierarchical, and matrix architectures. Each hybrid mix may thereby present unique advantages and disadvantages that cannot be readily understood before experimentation with the nonhybrid IA designs. Therefore, this study focuses on the three nonhybrid IA designs (ie, tunnel, hierarchical, and matrix) only. The features, advantages, and disadvantages of each design are outlined below, and additional examples of each IA design are presented in the Methods section of this paper.

The tunnel IA design is the most common IA in health interventions: 90%-100% of interventions for chronic illness or mental health support include some form of tunneling [14]. In a typical tunnel, IA users follow a step-by-step approach to access content in a predefined, sequential order. For example, a website that only allows access to new material once users have completed previous lessons can be considered to have a tunneled design. A possible advantage of this IA is that it reduces the complexity of information. However, it also reduces the perceived control of users, which may decrease engagement and lead to nonadherence and attrition [15]. The second IA archetype is the hierarchical design. Hierarchical designs organize content hierarchically, differentiating between major and minor content. Typically, users are first provided with a general overview of the major content present on the website. For example, the official United States government website on health organizes content by major topics such as “Health Insurance,” “Medications,” and “Vaccines and Immunizations.” After selecting the appropriate topic, users can explore nested, minor content to review in detail. Assumed advantages of this IA include increased control over content selection, familiarity, and simplicity. However, usability may be limited when users are unable to locate deeply nested content. The third IA concerns the matrix design. This IA design presents all available content on 1 home page or dashboard, thereby removing any differentiation between major and minor content or predefined sequential paths included in the hierarchical and tunnel designs, respectively. This allows users to freely navigate content in their preferred order and duration. Travel agency websites that display all available travel options first and then allow users to sort on date, price, or location are examples of matrix designs. The matrix IA design is considered engaging yet disorienting and is particularly appropriate for highly educated and experienced users looking for enrichment [15,16].

What Explains the Effects of IA?

Many scholars have condemned the black box approach to eHealth, which offers little understanding of the underlying mechanisms through which web-based interventions (and the tools, techniques, and strategies embedded in them) exert their effects [13,14,17]. IA design has the same issue. Although there are several assumed benefits (eg, increased usability and increased user control) of each IA design, as outlined above, there is no overarching conceptual model of IA effects. This makes it difficult to determine how IA affects the user experience of a health education website. Therefore, we examine the following 5 aspects of the user experience: user engagement, user perceptions of control, personal relevance, trustworthiness, and novelty, which may be influenced by IA design in depth.
These are depicted in the conceptual model (Figure 1). We do not hold specific expectations regarding the main effects of IA design but rather expect that each IA design may elicit a different user experience in comparison with the other IA designs, as detailed below.

**Figure 1.** Conceptual model of information architecture (IA). Solid arrows represent expected effects related to matrix IA design, dashed arrows represent expected effects related to hierarchical IA design, and dotted arrows represent expected effects related to tunnel IA design.

---

**User Engagement**

First, we hypothesize that IA design affects user engagement. User engagement is defined as “a quality of user experience characterized by the depth of an actor’s investment when interacting with a digital system” [18,19]. It is often conceptualized as a multidimensional construct composed of cognitive, affective, and behavioral components [20], which means that engagement can both refer to a subjective experience of flow and immersion as well as the actual act of using an intervention [15]. Several recent reviews suggest that user engagement is pivotal for creating an effective and enjoyable web-based experience [15,21].

Our expectations regarding IA design as a determinant of engagement are twofold. First, tunnel IA designs (in comparison with hierarchical and matrix IA) are thought to increase behavioral engagement because the sequential, predefined setup allows researchers to persuasively guide users through the web-based process, resulting in extended use [11,14]. In a study of a web-based smoking cessation intervention, users who viewed content in a set order accessed content more often and for longer [22]. This indicates that tunnel IA design should result in higher levels of behavioral user engagement. In contrast, a more flexible matrix IA design may increase the subjective experience of engagement by providing the user more control over the interaction, as outlined below.

**Perceived Active Control**

As stated earlier, tunnel IA designs have been found to decrease user perceptions of control [11]. User control is a “user’s ability to voluntarily participate in and instrumentally influence a communication” [23,24]. As matrix IA designs allow users to both influence the selection of content and the order in which content is consumed, this design is expected to increase perceptions of user control. Active user control is a dimension of interactivity [23,24], and interactive interventions, in turn, are associated with a more engaging experience [6,25]. Possibly, this is because users who are able to influence an intervention instrumentally consider this to be an enjoyable experience or become more emotionally invested in the intervention. It is important to note here that perceived interactivity and control appear to be more important than actual website interactivity [26,27]. Together, this indicates that matrix IA designs may...
also improve (cognitive or affective components of) engagement through increased user perceptions of control.

**Perceived Personal Relevance**

Perceived personal relevance refers to the extent to which people feel that information is relevant to themselves and their situation [28-30]. People are more motivated to process personally relevant content, leading to deeper processing and greater susceptibility to any persuasive attempts the content makes [28,31,32]. Perceptions of relevance have also been linked to educational enjoyment [33]. We expect that perceived personal relevance may increase knowledge acquisition through the same motivational pathway. Hierarchical and matrix IA designs are the only designs that allow users to select content. We expect that users, to some extent, select content based on what they consider most personally relevant. Therefore, we hypothesize that hierarchical and matrix IA designs (in contrast to tunnel IA design) increase the perceived personal relevance of the health information presented and that this leads to both greater knowledge acquisition and greater satisfaction.

**Perceived Trust**

Perceived trust is a belief that influences whether a patient is willing to engage with health education [34]. Trust in health information is influenced by source, message, channel, and recipient [35,36] as well as structural website features [37]. A previous study on the credibility of health websites showed that the presence of a navigation menu (as is included in most hierarchical IA designs) increases perceived website credibility, as it reinforces the notion that the website is produced by a professional organization [37]. This type of heuristic evaluation of information credibility can lead to a better experience on the health website [38]. Therefore, we hypothesize that hierarchical IA design positively influences participants’ trust in the health information presented and, in turn, the knowledge and satisfaction derived from the education.

**Perceived Novelty**

Finally, we considered perceived novelty as a potential explanatory variable. As the tunnel IA design is the norm in health interventions, other IA designs may offer more novel ways to access health information. Novelty in the context of interfaces can “act as a curiosity generating mechanism that arouses the imaginations of users and captures their interest in a site” [39]. Users pay greater attention and effort to novel media [40], subsequently leading to a greater uptake of information. Novelty has also been related to enjoyable experiences of flow and engagement [18,38]. Therefore, we expect that the less common IA designs (hierarchical and matrix) will increase user perceptions of novelty and that increased novelty will improve both user satisfaction and knowledge acquisition through increased attention to the content.

**Does One IA Design Fit All?**

A final consideration in examining the effects of IA is the role of individual preferences and capabilities. Many recommendations regarding IA design take user characteristics into account. For example, Lynch and Horton [16] describe matrix IA designs (which they refer to as webs) as more suitable for highly educated users with a high level of prior knowledge about the content. It has also been suggested that perceived control over website navigation may be more important to some users than to others [11]. However, the influence of individual differences on the effectiveness and experience of different IA designs has not been empirically tested.

This study used a previously defined set of user profiles of patients [41] who had undergone total joint replacement (TJR) surgery to explore the potential benefit of tailored IA design (Table 1). Each profile represents 1 of 3 ways through which communicative preferences and capabilities may manifest in patients. So-called managing patients prefer open, participative communication, particularly regarding personal circumstances, and have high capabilities and self-efficacy for understanding and applying health information. In comparison, optimistic patients have similar capabilities but find patient-provider communication of lesser importance and only have a slight preference for an open communicative style. Finally, modest patients value both open information and emotional support but have limited self-efficacy and skills in health communication. With these profiles and the recommendations for each IA design in mind, we hypothesize that users with higher preferences for open communication (ie, managing patients) will prefer IA designs that offer more control (ie, matrix), optimistic patients will not prefer any IA design in particular, and modest patients will prefer more supportive IA designs that guide them through the educational content step by step (ie, tunnel).

Table 1. Description of communicative preferences and capabilities of three total joint replacement patient profiles.

<table>
<thead>
<tr>
<th>Managing profile</th>
<th>Optimistic profile</th>
<th>Modest profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>High preference for open communication</td>
<td>Moderate preference for open communication</td>
<td>Moderate preference for open communication</td>
</tr>
<tr>
<td>High preference for emotionally supportive communication</td>
<td>Low preference for emotionally supportive communication</td>
<td>Moderate preference for emotionally supportive communication</td>
</tr>
<tr>
<td>High critical communication capabilities</td>
<td>Moderate critical communication capabilities</td>
<td>Low critical communication skills</td>
</tr>
<tr>
<td>High personal communication capabilities</td>
<td>Moderate personal communication capabilities</td>
<td>Low personal communication skills</td>
</tr>
<tr>
<td>High self-efficacy for health information</td>
<td>High self-efficacy for health information</td>
<td>Low self-efficacy for health information</td>
</tr>
</tbody>
</table>

aPatient profiles are based on Groeneveld et al [41].
Study Objectives

The aims of this study are threefold: (1) to test the effects of IA in the context of a TJR surgery patient education website on knowledge acquisition and satisfaction with web-based education; (2) to test possible working mechanisms of IAs, including user engagement, perceived user control, perceived personal relevance, perceived trust, and perceived novelty; and (3) to explore the potential of tailored IAs.

Methods

Design

In July 2018, we conducted a between-subjects experiment comparing the knowledge and satisfaction gained from a patient education website with three different IA designs. Ethics approval for this study was obtained from the Human Research Ethics Committee Delft University of Technology. Participants provided written consent and signed a data processing agreement formulated in concordance with the General Data Protection Regulation.

Participants and Procedure

Participants were recruited using a Dutch web-based consumer research service (respondenten.nl B.V.). Middle-aged to older adults (40-80 years) with self-reported chronic hip or knee joint complaints (including arthrosis, wear and tear, chronic inflammation, birth deficits, or unknown causes) were eligible for participation. To detect a small-to-medium effect ($\eta^2=0.15-0.25$) on satisfaction and knowledge using an $\alpha$ of .05 and a power of 0.80, a sample size between 159 and 432 participants was needed [42,43]. We aimed to recruit at least 100 participants per condition for a total sample of 300 participants. In total, we were able to enroll 235 participants, of which the data of 215 participants were included in the analysis (see the Results section). Participants received monetary reimbursement (15 euro [US $18.2]) for their participation.

The complete experiment was conducted on the web via survey software (Qualtrics). Each eligible participant was provided a hyperlink to the survey. After providing consent, participants filled out questionnaires regarding their communication preferences and skills, health, anxiety, and coping behavior, which were used to determine the patient profile [41]. Participants also stated the extent to which they already felt knowledgeable about TJR surgery (part A). In part B, participants were randomly assigned to 1 of 3 experimental conditions using Qualtrics’ built-in randomizer. The allocation sequence and assignments were concealed from all participants, the researchers, and the consultant hired for participant recruitment until all data were collected. Participants were initially asked to focus on either the website’s design or its content. After reviewing the website’s design, participants reported satisfaction and user perceptions. They were then asked to view the website for a second time while focusing on content. Then, they completed a knowledge test designed for the purpose of this study. The order of focus (design vs content) was counter-balanced. Finally, participants shared their sociodemographic information and received a code for reimbursement (part C). Eligible participants who had not started or completed the survey after 3 weeks were reminded via email once.

Materials

Design Process

The three websites were designed between March and June 2018 by a design agency (Panton B.V.) specializing in the design of products, services, and processes for health care under the supervision of the first author. The lead designer provided literature on IA [12] and was given access to patient profile role descriptions and anonymized data about patients’ communication preferences and capabilities collected in an earlier study (T Dekkers, PhD, unpublished data, February 2017). In June, prototypes of the websites were pilot tested. To discuss progress and ensure accuracy and quality of health information shared on the patient education websites, the design team met with the first author 10 times throughout the design process. At 2 points in the design process (after first conceptualization and after the pilot tests), the design team also met with the full research team, including an orthopedic surgeon.

Pilot Usability Study

Prototypes of the three websites were pilot tested with 7 patients (age range 46-77 years) scheduled for TJR surgery and 7 informal caregivers (age range 42-76 years) in June 2018. The pilot test focused specifically on usability of the websites rather than effectiveness in terms of knowledge acquisition. Interested patients present at the clinic for the primary care attended patient education were shown the prototypes after they provided written consent. They first freely explored the websites while mentioning aloud any (positive or negative) aspects that stood out. Then, they were asked to find information about the first checkup after surgery. This assignment was used to identify usefulness issues and software bugs [44]. Finally, patients were asked to report engagement using the User Engagement Scale-Short Form (UES-SF, see Measurements section). Throughout the pilot test, the cursor of the participants was tracked using screen capture software (CamStudio Recorder v2.7, Rendersoft Development). Screen captures were used both to identify unclear navigational cues and to get an initial impression of whether the users navigated through the IAs as intended (eg, whether patients explored more pages in the matrix design, made use of the table of contents in the hierarchical design, and moved step by step using the next and prior buttons in the tunnel design). The input of patients and caregivers was shared with the lead designer and implemented in the following iteration of the design. This led to significant improvements in usability, including less scrollable text, more prominently displayed contact information, vivid color accents, and larger buttons.

Websites

All websites contained the same textual content based on an existing patient education leaflet titled Instructions after an outpatient Total Hip Prosthesis (THP; Instructies na een Totale Heup Prothese [THP] in dagbehandeling) used by the local hospital (Reinier de Graaf Gasthuis, the Netherlands). The leaflet addressed practical concerns before and after outpatient THP surgery, including preparation for surgery, pain, medication,
and physiotherapy. All graphic design elements (including photos, fonts, and color) were equivalent across websites.

The tunnel IA website design had a chronological sequential ordering of topics presented as a timeline, starting with the day of the operation and ending with the 3-month follow-up and frequently asked questions. Navigation was limited to next and previous buttons placed below the text and in the timeline. Topics that were not yet accessible to the user were grayed out (Figure 2). The hierarchical IA website design presented participants with a choice menu in which they selected the phase of their patient journey (eg, in the hospital and able to walk a few steps). After selecting an option, users were presented with topics grouped in a table-of-content menu. Participants could further investigate their chosen topic using the menu and could return to the home page using the buttons or navigation path (ie, bread crumb trail). The matrix IA website design showed all topics in tiles on the home page and provided no suggested reading order. By clicking on the topic tiles or hyperlinks in the body of text, participants could switch between topics. Offline copies of the experimental websites are available on request by contacting the first author.

Figure 2. Annotated screenshots of tunnel, hierarchical, and matrix information architecture (IA) design of a Dutch patient education website to prepare patients for total joint replacement surgery. Tunnel IA: (A) next/previous buttons, (B) grayed-out text (not yet accessible), and (C) next/previous buttons. Hierarchical IA: (D) table of contents, (E) major grouping by recovery phase, and (F) return to main menu. Matrix IA: (G) topic matrix and (H) hyperlink. All screenshots depict the same content about pain and swelling (pijn en zwelling).

Measurements
The primary outcomes of interest are knowledge acquisition and website satisfaction. Satisfaction with web-based education captures both the attitude of patients toward website functioning (eg, satisfaction with comprehensibility and with emotional support derived from the website) as well as their affective attitude (eg, satisfaction with website attractiveness) [45,46]. The secondary outcomes used to test the conceptual model include user perceptions of engagement, control, personal relevance, trust, and novelty. We also measured use by capturing the total time spent on the website in minutes. Finally, we collected short qualitative feedback forms on the perceived advantages and disadvantages of the website.

Knowledge Acquisition and Satisfaction With Website
A total of 5 multiple-choice (MC) questions and 3 open questions about (self-)care after TJR surgery were used to assess knowledge acquisition. The questions were based on the information provided on the websites and included, for example:

- After the surgery, it is important to strengthen the muscles surrounding the hip joint. Which ways to do so...

Measurements
The primary outcomes of interest are knowledge acquisition and website satisfaction. Satisfaction with web-based education captures both the attitude of patients toward website functioning (eg, satisfaction with comprehensibility and with emotional support derived from the website) as well as their affective attitude (eg, satisfaction with website attractiveness) [45,46]. The secondary outcomes used to test the conceptual model include user perceptions of engagement, control, personal relevance, trust, and novelty. We also measured use by capturing the total time spent on the website in minutes. Finally, we collected short qualitative feedback forms on the perceived advantages and disadvantages of the website.

Knowledge Acquisition and Satisfaction With Website
A total of 5 multiple-choice (MC) questions and 3 open questions about (self-)care after TJR surgery were used to assess knowledge acquisition. The questions were based on the information provided on the websites and included, for example: after the surgery, it is important to strengthen the muscles surrounding the hip joint. Which ways to do so...
recommended by orthopedic surgeons? Each question included the following answer options: not been discussed, discussed, but I cannot remember the details, a correct answer, and an incorrect answer (distractor) [47]. For each correct MC answer, participants scored 1 point, and for each open question, an answer sheet was developed that assigned points from 0 (incorrect), 1 (partly correct), to 2 (fully correct). All points were summed and converted to reflect the percentage of correct answers (0%-100% correct).

Satisfaction with patient education was measured using the Website Satisfaction Scale [45,46] comprising three subscales: satisfaction with the (1) attractiveness, (2) comprehensibility of the information, and (3) emotional support received from the website. All items consisted of statements to which participants agreement was measured on a 5-point Likert scale (1=totaly disagree and 5=totaly agree). Statements included the website looks nice, the website is understandable, and the website give ease of mind. Both the overall index score of satisfaction and the separate subscales achieved excellent reliability (α=.82-.98).

**User Perceptions of Engagement, Active Control, Personal Relevance, Trust, and Novelty**

We included 5 constructs to explore the theoretical mechanisms through which (tailored) IAs may influence knowledge acquisition and satisfaction. The first is user engagement, as measured through the UES-SF [19]. We obtained permission to translate this validated questionnaire to Dutch according to the guidelines for cross-cultural adaptation of self-reported instruments [48,49] (personal communication by HL O’Brien, May 18, 2018). The instrument contains 12 questions, which form 1 index score (α=.88), and 4 subscales: focused attention (I was absorbed in this experience, α=.75), aesthetic appeal (the website was attractive, α=.87), reward (using the website was worthwhile, α=.71), and perceived usability (I felt frustrated while using the website, α=.79; Multimedia Appendix 1 [18,19,50]). The other user perceptions of interest included perceived active control (during the website visit, I could freely decide what I wanted to see, 4 items, α=.96) [27], personal relevance (the website was relevant to my situation, 2 items, α=.83) [51], trust (the website is sincere and honest, 3 items, α=.97) [34], and novelty (the website incited my curiosity, 3 items, α=.90) [50]. All questions were answered on a 5-point Likert scale (1=strongly disagree and 5=strongly agree).

**Statistical Methods**

We conducted chi-square (χ²) and analyses of variance (ANOVA) tests to check whether background characteristics were evenly distributed over experimental conditions. To test the main effect of IA, 2 ANOVA tests were conducted with satisfaction and knowledge gain as dependent variables. Follow-up pairwise t tests were performed to explore differences between the IA designs, and these were all corrected using the Bonferroni correction. Finally, ANOVA tests were performed with the secondary outcomes (user perceptions) as dependent variables, and the concept of tailored IAs was explored in a two-way ANOVA with condition and profile as the independent variables.

To construct a conceptual model of how IA influences satisfaction and knowledge acquisition, we used structural equation modeling. User perceptions of engagement, personal relevance, active control, trust, and novelty (hereafter, mediating variables) were regressed on IA. Satisfaction and knowledge were regressed on IA and the mediating variables. To improve the parsimony and fit of the model, we removed nonsignificant paths. As our hypotheses suggest that IA design may influence perceived control and subsequently user engagement, and ultimately satisfaction and knowledge, we also constructed a separate serial mediation model for this hypothesis specifically. Model chi-square (χ²), comparative fit index (CFI), standardized root mean square residual (SRMR), and root mean square error of approximation (RMSEA) were used to determine model fit. A model was considered to have a good fit when χ² divided by degrees of freedom ≤3 with P<.05, CFI≥.95, SRMR≤.09, and RMSEA≤.07 [52,53]. All analyses were conducted using R version 3.5.1 [54] with α=.05.

**Results**

**Participant Characteristics**

We enrolled 235 participants, of which, 215 participants were included in the analysis (Figure 3). A total of 20 participants completed the survey on a mobile device, despite instructions to view the survey and the websites on a laptop or personal computer. As the layout and, thus, the information architecture of the websites may appear distorted on mobile devices, these participants were excluded from analysis. There were no significant differences between the excluded participants compared with the included participants with respect to background characteristics, except for device use (P<.001). Excluded participants used the personal computer less (47% vs 9% nonsue) and tablet devices more (89% vs 41% use). No significant associations were found between background characteristics and experimental conditions, indicating that participants were evenly distributed over all three conditions. All participant characteristics are reported in Table 2. On average, participants were 57 years old (SD 7.7), female (155/215, 72.1%), attained lower secondary education (95/215, 44.2%), and were employed or self-employed (118/215, 54.9%). They used the internet daily (mean 3.2 hours, SD 2.1) mainly on personal computers or laptops (91%) and mobile phones (82%). Participants rated their overall health significantly lower (69 out of 100) than the Dutch average of 81.5 for people aged 50-59 years [55,56] and experienced considerable movement-evoked joint pain (mean 4.9, SD 2.3).
Figure 3. Participant recruitment and follow-up diagram. IA: information architecture.
Table 2. Participant characteristics (N=215).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)(^a)</td>
<td>57.18 (7.70)</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>155 (72.1)</td>
</tr>
<tr>
<td>Male</td>
<td>60 (27.9)</td>
</tr>
<tr>
<td><strong>Education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Primary education</td>
<td>3 (1.4)</td>
</tr>
<tr>
<td>Lower secondary education</td>
<td>95 (44.2)</td>
</tr>
<tr>
<td>Higher secondary education</td>
<td>36 (16.7)</td>
</tr>
<tr>
<td>Tertiary education</td>
<td>81 (37.7)</td>
</tr>
<tr>
<td><strong>Occupation, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>83 (38.6)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>35 (16.3)</td>
</tr>
<tr>
<td>Retired</td>
<td>37 (17.2)</td>
</tr>
<tr>
<td>Beneficiary</td>
<td>29 (13.5)</td>
</tr>
<tr>
<td>Other or none</td>
<td>31 (14.4)</td>
</tr>
<tr>
<td><strong>Relationship status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Married or long-term relationship</td>
<td>132 (61.4)</td>
</tr>
<tr>
<td>Divorced</td>
<td>41 (19.1)</td>
</tr>
<tr>
<td>Never married</td>
<td>35 (16.3)</td>
</tr>
<tr>
<td>Widowed</td>
<td>5 (2.3)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td><strong>Social support(^b), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Partner</td>
<td>124 (57.7)</td>
</tr>
<tr>
<td>Friend</td>
<td>75 (34.9)</td>
</tr>
<tr>
<td>Child</td>
<td>52 (24.2)</td>
</tr>
<tr>
<td>Neighbor</td>
<td>36 (16.7)</td>
</tr>
<tr>
<td>Family member</td>
<td>34 (15.8)</td>
</tr>
<tr>
<td>Colleague</td>
<td>7 (3.3)</td>
</tr>
<tr>
<td>Group (church or sports)</td>
<td>4 (1.9)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>No support</td>
<td>25 (11.6)</td>
</tr>
<tr>
<td><strong>Internet use in hours per day, mean (SD)(^c)</strong></td>
<td>3.17 (2.14)</td>
</tr>
<tr>
<td><strong>Device use(^b), n (%)(^a)</strong></td>
<td></td>
</tr>
<tr>
<td>Personal computer or laptop</td>
<td>194 (90.7)</td>
</tr>
<tr>
<td>Phone</td>
<td>175 (81.8)</td>
</tr>
<tr>
<td>Tablet</td>
<td>88 (41.1)</td>
</tr>
<tr>
<td><strong>Self-reported previous knowledge of hip replacement surgery, mean (SD)(^d)</strong></td>
<td>1.85 (0.92)</td>
</tr>
<tr>
<td><strong>Patient profile, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Optimistic</td>
<td>90 (41.9)</td>
</tr>
<tr>
<td>Modest</td>
<td>72 (33.5)</td>
</tr>
<tr>
<td>Managing</td>
<td>53 (24.7)</td>
</tr>
</tbody>
</table>
Effects of IA on Knowledge Acquisition and Satisfaction

All three websites received predominantly positive feedback via the open qualitative feedback forms; participants appreciated that they were clear and organized. Multimedia Appendix 2 summarizes the qualitative feedback on advantages and disadvantages for each IA. Table 3 and Figure 4 report the overall effects of IA. IA did not directly affect knowledge acquisition ($F_{2,212}=1.023; \ P=.36; \ \eta^2_p=0.010$) or overall satisfaction ($F_{2,212}=2.702; \ P=.07; \ \eta^2_p=0.025$). IA did have a significant effect on satisfaction with emotional support ($F_{2,212}=6.376; \ P=.002; \ \eta^2_p=0.057$). Post hoc analyses indicated that participants were significantly less satisfied with the hierarchical IA design (mean 2.86, SD 0.60) compared with the matrix (mean 3.17, SD 0.69) and tunnel (mean 3.22, SD 0.67) architectures. The hierarchical design was perceived as the least favorable in general: users devoted less focused attention (mean difference to tunnel $-0.31; \ P=.02$ and mean difference to matrix $-0.36; \ P=.01$) and less personally relevant (mean difference to tunnel $-0.44; \ P=.01$), and found that it provided the least active control (mean difference to matrix $-0.32; \ P=.02$).

Table 3. Knowledge acquisition, satisfaction, and user perceptions of patient education website by information architecture.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Tunnel IA (n=75)</th>
<th>Matrix IA (n=71)</th>
<th>Hierarchical IA (n=69)</th>
<th>$P$ value</th>
<th>$\eta^2$ b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Website satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attractiveness</td>
<td>3.69 (0.52)</td>
<td>3.65 (0.52)</td>
<td>3.50 (0.48)</td>
<td>.07</td>
<td>N/A c</td>
</tr>
<tr>
<td>Comprehension</td>
<td>4.24 (0.56)</td>
<td>4.21 (0.59)</td>
<td>4.17 (0.71)</td>
<td>.79</td>
<td>N/A</td>
</tr>
<tr>
<td>Emotional support</td>
<td>3.22 (0.67)</td>
<td>3.17 (0.69)</td>
<td>2.86 (0.60)</td>
<td>.002 d</td>
<td>.057</td>
</tr>
<tr>
<td>Knowledge acquisition</td>
<td>51.64 (19.55)</td>
<td>48.02 (19.75)</td>
<td>47.3 (19.63)</td>
<td>.36</td>
<td>N/A</td>
</tr>
<tr>
<td>User engagement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focused attention</td>
<td>3.16 (0.75)</td>
<td>3.00 (0.70)</td>
<td>2.85 (0.79)</td>
<td>.04 f</td>
<td>.30</td>
</tr>
<tr>
<td>Esthetic appeal</td>
<td>3.76 (0.68)</td>
<td>3.75 (0.68)</td>
<td>3.52 (0.76)</td>
<td>.08</td>
<td>N/A</td>
</tr>
<tr>
<td>Reward</td>
<td>3.81 (0.62)</td>
<td>3.78 (0.57)</td>
<td>3.58 (0.68)</td>
<td>.06</td>
<td>N/A</td>
</tr>
<tr>
<td>Perceived usability</td>
<td>4.08 (0.68)</td>
<td>4.05 (0.78)</td>
<td>3.98 (0.78)</td>
<td>.67</td>
<td>N/A</td>
</tr>
<tr>
<td>Perceived active control</td>
<td>3.84 (0.67)</td>
<td>3.95 (0.65)</td>
<td>3.63 (0.74)</td>
<td>.02 g</td>
<td>.035</td>
</tr>
<tr>
<td>Perceived personal relevance</td>
<td>3.08 (0.86)</td>
<td>2.73 (0.83)</td>
<td>2.64 (0.86)</td>
<td>.005 h</td>
<td>.50</td>
</tr>
<tr>
<td>Perceived trustworthiness</td>
<td>3.94 (0.56)</td>
<td>3.92 (0.57)</td>
<td>3.78 (0.59)</td>
<td>.21</td>
<td>N/A</td>
</tr>
<tr>
<td>Perceived novelty</td>
<td>3.43 (0.75)</td>
<td>3.46 (0.73)</td>
<td>3.10 (0.76)</td>
<td>.007 i</td>
<td>.046</td>
</tr>
<tr>
<td>Time spent in minutes:seconds</td>
<td>5:53 (4:24)</td>
<td>5:18 (4:15)</td>
<td>4:59 (4:09)</td>
<td>.44</td>
<td>N/A</td>
</tr>
</tbody>
</table>

aIA: information architecture.
bEffect size is only provided for significant differences.
cN/A: not applicable.
dHierarchical IA was significantly different from both tunnel IA ($P=.02$) and matrix IA ($P=.02$).
eHierarchical IA was significantly different from tunnel IA ($P=.05$).
fHierarchical IA was significantly different from tunnel IA ($P=.03$).
gHierarchical IA was significantly different from matrix IA ($P=.02$).
hTunnel IA was significantly different from both hierarchical IA ($P=.006$) and matrix IA ($P=.04$).
iHierarchical IA was significantly different from both tunnel IA ($P=.03$) and matrix IA ($P=.01$).
Model of IA Effects

The ANOVA tests demonstrated that the tunnel and matrix designs performed significantly better than the hierarchical IA design. To explain why tunnel and matrix IAs perform better compared with hierarchical IAs, we selected the hierarchical IA as the reference category in the mediation model.

The first mediation model (Model 1) specified that the effect of IA on knowledge and satisfaction would be mediated by user perceptions of engagement, active control, personal relevance, trust, and novelty. Specification of complete mediation results in a fully saturated regression model with zero degrees of freedom, as the number of observations is equal to the number of parameters [57,58]. Therefore, the first model was interpreted based on the regression paths instead of the fit indices (Table 4). All pathways (of which the exact P values are provided in Table 4) with P<.10 were considered in a second model (Model 2). For Model 3 and Model 4, we continued eliminating pathways with a more stringent cut-off of P<.05.

Overall, models 2 to 4 all achieved similarly good fit (Table 5). Model 4 (Figure 5) was selected as the final model, as it was the most parsimonious (expressed by highest degrees of freedom [59]). This model explained 74.3% of the variance in satisfaction and 6.8% of the variance in knowledge and achieved excellent fit ($\chi^2_{17,215}=14.7$; $P=.62$; RMSEA=0.000; CI 0.000-0.053; CFI=1.00; SRMR=0.044).
<table>
<thead>
<tr>
<th>Outcome and predictor or mediator</th>
<th>Path estimate (Model 1)</th>
<th>P value (Model 1)</th>
<th>Model 2</th>
<th>Model 3</th>
<th>Model 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>User engagement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA</td>
<td>0.190</td>
<td>.02</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Matrix IA</td>
<td>0.139</td>
<td>.08</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Perceived active control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA</td>
<td>0.142</td>
<td>.07</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matrix IA</td>
<td>0.215</td>
<td>.006</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Perceived personal relevance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA</td>
<td>0.243</td>
<td>.002</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Matrix IA</td>
<td>0.048</td>
<td>.54</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trust</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA</td>
<td>0.133</td>
<td>.09</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matrix IA</td>
<td>0.109</td>
<td>.17</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Perceived novelty</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA</td>
<td>0.208</td>
<td>.007</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matrix IA</td>
<td>0.225</td>
<td>.004</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User engagement</td>
<td>0.226</td>
<td>.045</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Perceived active control</td>
<td>0.006</td>
<td>.96</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived personal relevance</td>
<td>0.089</td>
<td>.22</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust</td>
<td>−0.007</td>
<td>.93</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived novelty</td>
<td>−0.006</td>
<td>.95</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Satisfaction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User engagement</td>
<td>0.382</td>
<td>&lt;.001</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Perceived active control</td>
<td>0.273</td>
<td>&lt;.001</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Perceived personal relevance</td>
<td>0.169</td>
<td>&lt;.001</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Trust</td>
<td>0.227</td>
<td>&lt;.001</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Perceived novelty</td>
<td>0.026</td>
<td>.60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA design</td>
<td>0.042</td>
<td>.59</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matrix IA design</td>
<td>−0.018</td>
<td>.82</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Satisfaction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunnel IA design</td>
<td>−0.011</td>
<td>.80</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matrix IA design</td>
<td>−0.017</td>
<td>.68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Knowledge</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User engagement × matrix IA</td>
<td>0.031</td>
<td>.19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived novelty × matrix IA</td>
<td>−0.001</td>
<td>.95</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust × matrix IA</td>
<td>−0.001</td>
<td>.93</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived personal relevance × matrix IA</td>
<td>0.004</td>
<td>.58</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived active control × matrix IA</td>
<td>0.001</td>
<td>.96</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User engagement × tunnel IA</td>
<td>0.043</td>
<td>.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived novelty × tunnel IA</td>
<td>−0.001</td>
<td>.95</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust × tunnel IA</td>
<td>−0.001</td>
<td>.93</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 5. Fit statistics of mediation models 2, 3, and 4.

<table>
<thead>
<tr>
<th>Model</th>
<th>Chi-square (df)</th>
<th>$P$ value</th>
<th>$\chi^2$ divided by df</th>
<th>CFI$^a$</th>
<th>SRMR$^b$</th>
<th>RMSEA$^c$</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 2</td>
<td>4.7 (9)</td>
<td>.86</td>
<td>0.522</td>
<td>1</td>
<td>0.027</td>
<td>0.000</td>
<td>0.000-0.041</td>
</tr>
<tr>
<td>Model 3</td>
<td>10.8 (13)</td>
<td>.63</td>
<td>0.833</td>
<td>1</td>
<td>0.042</td>
<td>0.000</td>
<td>0.000-0.057</td>
</tr>
<tr>
<td>Model 4</td>
<td>14.7 (17)</td>
<td>.62</td>
<td>0.864</td>
<td>1</td>
<td>0.044</td>
<td>0.000</td>
<td>0.000-0.053</td>
</tr>
</tbody>
</table>

$^a$CFI: comparative fit index.
$^b$SRMR: standardized root mean square residual.
$^c$RMSEA: root mean square error of approximation.
The model explains the effect of IA as follows: compared with hierarchical IAs, health information presented in a tunnel IA is perceived as more personally relevant (β=.18). This subsequently increases user satisfaction (β=.17). Matrix IAs, in comparison with hierarchical IAs, significantly increase the active control users perceive to have over the health information (β=.11), which also increases satisfaction (β=.27). Furthermore, the model shows that next to user perceptions of personal relevance and active control, user engagement and perceived trust in the health information affect users’ satisfaction with a patient education website. Although we hypothesized that perceived novelty would also be affected by IA and affect satisfaction and knowledge in turn, this was not the case. Finally, we already established that IA design did not directly affect knowledge acquisition. The model demonstrated that IA also did not indirectly influence knowledge, as none of the tested mediation pathways were significant. Knowledge acquisition was influenced by user engagement (β=.26), but user engagement itself was unaffected by IA.

**Serial Mediation by Perceived Control and User Engagement**

The serial mediation model, including perceived control and user engagement, confirmed that IA design did not significantly predict satisfaction (P=.07) or knowledge (P=.36). However, an indirect-only serial mediation by perceived control and user engagement on satisfaction emerged for matrix IA designs (β[indirect]=.052; z=2.053; P=.04) and hierarchical designs (β[indirect]=−.063; z=−2.545; P=.01), where matrix IA increased active control and subsequently user engagement and satisfaction, whereas hierarchical design decreased active control (Figure 6). Serial mediation was not present for tunnel IA (P=.65) or for knowledge (P_{matrix}=.10, P_{hierarchical}=.06, P_{tunnel}=.65).
Tailored IAs: Interactions With Patient Profile

Interaction effects between IA and patient profile indicated that some IA designs were preferred more by users with specific profiles ($F_{4,206}=2.646; P=.04; \eta^2_p=0.049$). In the post hoc analyses, a consistent difference was demonstrated between participants of the managing profile and modest profile using a tunnel IA design (Figure 7). Managing participants were significantly more satisfied with the tunnel design (mean difference to modest 0.489; $P=.04$), perceived it as more attractive (mean difference to modest 0.673; $P=.01$) and trustworthy (mean difference to modest 0.630; $P=.009$), and found it to provide more active control (mean difference to modest 0.764; $P=.009$).
Discussion

Principal Findings

The aim of this study is to investigate how the organization, display, and structural design of a website, that is, IA, influences patients’ experience with web-based patient education and the satisfaction and knowledge derived from the educational content. We wanted to understand whether user perceptions of engagement, control, personal relevance, trust, and novelty could explain how IA affects satisfaction and knowledge. Furthermore, we examined whether a user’s profile affected which IA design was most effective or enjoyable to explore the potential of tailored IA design. Research on IA in the context of web-based health education has been sparse [10], which has limited intervention designers’ ability to make informed design choices that enhance patients’ experiences with web-based education.

This study compared three IA designs: tunnel, hierarchical, and matrix design. We found that in comparison with hierarchical IAs, tunnel and matrix IAs slightly improve user satisfaction. This effect may be explained by increased user perceptions of personal relevance in the tunnel IA and increased perceptions of control in the matrix IA. Contrary to our hypotheses and earlier findings [11], no direct or indirect effects of IA on knowledge acquisition or website use were found. However, the findings did indicate that IA preferences differ between patients with different user profiles. Specifically, patients with a so-called managing profile, who prefer open communication and high communicative capabilities, are more satisfied with health education that is presented in a tunnel IA.

Our finding that tunnel IA design specifically affects satisfaction with emotional support is consistent with research showing that tunneled education improved the emotional well-being of patients with type 2 diabetes and chronic low back pain [60]. However, we did not replicate previous findings indicating that tunnelling increases the use of web-based health interventions [11,22]. We did perceive a trend in this direction: participants in the tunnel condition used the website longer on average. However, this difference was not statistically significant. IA design did not predict knowledge acquisition either, despite previous findings indicating that tunnelling improves knowledge acquisition [11]. Instead, user engagement emerged as the only predictor of knowledge acquisition. Some research on patient education indicates that cognitive factors such as working memory and cognitive load may be better predictors of knowledge acquisition than the user experience variables included in this study [61]. As IA design may facilitate cognitive processes, for example, by presenting information in smaller chunks as done in the hierarchical and tunnel designs, exploring whether IA design influences cognitive factors may be a worthwhile avenue for future studies that could help explain a larger portion of the variance in knowledge acquisition. In general, knowledge acquisition scores were low (47%–52%), which is in contrast with earlier findings that show that web-based patient education is effective for orthopedic patients [62] even when websites are consulted just once [63]. However, we are unsure whether these findings are due to inadequate education offered or poor source material (which was not changed when converted from paper to website) or because we did not test knowledge before the experiment. Regarding the latter, if participants had very little knowledge of TJR to begin with, it may be that although attained knowledge levels were low, they still represented decent knowledge acquisition. The participants’ low self-reported knowledge of hip replacement supports this assumption: 81% of participants said that they had no or very limited prior knowledge. However, to fully answer this question, future research on IA design including pre-post measurements of health knowledge is needed.

The results of IA design on user engagement were mixed; the matrix IA achieved the highest subjective (i.e., self-reported) engagement, but the tunnel IA was used the longest (albeit, not significantly longer). This reflects the dichotomous nature of engagement raised in the introduction, where engagement is thought to include both a subjective component of immersion and a behavioral component of use [15,64,65]. The findings indicate that IA design affects both but that matrix IA designs may be specifically suited for creating subjective experiences of engagement in patients. Furthermore, as only subjective self-engagement (and not duration of use) predicted actual knowledge scores, a very tentative conclusion may be that it might be more important to design engaging experiences rather than to design patient education materials that are used the longest. As most studies currently employ a the more use, the better perspective regarding engagement, use, and adherence to health interventions [66], this may require a different focus of researchers and designers alike.

Finally, this study focused on three simple IA designs for experimental clarity. Hybrid IAs that combine design elements from different IAs could mitigate the disadvantages associated with nonhybrid IAs. As users were most satisfied with matrix and tunnel IAs, hybrid matrix-tunnel designs should be explored further specifically. This study also identified that a large proportion of older adults with self-reported joint complaints use mobile phones (82%) and tablet devices (41%). As web-based IA designs cannot be ported to smartphones [13], IA designs suitable for health interventions distributed through mobile devices should be explored further. Finally, the field of IA has been affected considerably by the rise of recommender systems (RSs). These machine-based learning and information retrieval systems can predict and present relevant content, easing requirements for an adequate IA to help users locate content themselves. As this may diminish information overload [67], the potential benefits of combining RS techniques and IA in web-based health interventions warrant further research.

A secondary objective of this study is to explore the potential of tailored IAs. We found that participants with the highest information needs (so-called managers) preferred tunnel IAs. This finding supports the idea that patients’ web-based learning experiences may be improved when IA is tailored to relevant user characteristics. However, we did not envision beforehand that the tunnel IA would actually match the managing profile. Rather, we assumed that participants in this group would prefer a matrix IA, as their skills, high self-efficacy, and preferences for openness and participation are in line with the theoretical ideal user of matrix IA websites [12]. According to the
interactions should, therefore, be examined in tandem with they were small. The added value of highly customizable advantages in terms of improved user experience were present, satisfaction and knowledge acquisition and that although interfaces) that warrant further research. Yet, as more intricate customize the experience to their self-determined preferences may improve the fit between user and design, it may also and needs at the time of visiting. Although this design approach to tailor IA design to eHealth literacy levels instead of a general profile. In any case, the incongruence between anticipated and actual match of patient profile and IA design indicates that translating stated preferences to a tailored design is complex. Although the knowledge base on what works for whom is growing slowly, it may be more beneficial in the meantime to offer users a choice of IAs rather than dictating one design. Studies that explored the benefit of tailoring the mode of health information (eg, text, illustrations, audio-visual material) have successfully used user-initiated tailoring when working with multiple interfaces [71,72]. User-initiated tailoring requests users to customize a website’s content and graphical user interface directly. Such customizations improve users’ satisfaction, users’ attention, and users’ ability to recall knowledge [71,72]. Possibly, user-initiated tailoring may also be applicable to tailored IA design if users are offered a choice of IA designs when they first visit the website. A second consideration is to design IAs that support many different styles of health information processing. The work by Pang et al [73] on a website that was purposely designed to support 4 (rather than 1) distinct health information-seeking behaviors showed that users were more engaged with these dynamic interfaces. The communality between these studies is that users were not restricted or coerced to use the website in a particular way but instead were able to customize the experience to their self-determined preferences and needs at the time of visiting. Although this design approach may improve the fit between user and design, it may also introduce new issues (such as motivating people to adjust interfaces) that warrant further research. Yet, as more intricate eHealth interventions are developed and examined, it should be taken into consideration that these findings show that none of the examined IA designs had serious negative effects on satisfaction and knowledge acquisition and that although advantages in terms of improved user experience were present, they were small. The added value of highly customizable interventions should, therefore, be examined in tandem with the additional costs associated with developing multiple interfaces.

**Strengths and Limitations**

This study was conducted among adults who had self-reported joint complaints and may have viewed web-based education differently than patients scheduled for TJR surgery. However, previous studies have successfully tested health education websites in similar populations [11,71,72], and the high self-reported pain and lower health scores indicate that the study sample had considerable health concerns. As such, the sample can actually be considered a study strength as these individuals were likely motivated to learn about orthopedic health. At the same time, as the sample consisted solely of people with orthopedic health concerns, we know little of the generalizability of the findings of this study to other populations. Preferences for IA design may differ when using health education for purposes other than to prepare for TJR surgery (eg, to decide between alternative treatment options or to obtain support in managing a chronic illness), and additional research is needed to explore this.

Another limitation was self-selection, as participants were able to determine whether they wanted to join or leave the study. Between invitation for participation and inclusion in the study, 37% of participants were lost to follow-up. Of particular concern is that 6% of the sample dropped out after viewing the allocated website, as they might have done so based on their (negative) response to the website. This could make the study susceptible to type I errors [74,75]. This problem could not be remedied by intention-to-treat analysis due to the design of the experiment in which the participants that had dropped out generated no outcome data [75]. Therefore, we checked whether dropout was associated with allocation to a specific website, which was not the case. This made it unlikely that participants stopped because they were discontent with the allocated website. Another issue with self-selection was that participants could have been exceptionally interested in and already knowledgeable about TJR surgery. This would explain why we did not find any effects on knowledge. However, both self-reported prior knowledge of hip replacement and knowledge acquisition were generally low. A final limitation is that we determined satisfaction and knowledge gained from visiting the website once. As such, we cannot draw conclusions about experience with the website over time or knowledge retention after longer periods.

The strengths of this study include the experimental design. Although randomized experiments of website features known as A/B tests or web-based field experiments [76] are common in industry, the method is not often used in academic research on web-based health interventions. Various scholars have advocated moving beyond the black box approach which assesses only intervention efficacy. Testing specific features can help understand the mechanisms by which web-based interventions (do not) improve health outcomes [10,17,22]. By experimentally manipulating one feature and assessing both outcomes as well as mediating variables, this study takes a step in that direction. Second, the study took a human-centered and interdisciplinary approach to patient education design. The team included interaction designers, clinicians, and psychologists.
and followed an iterative design process that involved patients early via pilot studies to ensure the usability of all three variants of the website. We believe that this commitment to developing three distinct but comparable, usable, and enjoyable web-based experiences has made it more likely that the effects on satisfaction can be attributed to differences in IA alone.

Conclusions and Recommendations for Intervention Design

Overall, our findings indicate that IA has small but notable effects on users’ experiences with web-based health education interventions, at least in the context of orthopedic patient education. Tunnel IA design, in which users are guided through sequentially ordered content, improves perceptions of personal relevance and, in turn, user satisfaction. This design may be specifically appropriate for patients with high information needs. In contrast, providing users with more control over the way they progress through a web-based health intervention via a matrix IA design has positive effects on user perceptions of active control, which also contributes to higher satisfaction. Although additional research on IA design in different target groups and interventions is needed, hierarchical IA designs are not recommended at the moment, as hierarchical content is perceived as less supportive, engaging, and relevant, which may diminish the use and, in turn, the effect of the educational intervention.

Acknowledgments

This work is part of the research program Tailored health care through customer profiling (Project 314-99-118), which is financed by the Netherlands Organisation for Scientific Research (NWO) and Zimmer Biomet Inc. The authors thank the participants who took part in the pilot study and the consortium partners and reviewers for their constructive feedback on this work.

Conflicts of Interest

Part of the funding of this project is provided by Zimmer Biomet Inc (refer to the Acknowledgments section). This sponsor had no role in the study design of this protocol, data collection, analysis and interpretation, or writing of the report. In the case that this partner wants to apply for a patent based on research findings, publication can be postponed for a maximum of 3 months. No party has the right to prohibit the publication of these findings. The authors have full access to the study data.

Multimedia Appendix 1

Dutch translation of the User Engagement Scale-Short Form: validity, questionnaire items, and instructions for scoring.

[DOCX File, 33 KB - jmir_v23i3e15846_app1.docx ]

Multimedia Appendix 2

Perceived advantages and disadvantages of tunnel, hierarchical, and matrix information architecture designs (translated from Dutch).

[DOCX File, 22 KB - jmir_v23i3e15846_app2.docx ]

Multimedia Appendix 3

CONSORT-eHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 2224 KB - jmir_v23i3e15846_app3.pdf ]

References


Abbreviations

ANOVA: analyses of variance
CFI: comparative fit index
IA: information architecture
MC: multiple choice
RMSEA: root mean square error of approximation
RS: recommender system
SRMR: standardized root mean square residual
THP: total hip prosthesis
TJR: total joint replacement
UES-SF: User Engagement Scale-Short Form
User-Centered Development of a Web Platform Supporting Community-Based Health Care Organizations for Older Persons in Need of Support: Qualitative Focus Group Study

Verena Biehl¹,², MA; Heidrun Becker², Prof Dr; Alenka Ogrin³, MA; Alenka Reissner³, PhD; Johannes Burger⁴, MA; Andrea Glaessel¹,²,⁵, Prof Dr, MPH, MSc

¹Institute of Health Sciences, Zurich University of Applied Sciences, Winterthur, Switzerland
²Research and Development in Occupational Therapy, Zurich University of Applied Sciences, Winterthur, Switzerland
³Zveza društva upokojencev Slovenije (ZDUS), Ljubljana, Slovenia
⁴SYNYO GmbH, Vienna, Austria
⁵Institute of Biomedical Ethics and History of Medicine, University of Zurich, Zurich, Switzerland

Corresponding Author:
Andrea Glaessel, Prof Dr, MPH, MSc
Institute of Health Sciences
Zurich University of Applied Sciences
Katharina-Sulzer-Platz 9
Winterthur, CH-8401
Switzerland
Phone: 41 58 934 4397
Email: andrea.glaessel@zhaw.ch

Abstract

Background: The ongoing changes in population demographics increase the relevance of dignified aging across Europe. Community-based health care (CBHC) organizations are necessary to provide sustainable strategies for organizing care for older persons in need of support. To support the digitalization of these organizations, new business models and suitable web platforms are necessary.

Objective: This study, which is part of the European Active and Assisted Living (AAL) project called “ICareCoops”, aimed to explore concepts, approaches, and workflows of CBHC organizations to achieve a comprehensive understanding of extant services offered and relevant requirements to support these services with information and computer technology (ICT) solutions.

Methods: A qualitative study with six focus groups (FGs) with 40 participants was conducted in Switzerland and Slovenia to identify potential stakeholders’ needs and requirements for the user-centered development of a web platform. Data were collected from three different stakeholder groups: (1) older persons in need of support as care receivers, (2) significant others of older persons in need of support, and (3) managers or care providers of CBHC organizations. A semistructured interview guide with open questions was used for data collection. FG sessions were audio-recorded and transcribed verbatim. Thematic content analysis was used to analyze the content of the FG sessions. To assist with further web platform development, the responses of the FG participants were translated into user stories to describe technical requirements.

Results: By analyzing the transcripts, five main categories were identified: (1) ICT usage behavior of users, (2) challenges of web platform usage, (3) content and technical requirements for the web platform, (4) form and services of CBHC organizations, and (5) rationales of CBHC organizations. The main issues identified were the need for seniors to have individual contact with the CBHC organization and the possibility to coordinate routine services via the web platform, such as ordering meals-on-wheels or booking a caregiver to accompany an older person to the doctor.

Conclusions: The majority of participants showed a lack of familiarity with the usage of ICT. Nevertheless, they were open-minded regarding web platform usage to facilitate workflows and to benefit CBHC organizations. Cooperatives as an organizational model demonstrate a high potential to address users’ needs. Therefore, the web platform offers an essential tool for innovative health care models in the future. Searching for care services, contacting care providers, and communicating with care providers was preferred via personal contact and seemed to be the key element for user acceptance and for the successful implementation of a web platform like “ICareCoops” to support CBHC organizations.
community-based health care services; older persons in need of support; user-centered design; focus groups; qualitative research; web platform

Introduction

Nowadays, older persons aged 65 years and older are still less familiar than younger generations with information and computer technology (ICT) usage. In Western societies, there is still a remarkable generation gap. In addition to age, other social and environmental determinants, such as reliable internet access, play a role in the use of ICT. Nevertheless, the percentage of ICT users among persons over 65 years has been rising in recent years [1-3]. Older persons are more likely to need support in daily life to stay at home independently because of morbidity, immobility, or general frailty. In the coming years, the proportion of the population aged 60 years and older will increase worldwide, specifically one in five people will be aged 60 years or older in 2050 [4]. Because of this demographic development, dignified and healthy aging and caregiving is becoming a more relevant topic in the long-term perspective as European health care systems are facing challenges of sustainability and an increasing need of resources [4,5]. As a consequence of these demographic changes, not only will the demand for health care services for older persons in need of support increase but a coordinated cooperation of services will be necessary to maintain seniors’ autonomous living at home [4,6]. In particular, ICT has a growing potential to provide essential assistance for older persons in need of support in finding and coordinating individual requirements for assistance with living and health care services. These ICT tools still have to be developed and implemented in a way that is consistently user-friendly yet adaptable for evolving health care models [6-8].

Besides public health care services, more and more nonprofit organizations are becoming major players in delivering health care services in communities [9-11]. Nonprofit organizations are based on five criteria, which are (1) organized, (2) private, (3) not profit-distributing, (4) self-governing, and (5) noncompulsory [10]. These mainly community-based organizations deliver a broad spectrum of social and health-related services, such as providing informal counselling and social support, building individual and community capacity, coordinating health services, and supporting self-management in older persons in need of support [12]. A well-known example of a nonprofit organizational form, which also comprises community-based health care (CBHC) services, are care cooperatives. The difference between cooperatives and other forms of enterprises is that profit-making and economic stability are balanced by the interests of the community [13]. Cooperatives are autonomous associations of people who voluntarily cooperate for their mutual social, economic, regional, and cultural benefit. Cooperatives balance multiple stakeholders’ interests instead of shareholders’ interests alone [9]. Cooperatives as a person-centered business model can become health care actors with the potential for large cost savings, service improvement, and more sustainable cooperation between those responsible for health care.

To date, care cooperatives in Europe have been established mainly in Italy, Turkey, France, and Spain [14]. In Switzerland, there are some care cooperatives (eg, Spitex, a Swiss nonprofit outpatient care cooperative [15]) and medical centers in rural areas. In the past, some of the cooperatives developed into good practice examples, whereas others failed because of poor communication, coordination, etc. Especially for these reasons, ICT tools could have a large impact on improving their services, addressing not only the concrete needs of older persons in need of support but also the daily operations of such organizations. Although the care cooperative model seems to be highly suitable for CBHC services, in this study we did not focus on one specific organizational form of CBHC service in the nonprofit sector. Instead, we focused on different CBHC organizations to identify the potential benefits of ICT support in their daily operations. Web platforms are a useful tool, but to the authors’ knowledge they have not yet been broadly implemented in CBHC organizations.

This study is part of a larger project, the European Active and Assisted Living (AAL) project called “ICareCoops”, that is targeted at CBHC organizations and aims to develop a web platform [16] for implementing and managing CBHC services for older persons in need of support. From the beginning, high user acceptance of the web platform has been set as the project’s focus. Therefore, a user-centered approach was chosen, which is characterized by heavy involvement of future web platform users. This user-centered design optimizes future ICT user participation, and it is a common method to develop digital health-related tools [17,18]. This study is one part of the web platform development.

The objective of this study was to explore concepts, approaches, and workflow processes of CBHC organizations and their potential as care cooperatives. Specifically, we pursued a two-part goal: (1) to achieve a comprehensive understanding of extant services offered and relevant requirements including risks and challenges of using ICT, and (2) to support these services with ICT solutions, exemplified in two European countries (Switzerland and Slovenia).

Methods

Study Design

To address the study’s goal, a user-centered design based on participatory research was chosen. Moreover, by using focus groups (FGs), a qualitative methodology was applied to identify the most relevant requirements from the users’ perspective. FGs were useful to identify the needs of target groups and to gather a broad spectrum of information and opinions from older persons in need of support. In our case, stakeholders comprised the following three groups: (1) older persons in need of support as
care receivers of a CBHC service, (2) significant others of older persons in need of support, and (3) managers or care providers of a CBHC service in Switzerland or Slovenia. Discussing issues with multiple participants of the same stakeholder group reveals a broader variety of relevant aspects and useful ideas [19]. All participants were informed about the project and provided consent to participate in this study based on written and spoken information. FGs were treated with full confidentiality, and anonymity was maintained throughout the research process.

In qualitative studies, the role and reflexivity of the researchers is an influencing factor during the entire research process. Actions, perceptions, and especially context-relevant aspects are important and considered in the studied field—in this study, future users of web-based CBHC services for older persons in need of support. In qualitative research, the subjective perceptions of the researchers and users as a component of knowledge are applied to understand complex contexts [20].

To address all objectives within this qualitative study, we chose a mix of deductive and inductive approaches. The deductive component consisted of applying a workflow model (Figure 1) to demonstrate to the FG participants a potential template of a web platform and to discuss the different processes of a workflow within a CBHC organization in depth. Illustrating this simplified workflow model should enable tech-novice FG participants to discuss potential workflows that could be supported with ICT tools. To comply with the user-centered approach, the workflow model intentionally used everyday speech and its design was kept simple. In addition, the inductive component, with open-ended questions, facilitated gathering further information about FG participants. Detailed information on the data collection process is described further below under the “Data Collection” subsection.

Figure 1. Workflow model of a community-based health care organization, including potential tools for support from a web platform. AAL: Active and Assisted Living.

Sampling
For each FG, approximately 9 participants were invited by email and phone to join the FG to represent the needs and expectations of all three stakeholder groups. We considered differences in the requirements between the two countries, in the characteristics of the health care organizations (eg, year of foundation, size, ICT use), and between different stakeholders (older persons in need of support and their significant others and managers/care providers). To avoid the predominance of input from professionals, as well as mixing up knowledge and expectations of managers/care providers and older persons in need of support, the web platform requirements were discussed separately from three perspectives. Among the stakeholders, a heterogeneous group composition of participants was attained, allowing the collection of richer information [19].

Recruitment Strategy
Participants from different economic and cultural backgrounds were consecutively selected in Slovenia and Switzerland. Swiss participants were recruited from the German-speaking region of Switzerland. In Slovenia, organizations located around the city of Ljubljana were contacted. In both countries, potential participating CBHC organizations received information about the project and were requested to distribute the invitation to their members. Furthermore, we asked them to send managers from an institution. We also ensured to include a variety of technologically competent people. The intention was to gain a better insight into the variety of workflows and requirements needed for the envisaged web platform.

Ethical Approval
In Switzerland and Slovenia, ethical approval is required for clinical trials—for extraction of biological material or collection of health-related data [21,22]. This project is primarily concerned with the technical development of a software solution.
End users were invited to contribute to the process of requirements engineering of software solutions. Given the nonmedical context, ethical approval was not required for all involved countries. Collected data were used exclusively for generating software requirements and improving the prototype. No risks or damages were foreseen during the end user FG study. Personal data of the end users was anonymized, codified, and stored in a secure place, guaranteeing access only to authorized persons and safeguarding the right to privacy. The software prototype does not contain any personal information from end users. Informed consent highlighted the possibility of research results being published in scientific journals or being presented at conferences, always with the guarantee of anonymity. All participants had an exit right and could withdraw from the project at any time without giving a reason.

Data Collection
To gather sociodemographic data from our sample, participants were asked to complete a questionnaire. During the FG process, we followed a semistructured topic guide with four open-ended questions. All four questions were based on scientific literature searches, including best-practice models of workflows and web platforms of CBHC organizations.

For this study, we developed a simplified workflow model as a basis for discussion with the stakeholders (Figure 1). This model comprised the most relevant four steps within the workflow of a CBHC organization and expected stakeholder requirements. Subsequently, we tried to combine the consecutive workflows within the potential web platform of a CBHC organization:

1. Need for care support: from a user perspective, the workflow starts with an internet search.
2. Information: relevant information has to be presented on the web platform concerning the organization (eg, name, membership, region, services, etc).
3. Needs analysis: the workflow continues by contacting the CBHC organization and making an appointment to assess the demands of the user. In this step, we wanted to know which kinds of ICT users would use (eg, email, telephone, video call, apps, etc).
4. Allocation of services: after an assessment of needs, services had to be selected and offered.

The model considered the three different stakeholder groups. For all three target groups, needs for working and cooperating in a CBHC organization with a variety of requirements (eg, price checking, membership management, scheduling, communicating with others, etc) were discussed.

This workflow model was one component of the FG topic guide. Furthermore, the guide included an introductory section about the project, study-specific open-ended questions pertaining to users’ needs and expectations, time for further issues, and an outlook of the following project steps.

Study-specific open-ended questions used to derive user-specific requirements, expectations, and challenges related to ICT-based support of a CBHC organization are illustrated in Table 1.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify workflows including ICT solutions</td>
<td>• Which other services would be useful in your organization?</td>
</tr>
<tr>
<td></td>
<td>• If you think long term, which services could be relevant in the future?</td>
</tr>
<tr>
<td>Identify desirable ICT solutions</td>
<td>• Which ICT supports do you think would be helpful to care organizations?</td>
</tr>
<tr>
<td></td>
<td>• Which functions should be possible?</td>
</tr>
<tr>
<td>Identify barriers to ICT usage</td>
<td>• Which barriers/risks do you identify in the usage of ICT solutions? (eg, cultural, ethical, legal—personal and general)</td>
</tr>
<tr>
<td>Identify potential of a care cooperative</td>
<td>• Name the 2 to 3 most relevant advantages of founding a care cooperative from your point of view.</td>
</tr>
</tbody>
</table>

*Perspectives of older persons in need of support as care receiver, significant others of care receivers, and managers or care providers of community-based health care organizations.

ICT: information and computer technology.

Four researchers conducted the FGs—two in Switzerland and two in Slovenia. One researcher acted as moderator and one assisted by taking field notes. To guide the discussions and focus on the topic, questions were presented as PowerPoint slides. A duration of 2 hours for one session was not exceeded. Each FG session was audio-recorded and transcribed verbatim after receiving written consent from the participants. In all transcripts, protocols, and case reports, names and personal data were anonymized.

Data Analysis
Data were extracted by thematic content analysis based on written transcripts, which was conducted in three steps, characterized by an inductive and deductive strategy to receive two different kinds of data (Figure 2). In step one, the deductive data analysis, we aimed to obtain details about the workflows of CBHC organizations. Statements and responses from FG participants were summarized according to the topics in the workflow model. In step two, the inductive data analysis, information, new themes, and issues mentioned by FG participants were first read in-depth, open codes were generated,
and the data were condensed into concepts and categories. Microsoft Excel 2010 was used for the structured data analysis. In step three, user platform requirements had to be filtered systematically for further web platform development. Based on the results of steps 1 and 2, technically relevant results were translated into user stories of the syntax “<as an> <I want to> <so that>.” The user stories will be the basis for further technical web platform development in the future and were not part of this study, which focuses on an analysis of specific needs of potential web platform users. User stories are a method that was applied to gather user requirements for developing an agile web platform [23].

Figure 2. Strategies and steps of focus group data analysis. CBHC: community-based health care; FG: focus group.

Quality Assurance and Trustworthiness
Data security regulations regarding data storage were observed throughout the study. For data quality assurance, the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was applied [24]. For peer review, a pretest of the FG questions in the topic guide was conducted. Field notes were collected by a second researcher. After each FG session, both researchers reflected on the process for potential improvements with a written debriefing. For peer review, a second researcher coded 25% of the data from the transcripts. The results were discussed in order to reach consensus on each concept. All participants of the study received feedback in the form of a plain-language summary of the study results via email.

Results

FG Sessions
In Switzerland and Slovenia, six FG sessions, each with a maximal duration of 2 hours, were conducted with three target groups: (1) older persons in need of support as care receivers of a CBHC service, (2) significant others of older persons in need of a CBHC service, and (3) managers or care providers of a CBHC service. Of the 10 organizations who were invited, 70% (n=7) participated in the FGs by sending different stakeholders: managers, care providers, older persons in need of support, and significant others of older persons in need of support.

Sociodemographic Data
In total, six FGs with 40 participants (32 women, 8 men) were conducted. Personal characteristics indicated a large variety of tech-savvy and non–tech-savvy people and formal and informal care providers and receivers and their significant others. Sociodemographic data of FG participants are presented in Table 2.
Deductive Analysis of Organizations’ Workflows

Participants from the manager/care provider group mainly agreed on the workflow model (Figure 1). Usually, older persons in need of support call the organization by phone and ask for services. In most cases, service providers initiate a personal appointment with the service receiver to identify needs to establish a personal, face-to-face relationship with the older person in need of support.

To our understanding the first contact has to be free of charge. [Relative of care receiver 03_SI]

Personal contact is central to all of our members. This will remain the most important rationale of CBHC organization beyond the next ten years. [Care provider 04_Swiss]

After determining the patient’s needs, the organization arranges tailored services for the older person in need of support. The FG participants recommended involving older persons in need of support and their significant others in the decision-making process for care services. A test period of services would be beneficial for older persons in need of support. After this period, they could decide whether to continue with the services or not. Participants recommended that a contract should be signed between older persons in need of support and CBHC organizations to clarify arrangements, frequency of services, and payment terms. In most organizations, a person in the role of a distributor works in the office. Service users wished to have a contact person in the organization who could coordinate the requests and service offers. In a CBHC organization, a distributor is required to monitor services, contact older persons in need of support, and coordinate formal and informal care providers. Moreover, the same person determines conditions and deadlines of payments according to user needs and facilitates communication among all stakeholders. A participant in the provider FG in Switzerland emphasized, “The organization would not work without a contact person who coordinates all the stakeholders’ needs” [Care provider 02_Swiss].

Inductive Analysis

In the inductive analysis, five main categories were extracted from open coding of data from the three stakeholder groups: (1) ICT usage behavior of users, (2) challenges of web platform usage, (3) content and technical requirements for the web platform, (4) form and services of CBHC organizations, and (5) rationales of CBHC organizations. Each category is described in the following sections, including examples of codes. The results of categories 1, 4, and 5 are illustrated in Table 3. The results of categories 2 and 3 are presented separately in Table 4 and Multimedia Appendix 1, respectively.
<table>
<thead>
<tr>
<th>Category and subcategories</th>
<th>Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICT</strong> usage behavior</td>
<td></td>
</tr>
</tbody>
</table>
| Current ICT usage among older persons | - ICT usage rises in the next 10-20 years  
|                             | - No idea about options of ICT  
|                             | - Significant others more familiar with ICT usage  
|                             | - Small proportion of the elderly is familiar with ICT  
|                             | - Open-minded attitude regarding ICT usage  
|                             | - No information accessible without the internet  |
| Current ICT usage among CBHC organizations | - Use of ICT via phones, Excel, and voicemails  
|                             | - Computer cannot substitute a person or individualize the services  
|                             | - Coordination of services is performed by people (ie, not possible without them)  
|                             | - ICT usage by managers of organizations, only by a few members  |
| Usage of web platform       | - Benefit greater for managers of CBHC organizations  
|                             | - Participants would be interested in using the web platform  
|                             | - Future generations to benefit more  |
| **Form and services of CBHC organizations** |       |
| Organizational form: association or cooperative | - Associations as business models are more represented than cooperatives  
|                             | - Liability problems are excluded in associations  
|                             | - Associations allow spontaneous freedom of action  
|                             | - No difference between associations and cooperatives  |
| Current and desirable services of CBHC organizations | - Independent counselling without the intention of selling something  
|                             | - Carpools  
|                             | - General practitioners and health professionals in care cooperatives  
|                             | - Deposit of private data, such as patient’s provision or testaments  
|                             | - Individual services adjusted to available budget  
|                             | - Driverless vehicles (AAL project)  
|                             | - Rental robots (AAL project)  
|                             | - High-quality meals-on-wheels  
|                             | - Support in emergency situations (eg, correct phone numbers, weekend assistance)  
|                             | - Coordination of professional care  
|                             | - Expansion and optimization of palliative care  |
| Possible concepts for the work of CBHC organizations | - Simple neighborhood aid  
|                             | - Mixed generations (mutual aid)  
|                             | - Living concepts for mixed generations  
|                             | - Older persons as informal caregivers (mutual aid)  
|                             | - Refugees as informal caregivers  |
| **Rationales of CBHC organizations** |       |
| Rationales together with older persons in need of support | - Inhibition in asking for support (neighbors, family)  
|                             | - Concerns regarding nursing homes  
|                             | - Physical and mental limitations normal  
|                             | - Demand required for internet usage  
|                             | - Nonacceptance of support  
|                             | - Societal changes, disruption of family structures  
|                             | - Personal contact very important (prevent social isolation)  
|                             | - Autonomy as long as possible  |
| Rationales collaborating with care receivers/members of the organization | - Never say no to member requests  
|                             | - Social contact is necessary for needs assessment  
|                             | - Need to talk to someone, as social contacts decrease  
|                             | - Personal conversations essential  
|                             | - Care requires consideration of logistics (coordination is important)  
|                             | - Social contacts arise spontaneously  |
ICT Usage Behavior of Users

In this category, the target groups’ current ICT usage behavior was compiled. All statements concerning the issue of ICT usage of seniors supplement this category.

Researchers recognized a great variance in tech-savviness among participants. The user (older persons in need of support as care receivers) FG in Switzerland was more tech-savvy than managers or care providers. In contrast, the user group in Slovenia did not have any experience in using ICT. Thus, all FGs were conducted on a very different level of understanding regarding the development of a web platform. Overall, participants assumed that modern ICT cannot be used by approximately 50% to 80% of older persons in need of support because of lacking skills or familiarity with ICT usage. At present, only a small sample of tech-savvy seniors would benefit from such a web platform, although future generations may benefit from the web platform. A period of about 10 to 20 years is predicted for older persons in need of support to become sufficiently tech-savvy to use a web platform.

Older persons in need of support would be interested in improving their skills and therefore suggested courses as a requirement for establishing this web platform. They also assumed that care providers would benefit more from such a web platform from a management and organizational point of view.

The most common reported uses of ICT were phone calls for making appointments, emails for confirmation of appointment dates, and Excel spreadsheets to collect information about care receivers/members/providers. CBHC organizations knew that current ICT usage is very poor, but they did not have resources to invest in this issue and were satisfied with their current state. Most of the FG participants had difficulties in anticipating future needs and providing innovative ICT solutions; however, they all demonstrated an openness to using such a web platform if it was user-friendly and easy to access and navigate.

Challenges of Web Platform Usage

Participants were asked to discuss challenges of using the web platform. The identified barriers could be divided into four subcategories: (1) common issues, (2) ethical issues, (3) financial issues, and (4) cultural issues (Table 4). Low ICT usage among the target group of seniors was seen as a main challenge for the web platform; they would assume there to be an information overload on the internet and would therefore only use an easy and clearly arranged web platform.

If I go online and search, for example, meals-on-wheels, I will find so much information and...
I can’t handle this information. I need only some high-quality results in the region where I live. If the web platform could filter this information for my needs and was easy to use and clearly structured, I would appreciate this web platform. [Care receiver 04_Swiss]

Furthermore, trust in data protection among the target group was critical. They reported being afraid of storing sensitive data on a web platform.

**Content and Technical Requirements for the Web Platform**

As a main result of FG discussions, specific requirements for the web platform were mentioned and could be retrieved. The requirements covered common, technical, and content aspects of the web platform in regard to hardware and mobile apps; these requirements are summarized in **Multimedia Appendix 1**.

The ICT system should be very well built, and someone should monitor it and organize the work. For the care-providing organization, it is important to have good visibility and access to data. [Care provider 03_Slovenia]

All of the participants confirmed that there need to be people in the background to organize and manage all of the services and member requests; one participant in Switzerland called it an “intelligent system” [Relative of care receiver 01_Swiss]. All participants were quite open-minded regarding hardware and potential software solutions offered. They mentioned possibilities such as fingerprint identification, voice-guided tools, video calls, and video tutorials to explain the web platform. In total, participants named 60 requirements, which were then translated into user stories for further web platform development in a separate step of the project. The separate step is not part of this study. Examples of user stories include the following:

**I as a care provider have the option to contact the care receiver via an app, so that it’s possible to inform about changes in the schedule, etc.**

**I as a care receiver have video tutorials which explain important information (service), so that I understand and get an idea of the services offered or other important information (how can I become a member, how can I offer help...).**

Overall, the idea of CBHC organizations working with such a web platform was very well received, with the prerequisite that it would be user-friendly and accessible without a high cost.

**Form and Services of CBHC Organizations**

This category includes information concerning the business model of a CBHC organization comparing associations and cooperatives. The main task of a CBHC organization as a service provider is to fulfill the target group’s needs, which are also described by this category. For care providers, the organizational model of cooperatives is currently not widespread in Switzerland. A widely used business model for existing institutions is an association because it is easier to administer (eg, regarding liability of partners). Differences between acting as an association and acting as a cooperative in health care were not obvious to FG participants.

It is easier to work as an association in Switzerland than as a cooperative as legal form for various reasons. [Care provider 01_Swiss]

Nevertheless, the motivation to work with cooperative principles is untouched by this solution. Slovenian participants emphasized that they did not have cooperatives in Slovenia, but they assumed it was an engaging idea. In general, the suggestion of care cooperatives was convincing to participants in both countries.

The variety of current and desirable service offers in CBHC organizations is very broad and ranges from collective buying (eg, of medications) to assistance in housekeeping. Organizations offer an endless number of different services, except professional care. They do not offer health or nursing care because this is provided by special health care organizations. Participants mentioned the desire to simplify health care by including professional care and practitioners to coordinate all care services offered by CBHC organizations. To give an impression of services offered, care organizations brought information materials to the group sessions; their services included mowing the lawn, accompanying someone to the doctor, transportation services, and special training for seniors, such as computer courses or universities for seniors. It was also identified that seniors can rarely afford additional expenditures, such as care services.

Therefore, the services have to be affordable even to people with low incomes; usually they are co-financed by municipalities. [Care provider 01_Slovenia]

Moreover, dissatisfaction with professional care in health care organizations was revealed. Primarily for potential users of CBHC organizations, some services should be strengthened, such as high-quality meals-on-wheels, emergency aid at night and on weekends, and regional information for seniors convened at one place. In general, participants seemed to have a need for information about any issues related to seniors located in one place (eg, care, courses, communication, leisure, etc).

**The CBHC organization could act as an information center.** [Relatives of care receiver 03_Swiss]

CBHC organizations should (1) inform users via different channels (internet, telephone, in person, printed documents) about any issues related to seniors; (2) provide customized recommendations for care needs; and (3) store data about users and transfer them to relevant stakeholders, such as care providers or practitioners. Furthermore, ideas about AAL solutions were suggested, such as robots to support housekeeping or fully automated, driverless vehicles.

Participants discussed possible concepts for CBHC organizations to involve retired people in the informal care of seniors as well as intergenerational projects. Younger generations could assist older persons in need of support, and older persons in need of support could assist families in other areas of need (eg, babysitting). Furthermore, living concepts, where seniors live with younger generations in the same housing facility, were mentioned as desirable.
Rationales of CBHC Organizations

This category summarizes statements of the target groups about fundamental principles to be considered in CBHC organizations, as they seem to be of particular importance for collaboration with older persons in need of support.

Participants mentioned rationales for the collaboration of CBHC organizations with older persons in need of support; participants reported that autonomy was desirable if possible. Therefore, a decrease of physical and mental mobility is seen as an obstacle, as it could potentially lead to a loss of autonomy. Nowadays, family structures are supposed to be less stable and close so that older persons in need of support do not require support from the family.

I don’t want to disturb my children. They are very busy with a lot of other things. [Care receiver 06_Swiss]

Beyond that, older persons in need of support worry about moving to nursing homes. Here one can see a discrepancy between the intention to live independently, the fear of requesting support or moving to a nursing home, and the need for support caused by a decrease in physical and mental mobility. Participants confirmed that they needed support when using the internet; they would probably need supervision when using ICT.

Nearly all FG participants ranked having a personal contact within a CBHC organization as the most important feature. Older persons in need of support need to have a contact person within the organization that they refer to. They assumed social isolation would be a risk factor as ICT use increases.

It is not an exception that service providers and mediators of the informal care organizations are the only contact persons that seniors still have. [Care provider 01_Swiss]

Booking “social contact” as a service offering is perceived as taboo. For many, social contacts are to be established spontaneously and not by booking an appointment. Participants gave a clear definition of when personal contact to organizations is required: as soon as the care service becomes intimate (ie, someone coming into their house or taking over intimate care services like hygiene).

A further principle of all participating care organizations reported by participants is

... to provide as much support as possible to assist members. Usually we don’t say NO to our members. [Care provider 08_Swiss]

CBHC organizations tend to decline none of the requests of their members. In their daily business, they feel challenged and responsible for creating new solutions, also for nontypical and nonstandard needs.

Participants confirmed that there are volunteers motivated to act as informal caregivers, but efficient ways of collaboration need to be established. This could be achieved by paying overtime or monetary credits for volunteers. Collaboration should work with small bureaucratic effort for volunteers. Nonfeasible expenditure/investment would exclude this important group of informal care givers.

Discussion

Principal Findings

This qualitative FG study aimed to explore concepts, approaches, and workflows of CBHC organizations in order to achieve a comprehensive understanding of existing services offered and relevant requirements to support these services with ICT solutions exemplified in two European countries. The Swiss and Slovenian results are related to three stakeholder groups: (1) older persons in need of support as care receivers of a CBHC service, (2) significant others of older persons in need of support, and (3) managers or care providers of a CBHC service. Results from the deductive analysis of existing workflows of CBHC organizations and the potential need of ICT support in the different workflows will be discussed, as well as the results from the inductive analysis based on five main categories: (1) ICT usage behavior of users, (2) challenges of web platform usage, (3) content and technical requirements for the web platform, (4) form and services of CBHC organizations, and (5) rationales of CBHC organizations.

To conclude, the idea of CBHC organizations delivering formal and informal care is very popular and is recommended among stakeholders. Participants emphasized personal contact between members and CBHC organizations as a main rationale for CBHC organizations. Social contact is seen as highly important to older persons in need of support. The main challenge when using a web platform such as the one being proposed will be the knowledge gap in ICT usage among older persons in need of support. Therefore, an age-appropriate web platform design and seniors’ mistrust in data protection need to be addressed. ICT usage will likely rise during the COVID-19 pandemic, but it can also lead to even larger “digital divides” among older persons in need of support.

Results of technical and content-based requirements for the web platform showed the openness of potential users regarding hardware and software solutions. FG participants emphasized the importance of an “intelligent system” behind the web platform in the form of a person or organization that coordinates and leads the web platform. The workflow of a CBHC organization proposed by the project group (Figure 1) was largely acknowledged by FG participants. Furthermore, it can be concluded that stakeholder results between different FGs were widely congruent. Certainly, there were differences in the aspects discussed, as there were three different stakeholder perspectives, but they shared the same ideas about principles of CBHC organizations, challenges of ICT usage, and the content and technical requirements for the web platform. Major differences in the issues mentioned by the different FGs were noted in the results section and will be discussed further below.

ICT Usage and its Challenges

A main issue in the discussions about the web platform was the lack of knowledge of ICTs and the habits and skills of older persons in need of support with ICT applications. Apparently, older persons in need of support as care receivers and managers
Challenges for CBHC Organizations

In addition to issues related to ICT, stakeholders also identified more general aspects regarding challenges for CBHC organizations. Organizations involved in the study offer a wide variation ofCBHC organizations, and one key aspect is the integration of ICT into their operations. This includes the development of web platforms to support the exchange of information, communication, and social interaction among older persons and care providers. However, several challenges were highlighted, particularly in terms of accessibility and usability for older persons.

Many older persons in need of support are not familiar with ICT usage. This helps to gain a broad understanding of the variability of ICT usage among this target group in Europe. Daily internet usage in Switzerland is slightly above the European Union average. Managers and care providers insisted on their current concepts and workflows in their CBHC organizations and could not imagine a web platform supporting and coordinating members and care providers. Older persons in need of support were aware of their knowledge gap and lack of practice in using ICT. They were convinced that future generations would benefit from this web platform. Moreover, they were open-minded and interested in taking ICT courses to improve their skills. These results are confirmed by the literature. In Switzerland, 41% of people aged 70 years and older use the internet, whereas 97% of people younger than 30 years of age use it. Internet use on a frequent basis (several times a week) is common for 34% of people older than 65 years; the rate in this age group has more than doubled within the last year and is increasing. The United States is often seen as a pioneer regarding modern technologies. Already one-half of its population over 65 years uses the internet, which can be seen as a prediction for Europe. According to the Nielsen Norman Group, approximately 65% of people in the United Kingdom aged 65 to 74 years are using the internet. Older persons in need of support in Europe use the internet primarily for seeking information. Bilateral communication and social interaction via blogs, social networks, and web communities are not yet common among older persons in need of support living in Europe. Only about 10% of older persons in need of support use web 2.0 tools. However, in the United States, 34% of people older than 65 years use social networks for communicating with family and friends.

Therefore, it is not surprising that participants in this study are not yet familiar with the potential of ICT. According to the literature, web accessibility currently faces three key challenges: (1) the web is growing faster than accessibility efforts progress; (2) as content, presentation, and design of websites are getting more sophisticated, so must technical skills; and (3) the rise of user-friendly (social) web platforms enabled non-tech-savvy people to share huge amounts of data online and most of them are in inaccessible formats. These aspects should be considered when developing a web platform for older persons in need of support. Hence, FG participants revealed many challenges when using this web platform. The main obstacles were ethical issues, such as mistrust in data protection and privacy concerns; financial issues, such as costs to purchase hardware and for internet connection; cultural issues, such as age and the knowledge gap for ICT usage; and common issues, such as the assumed information overload on the internet. These findings can be confirmed by the literature. The study revealed frustration by users, which can result from searching for information—for example, when a Google search yields too many results. Furthermore, mistrust in the search results was a problem for users. They did not know how to select relevant information. This means that resources and knowledge of quality standards are currently lacking. These challenges of older persons in need of support regarding internet searching are congruent with the literature.

One additional factor was named in this study: participants identified social isolation to be a risk for older persons in need of support, which would rise with increased ICT usage. This aspect was mentioned in the context of cooperatives and challenges of using the web platform or ICT together. Furthermore, participants were afraid of older persons in need of support using apps to book a service or to talk to care providers via Skype instead of through a personal, face-to-face conversation. They confirmed that CBHC organizations or care providers in some cases are the last remaining contact that care receivers or older persons in need of support have. Therefore, they ranked personal contact in a CBHC organization as the most important component. They reported that booking personal contact as a service feature was considered taboo. In the literature, there is no agreement on whether social isolation and loneliness increases or decreases as a result of internet use. Various research results indicate that internet usage is connected to a reduction of social isolation among older persons in need of support and increased well-being. A decrease in loneliness and increase in social contacts were recently confirmed as benefits of internet usage for people living in assisted living communities. These studies were mainly conducted in the United States. The low rate of internet usage behavior among older persons in need of support in Europe could result in a lack of awareness of the possibilities related to ICT usage. Intensifying training classes for older persons in need of support can promote ICT usage, especially communication via web 2.0 tools. This could lead to a decrease in social isolation among older persons in need of support. It was especially important for the project team to obtain input from potential web platform users. We were reassured that CBHC services focus on individual contact. The anxiety of older persons in need of support that social isolation may rise with internet usage has to be considered. Recent research shows opposite outcomes, which reveal improved well-being and a decrease in social isolation. Therefore, fostering an increase in ICT usage in older persons in need of support and supporting their growing ICT skills needs be an aim of today’s society.
range of services, from accompanying someone to the doctor to mowing their lawn or cleaning their house. One of their principles seems to be to find solutions for any requests from their members or older persons in need of support. In both countries, Switzerland and Slovenia, only informal care was delivered by CBHC organizations. The reason might be the existing structures in the health care system, where professional care is delivered by special outpatient nursing services, such as Spitex in Switzerland, which is paid by insurance companies, the state, and care receivers [15]. The stakeholder group of significant others of care receivers emphasized that one inclusive organization, which offers and coordinates care services of care receivers, would be preferable.

One further issue is the legal form of CBHC organizations. Participants of this Swiss and Slovenian study were predominantly CBHC organizations acting as associations because only a few genuine care “cooperatives” exist in these two countries [37,38]. The International Cooperative Alliance defines a cooperative as an “autonomous association of persons united voluntarily to meet their common economic, social, and cultural needs and aspirations through a jointly-owned and democratically controlled enterprise” [39]. Cooperatives as an organizational form are less recognized in the health care sector in Europe, despite some examples from Italy [40-42]. In Switzerland and Slovenia, cooperatives in the health care sector are still uncommon. Instead, associations act like cooperatives. In Switzerland, for instance, an adaptation of the law would be necessary to enable organizations to found cooperatives and facilitate their work [10]. In Slovenia, the cooperative law was adapted several times, most recently in 2009, when the European cooperative legal order was introduced to Slovenian law [11]. This could be a potential explanation for the small number of existing care cooperatives in Slovenia.

Limitations

While many helpful requirements and needs were identified to develop the platform, some limiting aspects of the study have to be considered. One aspect concerns the study design. The overall framework of the project restricted the number of FGs and involved countries. Nevertheless, the heterogeneity of the countries was satisfying because Switzerland is, in contrast to Slovenia, one of the leading countries concerning technology in Europe. The majority of FG participants being women reflects the societal phenomenon that women are still more involved in caregiving, professionally and informally [43]. Therefore, the FG sampling is assumed to be comparable with the status quo of CBHC organizations. Based on these framing project conditions, the criteria of saturation could not be applied for data collection. Thus, the question cannot be answered whether additional FGs from the same target groups and countries would have yielded more or different information. In the end, one could assert that the FGs revealed enough information because we did not notice any additional information gain from Slovenia compared with Switzerland.

Participants mainly agreed on the proposed workflow model, which was the basis for the FG discussions. Nevertheless, this abstract workflow was a complex model that was not easy to understand for the participants. To compile the lessons learned, more time is required to develop an in-depth understanding and discussion of outcomes. Therefore, we focused the discussions on the questions of the topic guide.

Conclusions

The study revealed a complex variety of results; some of the major issues are summarized below:

- Workflows of CBHC organizations need to be simple and congruent with the discussed workflow model (Figure 1):
  - older persons in need of support and their significant others need information presented in a user-friendly way about the CBHC organization and their services;
  - at best, relevant information about the needs of older persons in need of support from a specific region needs to be presented on the CBHC web platform; and
  - older persons in need of support and care providers need applications to establish contact with each other. Potential tools can vary from telephone calls and personal meetings to online video calls or chat applications.

- Although an overall openness regarding ICT was identified, ICT usage behavior varied enormously among FG participants. This makes it even harder to develop customized web platforms for this target group.

- Challenges of the potential web platform seem to be related to general concerns, such as data protection, access to the internet and ICT, and knowledge gaps in using ICT in the target group.

- The organizational form of CBHC organizations as associations is preferable because of low-threshold structure and establishment. The form of cooperatives is not common in the countries involved in this study.

- Rationales of CBHC organizations are quite clear: maintain a user focus, respect autonomy of older persons in need of support, and maintain personal contact between CBHC organizations and older persons in need of support.

In summary, we conclude that the majority of current stakeholders (older persons in need of support, significant others, and managers/care providers) are not familiar or experienced with ICT usage. Coming generations will contribute more concrete ideas of useful requirements and will benefit more from the web platform. For this reason, training for using the web platform and for setting it up for the specific CBHC organization will be offered. Older persons in need of support seemed very open-minded regarding training for ICT usage; therefore, existing offers of training should be intensified to meet the demands of the older persons in need of support. Once the target users are trained to use ICT, they can experience benefits from the web platform, such as decreased social isolation, independent living, and adequate user-oriented health care services. Further research is required in this context.

The web platform has the potential to facilitate the foundation, work, and collaboration of CBHC organizations in Europe. Overall, personal contact is a main request of older persons in need of support and managers and care providers; in Slovenia, it was cited by almost all participants. Searching for care services, contacting care providers, and communicating with
care providers is preferred via personal contact and seems to be the key element for user acceptance and for the successful implementation of a web platform like “ICareCoops” [16] to support CBHC organizations.

Acknowledgments

We want to thank all participants for their support and contribution to this study. Without their voluntary participation and their openness to discuss their personal experiences and opinions, it would not have been possible to achieve these results. We thank our colleagues David Stamm and Matthew Kerry-Krause for proofreading the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Additional file requirements matrix.
[XLSX File (Microsoft Excel File), 25 KB - jmir_v23i3e24006_app1.xlsx ]

References

16. iCareCoops. URL: http://project.icarecoops.eu/ [accessed 2021-02-28]


Abbreviations

AAL: Active and Assisted Living
CBHC: community-based health care
COREQ: Consolidated Criteria for Reporting Qualitative Research
FG: focus group
ICT: information and computer technology
Please cite as:
Biehl V, Becker H, Ogrin A, Reissner A, Burger J, Glaessel A
User-Centered Development of a Web Platform Supporting Community-Based Health Care Organizations for Older Persons in Need of Support: Qualitative Focus Group Study
J Med Internet Res 2021;23(3):e24006
URL: https://www.jmir.org/2021/3/e24006
doi: 10.2196/24006
PMID: 33688837

©Verena Biehl, Heidrun Becker, Alenka Ogrin, Alenka Reissner, Johannes Burger, Andrea Glaessel. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 10.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
A Clinical Communication Tool (Loop) for Team-Based Care in Pediatric and Adult Care Settings: Hybrid Mixed Methods Implementation Study

Amna Husain\textsuperscript{1,2,3}, MD, MPH; Eyal Cohen\textsuperscript{4}, MSc, MD; Raluca Dubrowski\textsuperscript{5}, PhD; Trevor Jamieson\textsuperscript{6}, MD, MBI; Allison Miyoshi Kurahashi\textsuperscript{1}, MEd; Bhadra Lokuge\textsuperscript{1}, MHS; Adam Rapoport\textsuperscript{7,8}, MD, MHS; Stephanie Saunders\textsuperscript{1,9}, MA; Elaine Stasiulis\textsuperscript{10}, BSc, MA; Jennifer Stinson\textsuperscript{5}, RN-EC, PhD; Saranjah Subramaniam\textsuperscript{11}, MA; Pete Wegier\textsuperscript{11}, PhD; Melanie Barwick\textsuperscript{5,12,13}, PhD, CPsych

\textsuperscript{1}Temmy Latner Centre for Palliative Care, Sinai Health, Toronto, ON, Canada
\textsuperscript{2}Lunenfeld-Tanenbaum Research Institute, Toronto, ON, Canada
\textsuperscript{3}Division of Palliative Care, Department of Family and Community Medicine, University of Toronto, Toronto, ON, Canada
\textsuperscript{4}Pediatric Medicine and Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, ON, Canada
\textsuperscript{5}Child Health Evaluative Sciences, Research Institute, The Hospital for Sick Children, Toronto, ON, Canada
\textsuperscript{6}Department of Medicine, Unity Health Toronto, Toronto, ON, Canada
\textsuperscript{7}Pediatric Advanced Care Team, The Hospital for Sick Children, Toronto, ON, Canada
\textsuperscript{8}Emily's House Children's Hospice, Toronto, ON, Canada
\textsuperscript{9}School of Rehabilitation Sciences, Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada
\textsuperscript{10}Institute of Medical Science, University of Toronto, Toronto, ON, Canada
\textsuperscript{11}Humber River Hospital, Toronto, ON, Canada
\textsuperscript{12}Department of Psychiatry, Faculty of Medicine, University of Toronto, Toronto, ON, Canada
\textsuperscript{13}Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Amna Husain, MD, MPH
Temmy Latner Centre for Palliative Care
Sinai Health
60 Murray St, 4th Floor
Toronto, ON, M5T 3L9
Canada
Phone: 1 416 586 4800 ext 7884
Email: amna.husain@utoronto.ca

Abstract

Background: Communication within the circle of care is central to coordinated, safe, and effective care; yet patients, caregivers, and health care providers often experience poor communication and fragmented care. Through a sequential program of research, the Loop Research Collaborative developed a web-based, asynchronous clinical communication system for team-based care. Loop assembles the circle of care centered on a patient, in private networking spaces called Patient Loops. The patient, their caregiver, or both are part of the Patient Loop. The communication is threaded, it can be filtered and sorted in multiple ways, it is securely stored, and can be exported for upload to a medical record.

Objective: The objective of this study was to implement and evaluate Loop. The study reporting adheres to the Standards for Reporting Implementation Research.

Methods: The study was a hybrid type II mixed methods design to simultaneously evaluate Loop’s clinical and implementation effectiveness, and implementation barriers and facilitators in 6 health care sites. Data included monthly user check-in interviews and bimonthly surveys to capture patient or caregiver experience of continuity of care, in-depth interviews to explore barriers and facilitators based on the Consolidated Framework for Implementation Research (CFIR), and Loop usage extracted directly from the Loop system.
Results: We recruited 25 initiating health care providers across 6 sites who then identified patients or caregivers for recruitment. Of 147 patient or caregiver participants who were assessed and met screening criteria, 57 consented and 52 were enrolled on Loop, creating 52 Patient Loops. Across all Patient Loops, 96 additional health care providers consented to join the Loop teams. Loop usage was followed for up to 8 months. The median number of messages exchanged per team was 1 (range 0-28). The monthly check-in and CFIR interviews showed that although participants acknowledged that Loop could potentially fill a gap, existing modes of communication, workflows, incentives, and the lack of integration with the hospital electronic medical records and patient portals were barriers to its adoption. While participants acknowledged Loop’s potential value for engaging the patient and caregiver, and for improving communication within the patient’s circle of care, Loop’s relative advantage was not realized during the study and there was insufficient tension for change. Missing data limited the analysis of continuity of care.

Conclusions: Fundamental structural and implementation challenges persist toward realizing Loop’s potential as a shared system of asynchronous communication. Barriers include health information system integration; system, organizational, and individual tension for change; and a fee structure for health care provider compensation for asynchronous communication.

(J Med Internet Res 2021;23(3):e25505) doi:10.2196/25505

KEYWORDS
coordination of care; complexity; internet communication technology; collaborative care; implementation science; theory of behavior; interprofessional team; patient engagement; social networking technology; user-centered design; Consolidated Framework for Implementation Research; Quality Improvement Framework; Implementation Outcome Taxonomy

Introduction

Background

Collaboration is fundamental to the care of patients with complex needs [1]. Optimal patient outcomes require integrated cross-disciplinary expertise alongside patient and caregiver engagement [2,3]. Effective communication within the circle of care is essential for coordination, cooperation, collaboration, safety, quality, and cost-effectiveness; yet poor communication and fragmented care is too often the norm [2,3].

In this paper, we use the concepts of communication, coordination, cooperation, and collaboration as defined by Fuks et al [4] and as employed in Eikey et al’s [5] review of health information technologies and collaboration. Communication is the “exchange of messages and information among people; coordination is the management of people, their activities and resources; cooperation is the production taking place on a shared workspace.” Collaboration encompasses communication, coordination, and cooperation, but is much more than its parts [4,5]. Collaboration includes “the development and testing of rules of engagement and shared understanding that facilitates how people work together” [4,5].

A key element of quality care is that patients and families experience good continuity of care (COC); care that is connected and coherent over time [6,7]. Because informational, management, and relational continuity are aspects of COC, effective communication among team members is likely to improve the patient-level outcome of COC.

To promote effective communication, and to examine how this relates to other aspects of collaboration and COC, we developed Loop, a web-based, asynchronous clinical communication tool formerly called My Team of Care (myTOC) [8]. Loop enables private threaded communication among patients, their caregivers, and their health care providers. In this paper, “teams” refers to the members of these digital circles of care called “Patient Loops.”

Loop emerged from the need to facilitate open communication between all members of the circle of care, regardless of their role, organizational affiliation, or geographic location. Loop was developed using user-centered design principles. The interface is intuitive [9], allowing patients and caregivers to communicate with their various health care providers (HCPs) in the Patient Loop in a flexible and timely way [10].

To date, although similar tools have been developed and taken to market [11-14], no such tool has been successfully implemented at scale. This raises the question of whether communication tools such as Loop are useful and, if so, what factors might impact their implementation and clinical effectiveness and ultimate scalability.

A pilot randomized controlled trial (RCT) of Loop in patients with advanced cancer demonstrated that Loop was intuitive and usable by members of the patient care team and used as intended for team-based communication in some Patient Loops. There was a nonsignificant trend in improved patient self-reported COC in the intervention group over the 3-month study period [8]. Adoption was influenced by a complex set of system, organizational, team, and individual factors, which is consistent with evidence on determining factors associated with effective implementation [15]. This study examines implementation barriers or facilitators, while also exploring Loop’s clinical and implementation effectiveness.

Implementation of eHealth Technologies

eHealth is defined as the application of information, computer, or communication technology to some aspects of health or health care [16]. The widespread use and integration of eHealth interventions into routine care remains a challenge, and most eHealth technologies linger within the confines of the academic settings in which they are studied and are not sustained in practice [17]. Implementation science can address this problem by studying contextual factors [18], process [19], and intervention effects that result in eHealth technologies that are more externally valid, practical, and sustainable, while identifying issues that are important to stakeholders and users.
A theory-informed approach to studying eHealth technology implementation addresses weaknesses reported in existing studies, namely, that they are often based on one particular technology, setting, or health condition, making it difficult to access the available evidence that can inform implementation planning [16]. A recent systematic review of 37 eHealth technologies analyzed using the Consolidated Framework for Implementation Research (CFIR) [15] as an organizing framework recommended that eHealth technology implementation should consider the following highly salient factors: complexity, adaptability, compatibility, cost, and champions. Identifying and monitoring of these barriers can support implementation planning, inform the use of mitigating implementation strategies, and improve implementation effectiveness [20].

Implementation Frameworks

As there is no implementation science model that specifically addresses eHealth technology, we utilized well-established models of implementation to inform the process, factors, and outcomes for this study. The Quality Improvement Framework (QIF) [21] was derived from 25 implementation process frameworks to foster high-quality implementation. The QIF lays out 4 phases that serve as a useful blueprint for the implementation process: phase 1, initial considerations for readiness in the host setting; phase 2, creating a structure for implementation; phase 3, offering the intervention and monitoring ongoing structure; phase 4, sustaining the practice and improving future applications.

The CFIR [15] is a determinant framework comprising 39 key factors associated with successful implementation, structured within 5 domains: intervention characteristics, inner setting, outer setting, characteristics of individuals, and the implementation process. Recent research by Barwick and others [22,23] has identified a subset of factors found to be more salient across contexts. This knowledge can streamline the assessment of barriers toward more effective implementation.

Implementation outcomes [24] are distinct from clinical outcomes and capture effects of deliberate actions to implement interventions in new settings. Implementation outcomes have 3 important functions: (1) they serve as indicators of implementation success; (2) are proximal indicators of implementation processes; and (3) are key intermediate outcomes in relation to clinical outcomes. Implementation outcomes include acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration, and sustainability. When interventions fail to produce desired outcomes, it is important to know if the failure occurred because the intervention was ineffective (intervention failure) or whether it was implemented incorrectly (implementation failure).

Objectives

The study examined the implementation and clinical effectiveness of Loop across 6 health care settings. We assessed clinical outcomes (COC, client participation in decision-making), implementation outcomes (adoption, acceptability, appropriateness, and feasibility), and explored implementation barriers and facilitators. We hypothesized that an implementation approach informed by the core principles of implementation science (ie, process, factors, strategies, outcomes, and implementation team) would lead to adoption, and that higher Loop use would be associated with improved patient COC. We anticipated identifying similar salient determinant factors that have been documented across varied study contexts and interventions. The study reporting adheres to the Standards for Reporting Implementation Research (Multimedia Appendix 1) [25].

Methods

Study Design

The study design was a hybrid type II, involving the simultaneous testing of a clinical intervention and an implementation strategy with the aim of more rapid translation [26]. We used a mixed methods approach to examine the clinical and implementation effectiveness of Loop at 6 health care sites [26]. The study was approved by the Research Ethics Board of Sinai Health System, University Health Network, and SickKids Hospital, and was conducted in Toronto, Ontario, Canada, where health care is provincially funded.

Loop Intervention

Loop enables private communication groups centered on a patient, called Patient Loops (Figures 1 and 2). In each Patient Loop, there are 2 streams of communication, one that includes the patient and caregiver, and another that is for the health care providers only [27]. Messages are threaded for ease of viewing conversations. Messages may be tagged with customizable labels (eg, hypertension, pain, lymphedema), and marked to the attention of a specific member or members of the Patient Loop. The latter action triggers a deidentified link to be sent to the email of the intended recipient(s) [28]. Figures 1 and 2 depict the Loop interface, and Figure 3 shows how Loop functionality compares to other categories of eHealth tools.
Figure 1. Screenshots of Loop optimized for a smartphone.

Figure 2. Screenshot of Loop on a computer screen.
Site Recruitment
Six clinical sites participated in this study. All sites were in academic health organizations in Toronto, Ontario, Canada. Three clinical sites were recruited in the first roll-out, including a regional palliative care program (Site 1) that provides home-based palliative care, alongside home care organizations; an academic family health program (Site 2) that provides primary care to patients; and a brain metastases clinic (Site 3) housed within an outpatient regional cancer center. These first 3 sites were approached during the knowledge translation activities for the previous stages of the research program. For this study, we reached out to health care colleagues in various specialties to present the study aims to site leads. Once site leads expressed interest in participating, we presented to the broader clinical group at each site.

In a second roll-out, we recruited a pediatric blood and marrow transplant (Site 4) program, and a pediatric palliative care program (Site 5)—both pediatric sites are situated within the same quaternary pediatric teaching hospital; and an outpatient psychosocial oncology program (Site 6) at a regional cancer center. The sites recruited in this second roll-out approached us, having learned of the study from colleagues or the Loop Research Collaborative. Five of the sites were specialized in hematology-oncology, radiation-surgical oncology, psychosocial oncology, or palliative care. The family medicine program was included to examine Loop adoption in primary care. An implementation champion was identified at each site. All champions were clinicians, most had a leadership role, and they engaged other HCPs at their site to elicit participation in the study.

Recruitment of HCPs, Patients, and Caregivers
The implementation champion at each site identified initiating HCPs (iHCPs) for recruitment. Additionally, study staff identified and recruited iHCPs at implementation planning activities described below. iHCPs then identified patients or their caregivers who were screened for inclusion criteria. Once the iHCP and the patient were registered in Loop, both were asked to identify any additional HCPs from the patient’s circle of care who could be invited to participate on the Loop. Study staff or iHCPs invited additional HCPs via email, phone, and in-person. There was no limit to the number of additional HCPs invited to join the patient’s Loop, and all provided verbal consent upon joining. Study staff followed a standard procedure to invite and enroll participants. The Loop Help menu contains videos for a Loop “quick start” guide.

Inclusion Criteria
Patients/caregivers from adult centers were included if (1) they were aged 18 or older and had capacity to consent. Pediatric patients (18 years or younger) could consent themselves, if capable, otherwise their parent or guardian was consented; (2) the patient or caregiver had internet access; and (3) there were at least two HCPs involved in the patient’s care. An additional criterion for patients recruited from adult centers was an Eastern Cooperative Oncology Group (ECOG) Performance Status score of 2 or less [29,30]. There was no comparable performance status measure for pediatric patients.

Exclusion Criteria
Patients were excluded if they (1) they had a prognosis of less than 6 months as determined by a physician, except for adult and pediatric palliative care sites where it was difficult for clinicians to identify those that met this criterion; or (2) had cognitive impairment as determined by a physician or by study staff using the Bedside Confusion Scale for adult patients [31].

Sample Size
No sample size calculation for clinical effectiveness was possible due to the limited sample size of the feasibility trial. Based on the previous study in ambulatory cancer and palliative care [8], we anticipated it would be feasible to recruit 15 teams
during the first wave of recruitment at 3 sites and 5 teams from each additional site during the second wave, resulting in 60 teams or Patient Loops. Based on a 25% attrition rate at various steps of enrollment, onboarding, and assembling the team, we anticipated a total enrollment of 45 Patient Loops in this study.

Implementation Procedure
The initiating context for this implementation endeavor was research. The intention was to provide Loop to participating organizations with the aim of exploring implementation and clinical effectiveness. We did not set out to implement Loop within entire organizations. As such, we did not undertake certain implementation activities such as developing organizational implementation teams and ensuring sustainability, as these are process elements key to program- or organizational-level implementation. Previous research [32] has identified that initiating context or impetus for the implementation endeavor is important for implementation process and sustainability.

Implementation Phase 1
Phase 1 occurred over 3-6 months and focused on understanding the initial implementation considerations within each site (QIF Phase 1) [21]. An assessment of needs, capacity, and readiness was done at each site, led by study staff, and guided by the Hexagon Tool [33]. The purpose of these meetings was to explore process adaptations that might be required, clarify goals, provide information about collaborative care and Loop, and to establish buy-in for using Loop. We conducted workflow observations to understand HCPs’ clinical workflows. Focus groups and consultative meetings were held to introduce and refine a tailored implementation plan for the study. HCPs at each initiating site were invited to participate in the information meetings where they were recruited as iHCPs, registered on Loop, and baseline data were collected.

Implementation Phase 2
Phase 2 spanned 3-6 months and focused on infrastructure and workflow adjustments for implementing Loop (QIF Phase 2) [21]. Using the description drawn from the implementation framework, site implementation champions were identified among HCPs who expressed interest in this role, although no formal role designation was made at the program level. Site readiness assessments from phase 1 informed a general implementation plan for each site, which was discussed with site champions and HCPs for refinement. iHCPs at all sites were asked to identify patients who met inclusion criteria. Patients or, if appropriate, their caregivers were then consented, enrolled in the study, and registered on Loop, creating a Patient Loop. Patient participants could identify a caregiver to participate in the study, who was also consented and joined the Patient Loop. For this study, Phase 4 involved an ongoing process of reflection on future applications for Loop [21] and was concurrent with all phases. Study participants, implementers, and stakeholders reflected on implementation process, Loop use, and improvements. These reflections were captured during regular interviews and periodic stakeholder consultations.

Data Collection
Participant Characteristics
Site characteristics were gathered during Phase 1 activities and culminated in an implementation plan for each site. Baseline data for participant characteristics included demographics, internet preferences, performance status (Palliative Performance Scale) [34], and Age-Adjusted Charlson Comorbidity Index (ACCI) [35] for adult patient participants. In a sample of cancer patients, ACCI scores have been categorized as mild (0-1), moderate (2-3), and severe (≥4), corresponding to a significant difference in survival rates [35]. For patients recruited from adult centers, the iHCP determined if patients had high unmet health or social needs as defined by Schaink et al [36]. Although a Pediatric Comorbidity Index is being developed, there is currently no validated measure of comorbidity or complexity for pediatric patients [37].

Implementation Outcomes
Adoption
Adoption is defined as the intention, initial decision, or action to try or employ an intervention or evidence-based practice [24]. In this study, adoption was operationalized as a function of Loop use: (1) the number of patient care teams registered on Loop, (2) the number of participants in each user category on Loop, (3) the total number of messages by site, and (4) the median number of messages per team per site. Loop use metrics were collected from Loop software reporting and backend data export at an interim point and at the end of the study, and by participant self-report in the check-in interviews.

Acceptability
Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory [24]. This was assessed informally in the phase 1 preparatory meetings and within the CFIR interviews.

Appropriateness
Appropriateness is the perceived fit, relevance, or compatibility of the intervention for a given practice setting, provider, or consumer; or perceived fit of the innovation to address a
particular issue or problem [24]. This was assessed informally in the phase 1 preparatory meetings and in the CFIR interviews and monthly check-ins.

Feasibility

Feasibility is defined as the extent to which a new intervention can be successfully used or carried out within a given setting [24]. The feasibility of implementing Loop was assessed at the site level with respect to number of sites approached; number of sites that approached us with an interest in participating; number of HCPs interested and recruited; number of HCPs who identified patients for recruitment; number of patients, caregivers, and additional HCPs recruited; and number of active Patient Loops assembled.

Cost, fidelity, penetration, and sustainability were not measured in this study. Fidelity to the intervention, or the extent to which users adhered to the Loop tool as intended [24], did not apply because as an eHealth technology, Loop does not have optional multiple core components; rather, a message is sent or not. Penetration and sustainability [24] were not relevant because Loop was only made available to a discrete number of teams for the purpose of this study, and there was no intention of full implementation within each site as part of usual practice.

Barriers and Facilitators

Barriers and facilitators to Loop implementation were assessed using individual interviews informed by implementation outcomes [24] and CFIR [15] using 2 main qualitative approaches. A brief (5-20 min) monthly check-in phone call with patients, caregivers, and iHCPs was used to gather feedback and troubleshoot implementation and technical issues. Participants were asked about their Loop use over the previous month, and their perception of its acceptability, accessibility, usefulness, feasibility, including the impact of Loop use on workflow, and their willingness to continue using Loop beyond the study if given the opportunity. Study staff conducted and captured monthly check-in content in fieldnotes. Check-in phone calls were audio recorded and reviewed to support fieldnote rigor.

Semistructured interviews based on the CFIR and adapted for language and context were conducted by telephone to capture HCP perspectives on implementation barriers and facilitators (Multimedia Appendix 2). All CFIR domains and constructs were included except for trialability, as this factor did not apply in a research-initiated implementation endeavor. In addition, given the role of patients in the use of Patient Loops, we included a sixth domain related to Patient Beliefs and Experiences to capture HCP perspectives on how patients experienced Loop, which has been done in previous studies [23]. The interview protocol was piloted with 2 HCPs and revised for length, flow, and clarity. Interviews were conducted with the site lead and an additional iHCP from each site who were purposefully sampled to capture sites having higher and lower Loop use. CFIR interviews were 30-60 minutes long, conducted by 2 members of the research team experienced in CFIR interviews and analysis (ES and RD), and supervised by the implementation science lead (MB).

Clinical Outcomes

Clinical outcomes were collected at baseline and at 2-month intervals from all patients or caregivers, either by phone or in person using standardized measures administered via survey (Table 1). Measures assessed patient or caregiver experience of COC, symptom severity, and participation in decision making and goal setting. Internally developed questionnaires measured team effectiveness [38]. Details on circle of care communications occurring outside the Patient Loop were collected from iHCPs, patients, and caregivers at monthly intervals using an internally developed social network questionnaire and will be the focus of a separate paper. Clinical effectiveness outcome measures were not collected from the noninitiating (additional) HCPs to decrease respondent burden and encourage enrollment on Patient Loops.

Table 1. Patient and caregiver outcome measures.

<table>
<thead>
<tr>
<th>Construct</th>
<th>Survey</th>
<th>Validated in</th>
<th>Scoring details</th>
<th>Administered to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuity of care experience (COC)</td>
<td>Continuity and Coordination subscale, Picker Ambulatory Cancer Care Scale [7]</td>
<td>Patients with cancer</td>
<td>Range: 0-100 Higher scores indicate higher continuity of care</td>
<td>Adult and pediatric patients and their caregivers</td>
</tr>
<tr>
<td>Symptom severity</td>
<td>Edmonton Symptom Assessment Scale (ESAS) [39,40]</td>
<td>Adult patients with cancer</td>
<td>Range: 0-90 Higher scores indicate higher symptom severity</td>
<td>Adult patients</td>
</tr>
<tr>
<td>Symptom bother</td>
<td>Symptom Screening in Pediatrics Tool (SSpedi) [41,42]</td>
<td>Children with cancer and hematopoietic stem cell transplantation</td>
<td>Range: 0-60 Higher scores indicate higher levels of bother</td>
<td>Pediatric patients and their caregivers</td>
</tr>
<tr>
<td>Client participation in decision making and goal setting (CPDG)³</td>
<td>Client-Centered Rehabilitation Questionnaire (CCRQ) [43], CPGD domain</td>
<td>Discharged rehabilitation patients</td>
<td>Range: 0-100 Higher scores indicate more positive responses</td>
<td>Adult and pediatric patients and their caregivers</td>
</tr>
</tbody>
</table>

³CPDG: Client participation in decision-making and goal setting domain of Client Centered Rehabilitation Questionnaire (CCRQ).
Analysis of Participant Characteristics
Participant characteristics (patients, caregivers, and HCPs) are described by site using frequencies, medians or means, SDs, and ranges.

Analysis of Implementation Outcomes

Adoption
Loop adoption was dependent on the number of individuals in each Patient Loop. A Patient Loop was considered active if it included an iHCP and a patient or caregiver. We conducted a subanalysis of the proportion of Loops with at least one additional HCP as part of the care team assembled on Loop.

Monthly Check-in Interviews (Adoption, Acceptability, Appropriateness, Barriers, and Facilitators)
Monthly check-in data were analyzed using hybrid data-theory-driven content analysis [44] on MAXQDA 2018.2. An initial codebook based on monthly check-in questions was developed and iteratively revised throughout the analytic process. The first phase of coding involved 6 members of the project team (AH, MB, PW, StS, SaS, and BL) who independently coded the same 3 monthly check-in interview notes, followed by a discussion to achieve consensus and identify revisions to the codebook. Each coder then rated the same notes from 3 new interviews, which were again reviewed for consensus and codebook revisions. The 6 coders continued coding the remainder of the interview notes independently and met regularly to discuss any new codes and issues related to implementation. Following coding completion, 1 coder (AH) reviewed monthly check-in notes from all sites, identified common coding themes, and summarized excerpts using data-driven content analysis [45]. In addition, some divergent perspectives were analyzed to provide a range of perspectives. Excerpts and summaries were discussed by the 6 coders to achieve agreement on emergent summative statements. The main coder (AH) then synthesized summative statements from text segments within categories and further sorted and analyzed all coded segments by site. A second reviewer (MB) reviewed the summary tables, consisting of coding categories, exemplar excerpts from the interview notes, and summative statements by site.

CFIR Interviews (Acceptability and Appropriateness)
CFIR interviews were analyzed using an adapted rapid analysis method [46]. ES conducted the interview while RD simultaneously coded each interview against CFIR constructs using a pre-set template. After each interview, ES checked her notes against the audio recording for completeness, and then RD sent her coded notes to ES to do a final check for accuracy and completeness. In a second step, not part of the rapid analysis method but consistent with previous CFIR research [47], ES and RD independently assigned valence ratings to each construct based on its strength (–2, −1, 0, 1, 2) and direction (negative or positive) relative to Loop implementation. Disagreements on valence ratings were resolved by discussion and consensus with MB.

Implementation barriers and facilitators were compared within and across sites and CFIR constructs were explored as a function of high and low Loop use. Data overlap between CFIR constructs and monthly check-in data were explored using a mixed methods approach to achieve greater contextual understanding [48].

Analysis of Clinical Effectiveness Outcomes
We report descriptive statistics (means, SD, and ranges) for clinical outcome measures. We conducted an analysis of change in score of the main outcome of the Continuity and Coordination Subscale of the Picker (COC) between baseline and each timepoint. We did an exploratory repeated measures analysis of COC controlling for patient participation in decision making (CPDG domain of Client-Centered Rehabilitation Questionnaire [CCRQ]) and Loop use within the Patient’s Loop.

Results

Recruitment
A total of 57 HCPs and key informants took part in Phase 1 activities. We recruited 25 iHCPs across all sites who then identified 266 patients as potentially meeting participation criteria. Figure 4 charts the steps in participant recruitment (patients or caregivers) from which Loops were formed.
Of the 147 patient participants (or caregivers in their lieu) who were assessed and met screening criteria, 57 consented and 55 Loops were created, within which 51 patients participated in data collection. Of the 55 Loops created, attrition resulted in 31 Loops completing the follow-up period. Patients and iHCPs together identified 190 unique additional HCPs who were part of the patient’s circle of care (some HCPs were included in more than 1 Patient Loop). Research staff contacted each identified additional HCP an average of 4 times, using phone and email, to invite them to participate in the study. Of these individuals, 96 (50.5%) consented to join a Loop. Of the remaining additional HCPs, 47/190 (24.7%) did not respond to invitations by the research team, 30/190 (15.8%) declined to join, and 17/190 (8.9%) were unable to participate further in the study as the referent patient had died. We did not monitor reasons for declining to join.

**Participant Characteristics**

Baseline participant characteristics are presented in Tables 2 and 3. Of 51 patients for whom baseline data were collected, 59% (30/51) were female. Patients ranged in age from 1.4 to 90 years. Most patients had a cancer diagnosis (61%, 31/51), although the primary diagnoses ranged from pediatric genetic disorders to connective tissue diseases. For adult patients, performance status was collected with the Palliative Performance Scale, for which median scores ranged from 60% at Site 1 to 80% at Site 6. The minimum Palliative Performance Scale score was 50% and the maximum score was 100% across all sites. The median ACCI comorbidity score ranged from mild in primary care patients to severe among home palliative care patients, demonstrating variable morbidity–mortality within the sample.
Table 2. Patient and caregiver characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
<th>Overall sample</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participant, n</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>6</td>
<td>10</td>
<td>16</td>
<td>3</td>
<td>5</td>
<td>11</td>
<td>51</td>
</tr>
<tr>
<td>Caregiver</td>
<td>2</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td><strong>Gender, n</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>7</td>
<td>11</td>
<td>0</td>
<td>2</td>
<td>7</td>
<td>30</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caregiver</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>—</td>
<td>4</td>
<td>—</td>
<td>—</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>—</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td><strong>Age (years), median (range)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>68 (58-90)</td>
<td>62 (18-87)</td>
<td>58 (29-73)</td>
<td>17 (11-27)</td>
<td>14.5 (1.4-17)</td>
<td>52 (25-72)</td>
<td></td>
</tr>
<tr>
<td>Caregiver</td>
<td>73 (67-79)</td>
<td>—</td>
<td>39.5 (38-60)</td>
<td>—</td>
<td>—</td>
<td>65 (54-66)</td>
<td></td>
</tr>
<tr>
<td>Performance status, median % (range)</td>
<td>60 (50-80)</td>
<td>90 (60-100)</td>
<td>80 (60-100)</td>
<td>—</td>
<td>—</td>
<td>80 (70-100)</td>
<td></td>
</tr>
<tr>
<td><strong>Patient diagnoses, n</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>6</td>
<td>10</td>
<td>16</td>
<td>3</td>
<td>5</td>
<td>11</td>
<td>51</td>
</tr>
<tr>
<td>Noncancer</td>
<td>0</td>
<td>9</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td><strong>Age-Adjusted Charlson Comorbidity Index (ACCI), median (range)</strong></td>
<td>6 (3-8)</td>
<td>3 (0-9)</td>
<td>5 (0-9)</td>
<td>—</td>
<td>—</td>
<td>2 (0-6)</td>
<td></td>
</tr>
<tr>
<td>Complexity, n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>2</td>
<td>5</td>
<td>15</td>
<td>—</td>
<td>—</td>
<td>9</td>
<td>31</td>
</tr>
<tr>
<td>Mild</td>
<td>2</td>
<td>5</td>
<td>13</td>
<td>—</td>
<td>—</td>
<td>7</td>
<td>27</td>
</tr>
<tr>
<td>Severe</td>
<td>2</td>
<td>2</td>
<td>12</td>
<td>—</td>
<td>—</td>
<td>6</td>
<td>22</td>
</tr>
<tr>
<td>Resource utilization</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Psychosocial issues</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>9</td>
<td>13</td>
</tr>
</tbody>
</table>
### Table 3. Health care provider characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
<th>Overall sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care provider, n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initiating HCP (iHCP)</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>25</td>
</tr>
<tr>
<td>Additional HCP</td>
<td>11</td>
<td>14</td>
<td>26</td>
<td>6</td>
<td>19</td>
<td>20</td>
<td>96</td>
</tr>
<tr>
<td>iHCP gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>iHCP age (years), median (range)</td>
<td>41 (30-68)</td>
<td>39 (32-67)</td>
<td>40.5 (32-44)</td>
<td>62 (62)</td>
<td>37 (36-39)</td>
<td>49.5 (33-54)</td>
<td></td>
</tr>
<tr>
<td>iHCP type, n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>—</td>
<td>4</td>
<td>21</td>
</tr>
<tr>
<td>Clinical nurse specialist (CNS)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Nurse practitioner (NP)</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Clinical specialty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focused palliative care practice (N=6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family physician (N=5); NP (N=1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation oncology (N=3); Neurosurgeon (N=1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric hematologist/oncologist (N=2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palliative CNS (N=2); palliative NP (N=1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatry (N=4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Role, n</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administrative director</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Clinical programs director</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Clinical care</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>25</td>
</tr>
<tr>
<td>Years in health care, median (range)</td>
<td>10.5 (3-37)</td>
<td>12.5 (4-38)</td>
<td>14.5 (6-18)</td>
<td>28 (24-32)</td>
<td>13 (11-15)</td>
<td>15 (6-19)</td>
<td></td>
</tr>
<tr>
<td>Practice fee structure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fee for service</td>
<td>—</td>
<td>1</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Alternate payment plan</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>10</td>
</tr>
<tr>
<td>Salaried</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>—</td>
<td>9</td>
</tr>
<tr>
<td>Other, academic, or alternate funding plan</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

*aHCP: health care provider.

For 4 of 6 sites (Sites 1, 2, 3, and 6), iHCPs were asked to assess patient complexity based on the categories identified by Schaink et al [36]. The majority of patients were identified as having multimorbidity (87%, 27/31) and high resource utilization (71%, 22/31), while a minority were identified as having psychosocial issues (42%, 13/31).

Although internet access was an inclusion criterion, 1 out of 51 patient reported no internet access. Almost all patients and caregivers reported feeling “comfortable” or “very comfortable” using computers, and most felt “comfortable or very comfortable” using a smartphone. Of 51 patients or their caregivers, 24 (47%) used email and 16 (31%) used text to communicate with their HCPs; the remainder communicated by phone, in-person, or by pager.

**Implementation Outcomes**

**Adoption**

Loop adoption was based on use statistics pulled from Loop’s data server. Across all sites, the total number of participants, including additional HCPs, who joined Patient Loops was 262, with 52 Patient Loops created. The median number of HCPs per Patient Loop was 4 with a range of 1-13 (Table 4). Overall, 228 Loop messages were sent by patients, caregivers, and health care providers within the study period. A full breakdown of...
messages sent by user type and site is presented in Table 5. Across sites, a median of 1 message and a maximum of 28 messages were sent within a single team. Quartiles were calculated to characterize the number of messages as low, medium, and high Loop use based on the number of messages exchanged at each site: Q1 (low), Q2 (medium), and Q3 (high). Patients were the most active users, posting nearly 50% of all messages within Loop.

### Table 4. Team composition by Patient Loop (team) and by site.

<table>
<thead>
<tr>
<th>Composition</th>
<th>Site 1a</th>
<th>Site 2b</th>
<th>Site 3c</th>
<th>Site 4d</th>
<th>Site 5e</th>
<th>Site 6f</th>
<th>All sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members⁹, n</td>
<td>26</td>
<td>27</td>
<td>109</td>
<td>14</td>
<td>49</td>
<td>37</td>
<td>262</td>
</tr>
<tr>
<td>Teams, n</td>
<td>6</td>
<td>9</td>
<td>18</td>
<td>3</td>
<td>5</td>
<td>11</td>
<td>52</td>
</tr>
</tbody>
</table>

#### HCP⁸ per team

| Mean (SD)  | 3.17 (2.14) | 2.00 (1.00) | 4.89 (0.96) | 3.33 (1.15) | 7.80 (4.32) | 2.09 (1.22) | 3.79 (2.44) |
| Median (range) | 2 (1-7) | 2 (1-4) | 5 (4-7) | 4 (2-4) | 7 (2-13) | 2 (1-4) | 4 (1-13) |
| ≥1 secondary HCP | 5 | 5 | 18 | 3 | 5 | 7 | 43 |

#### Members per team

| Mean (SD)  | 4.33 (2.16) | 3.00 (1.00) | 6.06 (1.11) | 4.67 (0.58) | 9.80 (4.32) | 3.36 (1.36) | 5.04 (2.62) |
| Median (range) | 3 (2-8) | 3 (2-5) | 6 (5-8) | 5 (4-5) | 9 (4-15) | 3 (2-5) | 5 (2-15) |

⁹Six initiating HCPs were recruited from among 18 physicians within an expert palliative care program that has a large homecare component.

Six initiating HCPs were recruited from among 12 physicians in an academic family medicine site.

Three radiation oncologists and 1 neurosurgeon (iHCPs) were recruited from within a multidisciplinary program based in a regional cancer center, which included additionally 2 neurosurgeons, 1 registered nurse (RN), 1 physician assistant (PA), and 1 fellow in training. The PA and Fellow participated as additional HCPs on the Patient Loops.

Two out of 5 physicians, 4 patients, and 2 caregivers were recruited from a Pediatric Blood and Marrow Transplant program within a quaternary pediatric hospital. Additionally, this program has 3 nurse practitioners (NPs) and 4 RNs.

One NP and 2 clinical nurse specialists were recruited as iHCPs from a pediatric palliative care program, which includes 5 physicians, 1 nurse practitioner, and 2 clinical nurse specialists within a quaternary pediatric hospital.

Four out of 9 psychiatrists were recruited. Additionally, this adult psychosocial oncology program located within a regional cancer center has 16 social workers, 5 clinical psychologists, and 2 music/art therapists.

Includes patient, caregiver, and HCP members.

HCP: health care provider.
Table 5. Message frequency by site, user type, and Patient Loops (teams).

<table>
<thead>
<tr>
<th>Message Frequency</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
<th>All sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Messages (not including research administrator), N</td>
<td>39</td>
<td>80</td>
<td>62</td>
<td>9</td>
<td>26</td>
<td>12</td>
<td>228</td>
</tr>
<tr>
<td>Median (range)</td>
<td>3.5 (0-22)</td>
<td>3 (0-27)</td>
<td>1.5 (0-28)</td>
<td>4 (0-5)</td>
<td>1 (0-18)</td>
<td>0 (0-7)</td>
<td>1 (0-28)</td>
</tr>
<tr>
<td>Frequency quartiles (Hi, Med, Lo)</td>
<td>Q3 (Hi)</td>
<td>Q3 (Hi)</td>
<td>Q3 (Hi)</td>
<td>Q1 (Lo)</td>
<td>Q2 (Med)</td>
<td>Q2 (Med)</td>
<td></td>
</tr>
<tr>
<td>Messages sent by user type, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total messages (including research administrator), N</td>
<td>54</td>
<td>98</td>
<td>97</td>
<td>14</td>
<td>30</td>
<td>25</td>
<td>318</td>
</tr>
<tr>
<td>Patient</td>
<td>12 (22.2)</td>
<td>53 (54.1)</td>
<td>28 (28.9)</td>
<td>1 (7.1)</td>
<td>0 (0.0)</td>
<td>7 (28.0)</td>
<td>101 (31.8)</td>
</tr>
<tr>
<td>Caregiver</td>
<td>18 (33.3)</td>
<td>0 (0.0)</td>
<td>14 (14.4)</td>
<td>3 (21.4)</td>
<td>14 (46.7)</td>
<td>1 (4.0)</td>
<td>50 (15.7)</td>
</tr>
<tr>
<td>Health care provider</td>
<td>9 (16.7)</td>
<td>27 (27.6)</td>
<td>20 (20.6)</td>
<td>5 (35.7)</td>
<td>12 (40.0)</td>
<td>4 (16.0)</td>
<td>77 (24.2)</td>
</tr>
<tr>
<td>Research admin</td>
<td>15 (27.8)</td>
<td>18 (18.4)</td>
<td>35 (36.1)</td>
<td>5 (35.7)</td>
<td>4 (13.3)</td>
<td>13 (52.00)</td>
<td>90 (28.3)</td>
</tr>
<tr>
<td>Teams ≥1 message, n</td>
<td>5</td>
<td>7</td>
<td>10</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>33</td>
</tr>
</tbody>
</table>

The sum of all messages, including those sent by the Research Admin, were used as the denominator when calculating the % in this section.

Participants also reported their time spent on Loop in the monthly check-in interviews. We had 250 responses to the question of “Loop use in the previous month”; of these, 95 (38.0%) responses reported “some Loop use” over the previous month, and 155 (62%) reported “no Loop use” over the previous month. A participant likely responded at more than 1 timepoint to this question, and therefore, these are not independent responses.

**Acceptability**

Perception of Loop’s acceptability [24] as agreeable, palatable, or satisfactory was explored in Phase 1 of implementation, which centered on program composition and workflows, and identification of a site champion who could facilitate buy-in and recruitment. Using an iterative consultative planning process, each site arrived at a decision to proceed or to not proceed with Loop. Among the sites we initially approached, one site did not proceed to Phases 2 and 3 due to competing priorities with the roll-out of another eHealth tool. Among the sites that proceeded to Phases 2 and 3, all participants perceived Loop, the implementation plan, and study procedures as acceptable. Perspectives on acceptability at midpoints and study end are presented in the monthly check-in and CFIR interview analyses below.

**Appropriateness**

Loop’s perceived fit, relevance, or compatibility for setting and gap in care is reported in the monthly check-in and CFIR analyses below.

**Feasibility**

The extent to which Loop was successfully used within a site was operationalized by recruitment and use statistics, reported in Tables 4 and 5. These data show that Loop was used in each of the participating sites to some extent. It is important to note, however, that sites were recruited within a research context, and site participants may have been motivated to use Loop for this reason.

**Barriers and Facilitators**

**Monthly Check-In Interviews**

Monthly check-in interviews captured barriers and facilitators related to Loop use, ways in which Loop filled gaps in care, opportunity to use Loop, team composition and patterns of communication, Loop design and function, and overall satisfaction with Loop. Field notes, reported as excerpted first-person statements below, shed light on loop acceptability and appropriateness.

**Loop Use**

Among barriers to Loop use, iHCPs, patients, and caregivers reported that existing modes of communication, such as phone, in person, and email were commonly used for medical care needs. As such, participants did not perceive a relative advantage [15] to using Loop for team-based communication, and medical issues were not sufficiently complex to warrant the use of Loop.

> It’s not necessary to add new people on Loop...We have a system that is working well... Typically, just calling the nurse practitioner and/or emailing the nurse at the hospital works. I see the value in the Loop system, but it’s not necessary for where I am at. [Fieldnote, Parent Caregiver, Site 5, Month 2]

**Gap in Care**

Loop’s inclusion of patients in team communication was perceived to be facilitative to Loop use and was identified as fulfilling a gap in care.
There is a strong advantage to having the patient in the Loop and being privy to these conversations. [Fieldnote, iHCP, Site 2, Month 1]

The iHCP quoted above expressed how communication is a challenge, even when programs are part of the same organization and located in the same building. The conventional transfer of information via consult notes does not address this gap. Additionally, iHCPs said that Loop addressed a collaboration gap across the health care team. Participants also expressed that collaboration, specifically, is critical but lacking in the care they experience.

The collaborative care element is key, this is what is missing from the patient’s experience of the health system…it’s a crucial gap that Loop could fill, it’s just getting people on board to use it. There needs to be communication between different providers and different sites. The lack of communication leads to care being incredibly fragmented. [Fieldnote, Patient, Site 6, month 6]

Several participants perceived Loop as having potential to improve their medical care and to prevent the duplication of communication and services. In addition, Loop could provide a means to ask questions or provide updates that may not have been communicated during in-person visits.

I found that providers were ‘duplicating’ some of the same treatment issues and that maybe Loop could be useful for this. [Fieldnote, Caregiver, Site 1, Month 4]

Everyone is on Loop so I am feeling better about not needing to double up with messages. Anyone on the Loop can prescribe if the patient needs something. Any person on the Loop can do the duty needed, which is 11 people on Loop. I find that at home, we have so many services going on that one thing gets mixed up and all of a sudden all the information is wrong and I get stressed out. As a result, I feel like I am not sure what’s going on. Loop could help. [Fieldnote, Caregiver, Site 5, Month 2]

Opportunity to Use Loop

Participants across all sites frequently reported that no medical situation arose during the data collection period that prompted them to post a message in Loop. Patients were either medically stable or in remission and, therefore not requiring active treatment; or they were too sick to use Loop, admitted to hospital or a palliative care unit. Patient and caregiver Loop use was facilitated by instances when a specific situation arose, such as an emergency department visit, a need to coordinate an admission to long-term care, or to ask a question about symptoms. In other instances, a patient or caregiver used Loop to update the health care team, primarily about appointments they had scheduled.

Team Composition and Patterns of Communication

Although some users reported that partial teams could still be useful, assembling additional HCPs in a Patient’s Loop proved challenging. Participants frequently stated that unless the relevant team members were enrolled, Loop had limited usefulness.

Loop on the other hand is very simple and easy. The goal is to have one place for all the specialists; one place they can go to communicate. I feel that if you can’t get everyone to sign on, then it limits the usefulness of Loop. [Fieldnote, Caregiver, Site 6, month 1]

Participant messages that were left unreciprocated also posed a barrier to Loop use.

After trying this and getting no response, I didn’t want to use Loop more because I didn’t want to feel that I was badgering others. [Fieldnote, Patient, Site 6, month 6]

Some iHCPs reported that they did not post messages unless patients posted first, perceiving the patients or caregivers as drivers of care-based communication. Of note, in at least one instance, an adolescent patient stated that he would not post messages in Loop unless the HCPs posted first. Patients and caregivers whose messages were reciprocated indicated that they were likely to use Loop again.

Design and Function

Loop’s user interface was generally considered to be simple and intuitive, and the asynchronous nature of the messaging was useful for nonurgent messages, and thereby, likely to reduce burden. Nonetheless, patients and caregivers who had access to their hospital’s patient portal, which allows them to view reports and test results, found the portal met many informational needs, if not their communication needs. Some users expressed that integration of Loop into the patient portal would be helpful.

I really, really, like the simplicity of Loop’s design, and I feel that it is simple to access for those that might not be tech savvy. [Fieldnote, Patient, Site 1, month 2]

There was some confusion among participants about Loop’s purpose and the types of messages that were appropriate to post.

I felt unsure about what concerns can be put on the system. Right now, I generally send emails to my HCPs regarding care plans. There are 12 members in my Loop, but no activity. [Fieldnote, Caregiver, Site 5, month 2]

iHCPs commonly believed Loop should ideally be integrated into the hospital’s electronic medical record (EMR). Because Loop requires its own login and is not embedded in the EMR, its use was cumbersome and did not align with their existing workflow, particularly if only a few of their patients were using it.

Implementation Context

Given that research was the initiating context for the implementation endeavor, research team members played key roles in supporting implementation that would not be sustainable otherwise. Study staff helped users to register on Loop, explaining what tagging “attention to” someone means when posting a message, and clarifying what kinds of messages were.
appropriate to post. Study staff posted bimonthly messages with audit information such as the number of messages posted in the participant’s Patient Loop, number of messages in the most active Patient Loop across all sites during the same period, how to use Loop, and updates about study.

**Workflow and Compatibility**

iHCPs had pre-existing processes or workflows that were supported by administrative or other clinical staff. In some settings, clinical administrative staff or trainees were tasked with communicating with patients and other HCPs, which meant HCPs did not experience the back and forth “telephone tag” that is common when communicating with patients and other HCPs. This removed some of these inefficiencies in communication that we anticipated would be a stimulus for Loop use. Furthermore, some iHCPs reported that they would want an intermediary to function in a similar administrative or facilitative role within Loop.

Other workflows relied on the patient (or family) to initiate communication, as with the transfer of information between organizations. In this situation, Loop’s advantage in reducing the patient or caregiver’s responsibility for transmitting information from HCP to HCP was not realized.

The patient is very helpful in communicating for herself. For example, she acts as the focal point for communication, prints out test results, and updates for me and provides them at the beginning of a visit for me to review. [Fieldnote, iHCP, Site 1, month 3]

**Overall Satisfaction With Using Loop**

Monthly check-in interviews provided feedback on participants’ satisfaction with Loop. Across all timepoints, 45 responses indicated users were “somewhat satisfied” to “very satisfied,” and 7 responses indicated users “somewhat dissatisfied” and “very dissatisfied.” Satisfaction feedback was only elicited if the participant had used the system in the previous month. We inferred that any interview that did not have a response for “satisfaction” or was coded as “unable to rate” had no Loop use. The denominator for the satisfaction question was 279 responses, and do not reflect independent responses because the same participants may have replied to this question at more than 1 timepoint.

**COVID-19 Pandemic**

The pandemic restrictions began in March 2020 in Canada and impacted recruitment and follow-up at Sites 4, 5, and 6. During this time, a parent caregiver would have liked to use Loop to check information about upcoming appointments, but at month 1, none of the additional HCPs had yet been assembled on their Loop. One iHCP reported loving the idea of Loop but felt it was difficult to build buy-in with other HCPs and patients during the pandemic. All contact with patients and other HCPs had shifted to virtual means and they found it hard to remember to talk about Loop. Another shift was that the pandemic led to removal of prior provincial restrictions on the use of alternative forms of communication and most care encounters became virtual. New billing codes for encounters by phone or videoconferencing were introduced. This change resulted in alternate methods of communication becoming incentivized and presented an unanticipated barrier to Loop use.

**CFIR Interviews**

CFIR interviews served to identify contextual barriers and facilitators according to this widely accepted determinant framework. CFIR comments were captured for each construct regarding its presence or absence in relation to supporting the implementation of Loop. Sites 2 and 6 had only 1 CFIR interview; sites 4 and 5 had 2 CFIR interviews; and sites 1 and 3 had 3 CFIR interviews. Notes for each site were summarized by construct by ES and RD and discussed with MB. Valence was rated for each construct by interview, but the mode could not be calculated for 2 sites where only 1 HCP was interviewed, and so valence is not reported numerically. Rather, coders reviewed the construct summaries by site and coded them as to whether they were perceived as supportive of implementation or not (yes/no), and as being present or absent in Loop implementation (+/-). Table 6 presents these findings: where codes were mixed, this is noted, and where constructs did not manifest in the interview, they are left blank.
Table 6. Salient CFIR<sup>a</sup> constructs by site.

<table>
<thead>
<tr>
<th>CFIR domains and constructs</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
<th>Site 4</th>
<th>Site 5</th>
<th>Site 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviews, n</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Message frequency quartiles (Hi, Med, Lo)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Q3 (Hi)</td>
<td>Q3 (Hi)</td>
<td>Q3 (Hi)</td>
<td>Q1 (Lo)</td>
<td>Q2 (Med)</td>
<td>Q2 (Med)</td>
</tr>
<tr>
<td><strong>Intervention characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention source</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>—</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Evidence strength and quality</td>
<td>—</td>
<td>—</td>
<td>Mixed</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Relative advantage</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Adaptability</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
</tr>
<tr>
<td>Complexity</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Outer setting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient needs and resources</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Peer pressure</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cosmopolitanism (no score)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
<td>—</td>
</tr>
<tr>
<td>External policies and incentives</td>
<td>Yes (+)</td>
<td>—</td>
<td>Yes (+)</td>
<td>—</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Inner setting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural characteristics</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Mixed</td>
</tr>
<tr>
<td>Networks and communications</td>
<td>—</td>
<td>—</td>
<td>Yes (-)</td>
<td>—</td>
<td>Yes (+)</td>
<td>Mixed</td>
</tr>
<tr>
<td>Culture</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Implementation climate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tension for change</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>—</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Compatibility</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
</tr>
<tr>
<td>Relative priority</td>
<td>—</td>
<td>Yes (-)</td>
<td>Mixed</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Organizational incentives and rewards</td>
<td>—</td>
<td>—</td>
<td>Yes (-)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Goals and feedback</td>
<td>—</td>
<td>—</td>
<td>Yes (-)</td>
<td>—</td>
<td>Yes (+)</td>
<td>—</td>
</tr>
<tr>
<td>Learning climate</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Leadership engagement</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>Yes (-)</td>
<td>—</td>
<td>Yes (-)</td>
<td>—</td>
</tr>
<tr>
<td>Available resources</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Access to knowledge and information</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Characteristics of individuals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge and beliefs about the intervention</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Individual stage of change (no score)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>—</td>
</tr>
<tr>
<td>Individual identification with organization (no score)</td>
<td>—</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>—</td>
</tr>
<tr>
<td>Other personal attributes</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planning</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Yes (+)</td>
<td>Mixed</td>
</tr>
<tr>
<td>Opinion leaders</td>
<td>—</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>Yes (+)</td>
<td>—</td>
<td>Mixed</td>
</tr>
<tr>
<td>Formally appointed internal implementation leaders</td>
<td>—</td>
<td>—</td>
<td>Yes (-)</td>
<td>Yes (+)</td>
<td>Mixed</td>
<td>—</td>
</tr>
</tbody>
</table>

<sup>a</sup>CFIR: Consolidated Framework for Implementation Research

<sup>b</sup>Hi, Med, Lo: High, Medium, Low

https://www.jmir.org/2021/3/e25505

J Med Internet Res 2021 | vol. 23 | iss. 3 | e25505 | p.291

(page number not for citation purposes)
Several CFIR constructs were perceived as supporting implementation and as having manifested in Loop implementation across most sites. These are annotated as “Yes (+)” in Table 6.

**Intervention Characteristics (Intervention Source and Complexity)**
Respondents were aware of and had positive regard for where Loop originated, and this was perceived to be supportive of its implementation. Loop was viewed as easy to use, which was also facilitative for its implementation.

**Outer Setting Characteristics (External Policies and Incentives)**
Respondents perceived the outer health system context as supportive of tools that could improve communication within the patient’s circle of care and saw this as supportive of Loop implementation.

**Inner Setting Characteristics (Culture, Available Resources, Access to Knowledge, and Information)**
Organizational culture was perceived as supportive of initiatives to implement evidence-based interventions such as Loop. Respondents felt they were well supported by the research team and had access to requisite knowledge and information about Loop in a way that supported implementation.

**Characteristics of Individuals (Knowledge and Beliefs About the Intervention, Individual Identification With the Organization, Other Personal Attributes)**
Respondents felt they were familiar with facts, truths, and principles related to Loop, perceived their organization was committed to evidence-based care, and possessed the requisite tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

**Process (Planning, Reflecting, and Evaluating)**
Respondents were aware of the plan in place to support Loop implementation and perceived this as facilitative. They also valued the opportunity to reflect on their experience and use of Loop during the monthly check-in interviews, although they were unsure as to how their reflections were used to inform ongoing implementation.

**Characteristics of Recipients (Patient Beliefs and Patient Experience)**
Respondents felt patients believed in the usefulness of Loop and that, for the most part, their experience of using Loop was positive.

Several CFIR constructs were perceived having the potential to support implementation generally but were perceived as absent with respect to Loop implementation across most sites—indicated as Yes (–) in Table 6.

**Intervention Characteristics (Relative Advantage and Adaptability)**
Respondents felt that although Loop had potential over alternative solutions, this relative advantage was not realized. They would have liked Loop to be adaptable to their workflow and environment, specifically with respect to its integration with the local EMR or patient portals.

**Inner Setting Characteristics (Structural Characteristics, Tension for Change, Compatibility, Relative Priority, Organizational Incentives and Rewards, and Leadership Engagement)**
With respect to the structural characteristics of the implementing organizations, respondents felt that Loop should ideally be integrated with the EMR they were already using. The lack of integration was perceived as a major barrier to Loop use as it meant users had to take several extra steps to enter and extract Loop information to put into the medical record.

*Having more than one system to work with is always going to be very awkward.* [CFIR interview, iHCP, Site 1]

The lack of integration between Loop and EMRs also emerged as a barrier with respect to Loop’s compatibility with existing workflows. These workflows are dictated by and facilitated through the EMR; anything outside of the EMR is difficult to manage.

*It’s already complicated by the fact that nurses who take care of the same patients, do not use the same record-keeping system as I do... so there is already additional work needed to fill this gap.* [CFIR interview, iHCP, Site 1]
Tension for change was low across all sites, given the perception that Loop was needed by only a small number of more complex patients. Respondents noted a lack of organizational incentives and rewards and limited involvement from organizational leadership. Several changes would be needed to implement Loop more effectively, including leadership engagement, use of reminders, and elimination of multiple passwords across various systems through integration with EMRs and portals.

**Process (Formally Appointed Internal Implementation Leaders and External Change Agents)**

Most of the constructs related to engaging others in the implementation process received mixed and largely negative ratings. Respondents commented on the limited influence of opinion leaders, champions, and external change agents.

We explored CFIR constructs found to be salient in this study relative to other studies in which CFIR was assessed by interview (see Table 7). Although 2 of the comparison studies [22,49] compared high and low implementing sites, 2 studies did not ([23] and this study). All 4 studies explored implementation in different contexts and for different interventions yet results for salient constructs are surprisingly similar in at least two or more of the studies, which suggest that several consistently robust constructs are commonly associated with implementation. Highly salient constructs across studies include relative advantage; patient needs and resources; external policies and incentives; tension for change; available resources; knowledge and beliefs about the intervention; and implementation planning. Salient to at least two studies were constructs of adaptability, complexity, structural characteristics, culture, compatibility, leadership engagement, access to information and knowledge, reflecting and evaluating, and beliefs of the health care recipient.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention characteristics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention source</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Evidence strength and quality</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Relative advantage^d</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (–)</td>
</tr>
<tr>
<td>Trialability</td>
<td>—</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Adaptability^e</td>
<td>—</td>
<td>—</td>
<td>Yes</td>
<td>Yes (–)</td>
</tr>
<tr>
<td>Complexity^e</td>
<td>—</td>
<td>—</td>
<td>Yes</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Outer setting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient needs and resources^d</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Cosmopolitanism</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>External policies and incentives^d</td>
<td>Yes</td>
<td>—</td>
<td>Yes</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Inner setting</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural characteristics^e</td>
<td>—</td>
<td>Yes</td>
<td>—</td>
<td>Yes (–)</td>
</tr>
<tr>
<td>Networks &amp; Communications</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Culture^e</td>
<td>—</td>
<td>Yes</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Implementation climate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tension for change^d</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Compatibility^e</td>
<td>—</td>
<td>Yes</td>
<td>—</td>
<td>Yes (–)</td>
</tr>
<tr>
<td>Relative priority</td>
<td>Yes</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Goals and feedback</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Learning climate</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Readiness for implementation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership engagement^e</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
<td>Yes (–)</td>
</tr>
<tr>
<td>Available resources^d</td>
<td>Yes</td>
<td>Yes</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Access to information and knowledge^e</td>
<td>—</td>
<td>—</td>
<td>Yes</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Characteristics of individuals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge and beliefs about the intervention^d</td>
<td>—</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Individual identification with organization</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Other personal attributes</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planning^d</td>
<td>Yes</td>
<td>Yes</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Planning for sustainability</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Opinion leaders</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Yes (+)</td>
</tr>
<tr>
<td>Formally appointed internal implementation leaders</td>
<td>—</td>
<td>Yes</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Champions</td>
<td>—</td>
<td>—</td>
<td>Yes</td>
<td>—</td>
</tr>
</tbody>
</table>
Clinical Outcomes

The primary outcome of COC was the Picker COC for which higher scores denote better COC. At baseline, the COC mean (SD) was 48.62 (29.88) for 48 patients. At month 2, the mean (SD) was 53.95 (29.18) for 19 patients. At month 6, the mean (SD) was 60.71 (26.79) for 14 patients. The descriptive statistics for all the surveys at each timepoint are presented in Table 8. COC scores showed a significant ($P<.001$) mean change (SD) of 24.23 (SD 26.01) in the positive direction at month 6 from baseline; however, none of the other timepoints showed a significant change in COC score and the rates of incomplete data limit any inference (Table 9). Similarly, an exploratory repeated measures analysis using generalized estimation method with autoregressive (AR-1) covariance structure for adjusting for repeated measures within patients with the outcome of COC, controlling for CCRQ and number of messages per Patient Loop, yielded no significant associations. We were unable to draw conclusions from the survey data with regard to appropriateness.

Table 8. Patient Surveys: Summary Descriptive Statistics.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline, n/mean (SD)</th>
<th>M2, n/mean (SD)</th>
<th>M4, n/mean (SD)</th>
<th>M6, n/mean (SD)</th>
<th>M8, n/mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COC$^a$</td>
<td>48/48.62 (29.88)</td>
<td>19/53.95 (29.18)</td>
<td>13/52.88 (24.02)</td>
<td>14/60.71 (26.79)</td>
<td>5/55.00 (22.71)</td>
</tr>
<tr>
<td>SSpedi$^b$</td>
<td>6/22.50 (12)</td>
<td>4/23.50 (4.12)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESAS$^c$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>40/17.02 (11.76)</td>
<td>16/16.25 (10.61)</td>
<td>13/16.54 (11.54)</td>
<td>14/17.71 (13.41)</td>
<td>5/17.00 (14.58)</td>
</tr>
<tr>
<td>Emotional</td>
<td>40/6.25 (5.93)</td>
<td>16/6.50 (6.34)</td>
<td>13/6.31 (6.34)</td>
<td>14/6.57 (6.93)</td>
<td>5/8.60 (7.02)</td>
</tr>
<tr>
<td>Well-being</td>
<td>40/4.33 (2.57)</td>
<td>16/4.44 (2.61)</td>
<td>13/4.62 (2.72)</td>
<td>14/4.21 (3.07)</td>
<td>5/4.20 (1.30)</td>
</tr>
<tr>
<td>Total symptom score</td>
<td>40/27.60 (17.65)</td>
<td>16/27.19 (17.21)</td>
<td>13/27.46 (18.80)</td>
<td>14/28.50 (22.60)</td>
<td>5/29.80 (20.29)</td>
</tr>
<tr>
<td>CCRQ$^d$, CPDG$^e$</td>
<td>44/81.25 (18.05)</td>
<td>19/83.77 (15.94)</td>
<td>12/77.15 (8.85)</td>
<td>13/82.40 (27.09)</td>
<td>5/95.00 (5.43)</td>
</tr>
</tbody>
</table>

$^a$COC: Picker Ambulatory Cancer Care Scale, Continuity, and Coordination subscale.

$^b$SSpedi: Symptom Screening in Pediatrics Tool.

$^c$ESAS: Edmonton Symptom Assessment Scale.

$^d$CCRQ: Client-Centered Rehabilitation Questionnaire.

$^e$CPDG: Client Participation in Decision-making and Goal setting domain of CCRQ.

Table 9. Comparing patient baseline and follow-up COC$^a$ measurements.

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>N</th>
<th>Mean change in score (SD)</th>
<th>Comparison timepoints</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>M2</td>
<td>18</td>
<td>10.97 (36.76)</td>
<td>M2 to baseline</td>
<td>.246</td>
</tr>
<tr>
<td>M4</td>
<td>13</td>
<td>10.00 (41.50)</td>
<td>M4 to baseline</td>
<td>.402</td>
</tr>
<tr>
<td>M6</td>
<td>13</td>
<td>24.23 (26.01)</td>
<td>M6 to baseline</td>
<td>.006</td>
</tr>
<tr>
<td>M8</td>
<td>5</td>
<td>18.50 (20.36)</td>
<td>M8 to baseline</td>
<td>.112</td>
</tr>
</tbody>
</table>

$^a$COC: Picker Ambulatory Cancer Care Scale, Continuity, and Coordination subscale.
Discussion

Principal Findings
This hybrid type II mixed methods implementation study found that gaps in communication and collaboration persist. In the absence of a shared clinical communication tool, health care providers have increasingly adopted email and texting with patients and caregivers over the last decade, and this virtualization has been accelerated by the COVID-19 pandemic [50-52]. Although participants acknowledged these forms of communication have their disadvantages and they could see potential in using Loop, this relative advantage was not realized largely due to the lack of Loop integration with existing health information systems (compatibility). There was a range of message frequency observed, with sites #1, #2 and #3 showing relatively more use than the others. These differences were not reflective of different construct profiles at the sites. Participants who used Loop were mostly satisfied. As in our previous study, patients were more likely than HCPs to initiate communication on Loop [8]. The implementation of Loop was done in the context of research, rather than as an organizational change initiative, and was therefore constrained in scope and time. The lack of broad organizational engagement, relative priority, and tension for change in the implementing organizations further hampered Loop’s implementation. We were unable to make inferences about Loop’s clinical effectiveness due to insufficient follow-up and survey data.

Implementation Effectiveness
In the context of this research implementation of Loop, our approach fell short in several ways and effective implementation remained elusive. Several studies have demonstrated that engaging local champions who sustain commitment and garner organizational support facilitates successful practice change [53-56]. Although we identified committed site champions, their role was informal. Engagement efforts largely fell to research staff and we did not seek to establish broad organizational support for this time-delimited implementation endeavor. This level of engagement was insufficient to influence greater adoption of Loop; however, sample size limits the conclusions we can draw. Moreover, it is likely that the lack of Loop compatibility and nonintegration with local EMRs would have proven to be a nonmodifiable barrier to implementation despite more active engagement.

Phase 1 activities and CFIR interviews affirmed that Loop was deemed acceptable at all sites. As in our previous pilot RCT [8], we demonstrated the feasibility of implementing Loop operationally, while once again experiencing challenges in enrolling additional HCPs, and finding the optimal patient and health care context (opportunity) to show the value of team-based communication.

Lack of compatibility and relative advantage were key implementation barriers in this study. Successful implementation of a novel tool, particularly one that disrupts [57] existing workflows, requires finding the optimal context and patient population to achieve early gains. HCPs frequently expressed that Loop ought to be integrated with the EMR used for charting. Indirect integration or workarounds that involved exporting messages as PDF and uploading them into the EMR were too cumbersome. Adding to this technological conundrum is that, in Ontario, as in many global jurisdictions, care teams straddle multiple EMRs even within the same organization. Many organizations must revert to custom nonscalable models for third-party tool integration. Although the landscape is shifting—for example, the 21st Century Cures legislation in the United States promotes greater standards adoption including HL7 FHIR [58]—this is far from the status quo in Canada. Furthermore, communication standards, as one might use for Loop, are not included in these health technologies, which are focused on the exchange of discrete data such as laboratory results, medications, or documents.

Some organizations have launched patient portals, but these too differ from one organization to another, perpetuating information silos. Of note, 2-way communication is not a standard feature of all patient portals. Patients and caregivers who had access to a patient portal felt that Loop would be more useful if it were integrated with their patient portal. This integration makes sense given that in both our Loop feasibility RCT and in this study, patients and caregivers were more often the drivers of communication. However, the prevailing institutionally tethered models may limit the addition of crucial external team members. Moreover, while patient portals with messaging capability have been shown to improve patient satisfaction and increase the “meaningful use” of data, few studies show that they improve health outcomes [59]. The nature of portals is changing with the emergence of institutionally agnostic commercial models such as Apple’s Health Records entering the space, which may offer an opportunity for communication in the patient’s circle of care.

Although participants perceived Loop’s relative advantage over existing communication channels, this advantage was not actualized, presenting a key barrier [60-62] that would have been difficult to address using deimplementation strategies [63]. Patients, caregivers, and HCPs are reluctant to use yet another tool for communication. They would rather leverage Loop-like functionality (security, organized storage, and retrieval of clinical communication) in tools they already use to communicate in the nonhealth care aspects of their lives. However, none of the email platforms commonly in use provide these functions. Moving to a new communication tool will require realizing greater relative advantage, because efforts to deimplement commonly used means of communication are unlikely to work.

The Collaboration Space Model proposed by Eikey et al [5] outlines the following processes related to collaboration: workflow, communication, and information exchange [5]. The model also proposes 2 outcomes related to collaboration: maintaining awareness and establishing common ground. Applying this model to our study, we observed that participants who used Loop expressed that Loop had a mostly positive impact on the processes of communication and information exchange, and the outcome of maintaining awareness. Of note, a number of participants did not use Loop. The predominant perspectives were that Loop was disruptive of existing workflow. Although there were instances of coordination and cooperation occurring in Patient Loops, we did not observe an...
impact on the higher-order collaboration outcome of establishing common ground. In addition to the barriers already discussed, our study was not designed to focus on the requirements for collaborative care in the context of a single site. In the absence of being able to effect change in organizational processes and structures, the adoption of Loop was hampered.

Clinical Effectiveness
Pooled survey data across all sites suggested an isolated improvement in continuity and coordination of care from baseline to month 6 but not at other timepoints. This should be interpreted with caution because fewer than 50% of participants completed survey responses beyond baseline.

Health System and Policy Environment
Since the start of the Loop research program in 2012, we have navigated an ever-shifting landscape. Ontario’s health care environment has experienced major policy changes in the past 3 years, including the restructuring of regional health authorities (Local Health Integration Networks) into a new model of networks of care called Ontario Health Teams. While this new organizational structure may hold promise for the scaling of eHealth solutions in the future, the transitional period has resulted in deferred decision making. Although we cannot be certain, these system changes may have impacted the progress of our work in terms of informing policy and partnering with provincial organizations for the sustainability of Loop beyond the research program.

A relevant policy shift emerging from the COVID-19 pandemic was the necessity of providing care outside the in-person visit, and permission to communicate and bill for care using phone and video. The perspectives that emerged during our study suggest that the net effect of this system shift was unfavorable for Loop use.

Health Equity, Accessibility, and Future Research
A larger structural issue is related to models of compensation for physicians, nurses, and other HCPs that incentivize in-person or synchronous virtual encounters. Physician fee for service, capitated, and alternate payment plans likely impact the use of Loop. Notably a recent study found very high rates of patient and provider desire to engage in asynchronous messaging preferentially versus using synchronous video or phone in a primary care [64], capitated setting where the family physician and patients accrue benefits without penalties. For physicians working in the fee for service model, including most specialists, there are no billing codes for asynchronous communication. Similarly, there are different models of compensation for nurses. As an example, in Ontario, home care nurses are required to do a certain number of face-to-face visits under one model. The nurses who participated in our study were salaried. All iHCPs were affiliated with academic organizations, likely influencing their willingness to participate in research. We were unable to observe a difference in Loop adoption across different forms of HCP compensation.

Some health system changes were facilitative for Loop. In 2019, the College of Physicians and Surgeons of Ontario disseminated 4 interrelated policies for improving COC in Ontario [65]. While this action raised COC as a priority, it focused mainly on ensuring that physicians provide appropriate options for after-hours care and reliable processes for effective transitions in care. It is possible that compliance with these recommendations will advantage use of asynchronous team-based communication. However, these recommendations have been met with resistance from various stakeholders and their implementation and long-term impact remain uncertain.

Future Research, Health Equity, and Accessibility in eHealth Tools
The challenges encountered in this study are common in studies of eHealth tools, and more generally of implementing complex interventions in complex settings. However, a compelling finding was that Loop disrupted workflows and workarounds that have developed in the absence of standardized tools for communication. Loop could not transcend established communication modalities despite their inability to enable team communication and collaboration. Future research could specifically focus on a health care region, integrate Loop with existing eHealth tools, pilot a compensation structure for asynchronous communication, deimplement or re-design optimal communication workflows from the ground up, and support requirements or conditions for collaboration to occur. In addition, future research should examine the impact of eHealth implementation on health disparities, which have been shown to increase with the introduction of patient–provider messaging tools [66]. Despite the considerable and seemingly intractable barriers identified in this study, the trend toward more digital communication in health care is inevitable and it is likely that an interoperable system of communication and documentation will emerge in time. It is important that tools such as Loop be available and accessible to all, so that health inequities are not further magnified.

Limitations
The research context of this implementation endeavor likely introduced bias insofar as health care providers and patients were possibly more inclined to use Loop to fulfill their commitment as research participants. In addition to participant, team, and site selection bias, we acknowledge the possible researcher bias: the main reviewer (AH) for the qualitative check-in analysis is also the lead for the Loop research program.

Recruitment may have been impacted by issues of equity and access. Although smartphone and internet penetration are rising in Ontario, increasing from 81.4% in 2010 [67] to 92.2% in 2018 [68] with 89.1% of Ontarians reporting having a smartphone for personal use in 2018 [69], there are persisting disparities in access among the rural and marginally housed [70,71]. Given that internet access is a core component of Loop, access is not equitable to all potential patients.

Beyond the anticipated patient attrition rates, there was an unexpectedly low completion rate for clinical survey data beyond baseline. This limited the inferences that could be made about Loop’s clinical effectiveness. Participants from whom we were unable to collect data may have been more likely to talk about barriers to using Loop, and this too may have skewed our qualitative analyses. The challenges in recruiting participants at each of the sites limited our ability to mitigate attrition by over-recruiting within the timelines of the study. As in the
previous study, recruiting additional HCPs to participate on the patient’s Loop team remained difficult and limited the use of Loop among those already enrolled.

The COVID-19 pandemic resulted in dramatic changes to the health care system in Ontario starting in March 2020, impacting recruitment, relative advantage in light of encouraged use of phone and email and permissible billing, and data collection in the follow-up periods (Phases 2 and 3) at Sites 4, 5, and 6. In the first 2 months of the pandemic, all research study recruitment in Ontario was paused unless deemed essential to the health of the participant or relevant to the pandemic. Although the impact was felt on many levels including study staff workflow, the main challenge was that the attention of many HCPs and health care leaders was focused on planning for the health care challenges posed by the pandemic.

The study was limited in being able to support the collaborative requirements at each site. Therefore, a weakness of the study was its focus on Loop without being able to substantively support the structures and processes that would have allowed us to impact collaboration.

Conclusions

This study highlighted the importance of system and organizational context and several key determinants of effective implementation. From the start of the Loop program of research, regulatory guidelines have restricted the use of email and text due to privacy concerns and created data silos within organizations. Despite these restrictions and in the absence of other practical tools for communication, there has been a steady increase in the use of email, text, and other forms of messaging to provide the care that patients need. The COVID-19 pandemic shed light on the essential components of that care. Delivering care became the priority and the regulatory guidelines became pragmatic. The health system learned that a considerable proportion of the care HCPs provide in person can be provided virtually, by video or phone, if the HCP is compensated for this mode of service delivery. If a rational approach to the regulatory framework continues and health leadership prioritizes an integrated digital infrastructure, we may yet achieve the goal of care being provided by the right person, in the right place, at the right time, and with the right tools.

Key facilitative factors again show themselves to be essential for effective implementation. Perceived relative advantage only goes so far, and this study demonstrates, yet again, that compatibility, relative advantage, tension for change, and engagement are essential implementation components that must be realized.

Fundamental structural challenges remain for the implementation and scaling of a shared system of asynchronous communication, including digital integration and a fee structure for compensation. If a new hybrid model of care emerges from the pandemic, it is likely to de-emphasize in-person encounters between patients and HCPs, disrupt existing workflows, and allow the intentional design of new pathways for care that prioritize team communication, access, and COC. Until these changes manifest, effective implementation of Loop and similar communication platforms will continue to be elusive.

Acknowledgments

This research was funded by the Canadian Cancer Society (Innovation to Impact grant #704797). The Temmy Latner Centre for Palliative Care, Sinai Health, provided in-kind support. We wish to acknowledge additional members of the Loop Research Collaborative: Joe Cafazzo, Peter Weinstein, Monika Krzyznanowska, Peter Selby, Andrea Bezjak, Mayura Loganathan, and Russell Goldman. Additionally, we are grateful for the work and support of the following individuals: Maya Watson, Amy Clarke, Rahim Moineddin, Jodheme Goldhar, and the implementation champions and health care providers at each of our recruitment sites.

Authors’ Contributions

Except for the first author (AH [principal]) and the last author (MB [senior]), all coauthors are listed in alphabetical order.

Conflicts of Interest

AH has submitted an invention disclosure application for Loop to the Sinai Health Technology Transfer office; however, no commercialization activity has been undertaken. There is an intellectual property agreement with regard to Loop between the collaborating organizations, Sinai Health, University Health Network, and Sick Children’s Hospital. Other authors have nothing to declare.

Multimedia Appendix 1

Standards for Reporting Implementation Studies: the StaRI checklist for completion.

[PDF File (Adobe PDF File), 249 KB - jmir_v23i3e25505_app1.pdf ]

Multimedia Appendix 2

Semi-structured interview for Health-Care Providers based on the Consolidated Framework for Implementation Research.

[PDF File (Adobe PDF File), 277 KB - jmir_v23i3e25505_app2.pdf ]
References


67. Household Access to the Internet at Home, by Household Income Quartile and Geography. URL: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=2210000701 [accessed 2021-02-16]
68. Internet Use by Province. URL: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=2210008301 [accessed 2021-02-18]
69. Use of Internet Services and Technologies by Age Group and Household Income Quartile. URL: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=2210011301 [accessed 2020-09-16]

Abbreviations
- ACCI: Age-Adjusted Charlson Comorbidity Index
- CCRQ: Client-Centered Rehabilitation Questionnaire
- CPDG: Client Participation in Decision Making domain of CCRQ
- CFIR: Consolidated Framework for Implementation Research
- COC: continuity of care
- ECOG: Eastern Cooperative Oncology Group
- EMR: electronic medical record
- HCP: health care provider
- iHCP: initiating health care provider
- QIF: Quality Improvement Framework
- RCT: randomized controlled trial

©Amna Husain, Eyal Cohen, Raluca Dubrowski, Trevor Jamieson, Allison Miyoshi Kurahashi, Bhadra Lokuge, Adam Rapoport, Stephanie Saunders, Elaine Stasiulis, Jennifer Stinson, Saranjah Subramaniam, Pete Wegier, Melanie Barwick. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 03.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Adaptation of Extended Reality Smart Glasses for Core Nursing Skill Training Among Undergraduate Nursing Students: Usability and Feasibility Study

Sun Kyung Kim1,2*, PhD; Youngho Lee3*, PhD; Hyoseok Yoon4*, PhD; Jongmyung Choi3, PhD

1Department of Nursing, Mokpo National University, Muan, Republic of Korea
2Department of Biomedicine, Health & Life Convergence Sciences, BK21 Four, Mokpo National University, Muan, Republic of Korea
3Department of Computer Engineering, Mokpo National University, Muan, Republic of Korea
4Division of Computer Engineering, Hanshin University, Osan, Republic of Korea

*these authors contributed equally

Corresponding Author:
Sun Kyung Kim, PhD
Department of Biomedicine
Health & Life Convergence Sciences, BK21 Four
Mokpo National University
1666, Yeongsan-ro, Cheonggye-myeon
Muan-gun, Jeollanam-do
Muan
Republic of Korea
Phone: 82 614506292
Email: skkim@mokpo.ac.kr

Abstract

Background: Skill training in nursing education has been highly dependent on self-training because of Korea’s high student-faculty ratio. Students tend to have a passive attitude in self-practice, and it is hard to expect effective learning outcomes with traditional checklist-dependent self-practice. Smart glasses have a high potential to assist nursing students with timely information, and a hands-free device does not interrupt performance.

Objective: This study aimed to develop a smart glass–based nursing skill training program and evaluate its usability and feasibility for the implementation of self-practice.

Methods: We conducted a usability and feasibility study with 30 undergraduate nursing students during a 2-hour open lab for self-practice of core nursing skills, wearing smart glasses for visualized guidance. The usability test was conducted using a 16-item self-reporting questionnaire and 7 open-ended questions. Learning satisfaction was assessed using a 7-item questionnaire. The number of practice sessions was recorded, and perceived competency in core nursing skills was measured before and after the intervention. At the final evaluation, performance accuracy and time consumed for completion were recorded.

Results: Smart glass–assisted self-practice of nursing skills was perceived as helpful, convenient, and interesting. Participants reported improved recollection of sequences of skills, and perceived competency was significantly improved. Several issues were raised by participants regarding smart glasses, including small screen size, touch sensors, fogged lenses with masks, heaviness, and heat after a period of time.

Conclusions: Smart glasses have the potential to assist self-practice, providing timely information at students’ own paces. Having both hands free from holding a device, participants reported the convenience of learning as they could practice and view the information simultaneously. Further revision correcting reported issues would improve the applicability of smart glasses in other areas of nursing education.

(J Med Internet Res 2021;23(3):e24313) doi:10.2196/24313

KEYWORDS

nursing education; skill training; self-practice; smart glass; usability; feasibility

https://www.jmir.org/2021/3/e24313
Introduction

Advancements in life science and biotechnology have transformed the hospital environment, and the need for qualified health professionals has never been higher [1]. In most countries, nurses comprise the largest proportion of the hospital workforce; thus, nurse staffing with a sufficient number of skilled nurses is essential for quality care [2]. It is the responsibility of nursing schools at the undergraduate level to ensure quality care and patient safety with a well-organized curriculum. Practical training is as necessary as theoretical nursing education, and the importance of nursing skill training has been well recognized [3].

Acquisition of mastery in clinical nursing skills not only improves the overall quality of patient care, but also leads to a successful and confident nursing career [4]. Given the growing need for better assurance of practical ability, the Korean Accreditation Board of Nursing Education (KABONE) [5] identified 20 core nursing skills in which nursing students are expected to attain a good level of performance in their accreditation process [6]. Although performance exams have been widely implemented in other licensure examinations and for nurse licensure in other countries such as Canada [7], nursing education in Korea has fully relied on self-practice.

Regardless of the importance of skill training, challenges exist for running educational training programs in Korea. Schools lack the ability to accommodate necessary training because of high student-teacher ratios, so self-practice has been introduced as an alternative method for nursing skill training [8,9]. Considering the insufficient coaching and supervision, educational strategies are needed to improve the effectiveness and efficacy of this self-practice.

At present, students use a written checklist for self-practice, which provides text-based descriptions for each step. However, using these checklists without proper instruction from lecturers means that there is a high risk that students will misconduct their self-practice and repeat wrong performances. Prior studies have indicated that text alone is limited in delivering messages clearly when it contains complex issues [10,11]. The use of an image, which may be worth a thousand words [12], can make complex processes visible, which could effectively reduce the cognitive load involved in acquisition of skills [13]. Knowing that precise step-by-step implementation is essential, both comprehensive understanding and perfect memorization of each step would ensure excellent skill performance.

Visualization can be an effective solution, and its value for better learning engagement and active learning has been used recognized in education [14]. A benefit of visual representation is that a complicated process can be memorized more easily with graphically illustrated essential concepts. Currently, there has been a growing interest in using extended reality (XR) technology for training health care professionals [15]. With improvements in technology involving wearable devices, such as smart glasses, XR has been applied in many health care training programs [16-19]. The findings of these studies showed promising outcomes as effective alternatives to traditional educational programs. XR technology allows for new learning experiences via superimposition of holographic visualization on what users see in the real world.

Previous studies found passive attitudes among students participating in self-training programs, leading to a lack of competency in future nursing practice [10,20]. Furthermore, knowing that the training was insufficient, students lacked competency after completion of this unattended training, causing them anxiety and stress in nursing practice. XR technologies could be a solution, effectively assisting students’ self-training so that students are more likely to perceive that self-training is well structured and of high quality. In addition, the burden on faculty members to provide individual guidance can be alleviated because instant correction, where students reflect on timely information provided by smart glasses, is possible. Effective delivery of visualized education materials via an XR device could potentiate the learning experience without excessive consumption of educational manpower for supervision.

Along with visualization, timely information facilitates skill acquisition and completion. It is necessary to provide the experience of performing a true-to-life working process [21]. In addition, interacting with advanced technology could facilitate students’ motivation for self-practice. Previous studies showed that higher levels of attention and better learning engagement were achieved when implementing XR in education [22-24]. Using smart glasses enhances users’ engagement in performance [25]. Smart glasses improve the efficiency of practice, helping students master each skill with timely information without compromising performance. For complex skills, favorable consequences are expected to be higher, allowing students to experience a sense of accomplishment, completing exercises in a perfect manner, which would lead to improved competency in core nursing skills.

Smart glasses using augmented reality (AR) have previously been applied to support nursing care activities (eg, wound care management, mass casualty triage classification, and central line placement) [26]. These studies mostly focused on ease of obtaining knowledge and advanced features assisting the smart glasses’ performance. The positive implications of using smart glasses to assist in nursing activities were assured. The purpose of our study was to test the feasibility and usability of implementing a core nursing skill training program that combined visualization and XR technology for undergraduate nursing students. We hypothesized that a smart glass–based nursing skill training program would not only assist practice but also induce active engagement of students into self-training.

Methods

Design of Graphical Images for Screens

We developed an XR image guide training program for 2 core nursing skills, specifically, blood transfusion and intradermal injection administration. Of the 20 core nursing skills listed, these 2 skills were randomly chosen from those ranked high in difficulty level, classified by KABONE according to the procedures’ complexity. The numerous steps of these skills were split into several graphical images to be displayed on smart
glasses. Each graphical image transposed to the smart glasses paralleled the text information in the original checklists. The contents of the XR image guide training program are shown in Table 1. The contents were developed and revised several times, considering conciseness and adequacy, which involved expert review by a team of 3 nursing faculty members (2 experts in fundamental nursing and 1 in nursing informatics) and user evaluation by nursing students. Students who participated in this user evaluation were asked whether the meaning was well delivered and could be recognized at a glance without misunderstanding the graphical image. The image was drawn as concisely as possible because of the small capacity of the screen within smart glasses. The conformity between the final version of the graphical image and text information in the checklists was reviewed by 2 professors who had more than 5 years of teaching experience in the fundamental nursing curriculum.

Table 1. Description of core nursing skills for smart glass–based self-practice.

<table>
<thead>
<tr>
<th>Item</th>
<th>Steps, n</th>
<th>Core task</th>
<th>Necessary equipment and supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion</td>
<td>23</td>
<td>1. Preparing equipment and supplies.</td>
<td>Number of items: 18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Connecting blood product and injecting at right rate.</td>
<td>Manikin, blood product, alcohol swab, 3-way stopcock,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Noticing and warning for possible side effects.</td>
<td>gloves, IV pole, tray, watch with a second hand, stethoscope, sphygmomanometer, thermometer, kidney basin,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Recording the nursing practice and patients’ conditions.</td>
<td>recording paper, letter of consent, document needs sign, containers for general medical and damageable waste, and hand sanitizer.</td>
</tr>
<tr>
<td>Administration of intradermal injection</td>
<td>27</td>
<td>1. Preparing equipment and supplies.</td>
<td>Number of items: 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Making diluted solution for AST.</td>
<td>Prescription, two 1-ml &amp; 5-ml syringes, alcohol swab,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Administering of intradermal injection</td>
<td>manikin, vial, ampoule of normal saline, tray, recording</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Reading the results of skin test.</td>
<td>paper, containers for general medical and damageable waste, and hand sanitizer.</td>
</tr>
</tbody>
</table>

AST: antibiotic skin test.

Preparation for User Study With a Smart Glass–Based Self-Training Program

A group of 5 students was given 2 hours of self-training and shared 2 Vuzix smart glasses. Students were encouraged to use the smart glasses at least once, with scheduled turns for the first use. According to KABONE, the estimated time to complete each skill was 10 minutes [5]. Before the beginning of their practice, brief instructions regarding how to operate the smart glasses (eg, content of the screen, how to find an item in the menu, turning to the next image) were provided, and individual students were given opportunities to wear the glasses and practice for about 5 minutes. After 2 hours of self-training, a performance test regarding accuracy and proficiency was conducted by an educator who had more than 5 years of experience in nursing education. During the test, the time for performance completion was measured by a research assistant.

Each image slide consists of 2 or 3 zones (Figure 1): (1) heading with sequence of the present step, (2) symbols and pictures representing the required performance in the present step, and (3) warning text that a step needs extra caution (when necessary).
The graphical images appeared in the order of actions following the sequence of the original text-based checklists. The 2 core skills of blood transfusion and intradermal injection administration were adapted to 23 and 27 screens, respectively (Figures S1 and S2 in Multimedia Appendix 1).

Implementation of Our Smart Glass Application and Interface Design

The Vuzix Blade has a display only in the right eye, the display size is $480 \times 853$, and the shape of the display is a square. Vuzix’s appearance is similar to that of ordinary glasses, and it supports voice recognition and touchpads. It supports Bluetooth and Wi-Fi networks and has a camera attached to take photos and videos or engage in remote collaboration. It is a stand-alone device that weighs 93.6 g and does not require additional equipment. It has a screen saver, so users can use it like a transparent glass in normal times and turn on the display when they need information. The Vuzix Blade currently runs Android 5.1, which supports application programming interface (API) 22 for the target API. Developers can develop the software using Java or Kotlin using Android Studio. Differences from general Android programming include the voice recognition API, touch interface API, and heads-up display API for graphical user interface [27].

We set up our device as an always-on display. In general, smart glass displays are on-demand displays that turn off the screen after a certain period to save power. When information is only available for a short time upon request, job performance declines because of psychological pressure [28]. If the students had to touch the touchpad or call a voice command every time they requested information, it would waste their time, and they could become exhausted by simple repetitive tasks. Thus, we turned off the screen saver and kept the display on while the students practiced.

The Vuzix Blade allows user interface elements to be navigated with simple left/right/up/down navigation. The menu is expressed in a square shape at the bottom of the screen. Students can select a submenu by swiping and tapping the touchpad. When a student chooses a submenu, the corresponding image is displayed. We implemented a simple input method to reduce malfunctioning when students use the touchpad. When selecting a task in the list, they are only allowed to use the left/right swipe and one-finger tap. When flipping the slide, only left/right swipes were permitted. It was originally set up to swipe when moving to the upper menu, but we assigned a two-finger tap for moving to the upper menu.

Usability Test

Seventeen items were used for the quantitative usability test. Items were developed based on previous studies in which
relevant items were selected and revised to be aligned with the purpose and methodology of this study. The study participants reported perceived usefulness items and ease of use items on 5-point scales, from strongly disagree (1 point) to strongly agree (5 points).

**Learning Satisfaction**

Level of satisfaction was assessed using 7 questions rated on a scale of 1 (strongly disagree) to 10 (strongly agree). Developed by Ji and Chung [29], questions were modified to fit the nursing education program best. With a maximum score of 70, a higher score indicates greater satisfaction with the education program.

**Nursing Competency**

Levels of perceived competency on 2 core nursing skills (administration of intradermal injection and transfusion) were assessed using a 10-point Likert scale. Developed by Han, Cho, and Won [30], a higher score indicates a greater level of competency for each skill.

**Observation Data**

During the 2-hour self-practice program, the overall number of practice attempts and number of practice attempts wearing smart glasses were observed and recorded by a research assistant. Developed by KABONE, a standardized checklist was used to measure the performance of 2 nursing skills (administration of intradermal injection and transfusion). The checklist consists of procedures of each skill, from preparing materials to writing nursing records after completion of skills. Scoring ranged from 0 to 100; a higher score indicates more accurate and precise performance without mistakes or omitted steps. At the nursing skill performance examination, individuals’ time spent on performance completion was measured and recorded by a research assistant.

**Qualitative Responses**

Seven qualitative questionnaires were used to obtain comprehensive and detailed information about students’ experiences using smart glasses for core skill nursing training. The questionnaire included the following: (1) How did you find the smart glass–based training in general? (2) Was this program easy to use? Did you need additional instructions? (3) Was there any content causing confusion or difficulties? (4) Did you experience any difficulties while operating smart glasses? (5) Do you think it will be helpful for your future clinical practice? If so, how? (6) Would you make any recommendations that are needed to improve this training program? (7) If you have any other comments regarding this smart glass–based training program, feel free to add them.

**Ethical Considerations**

The application of smart glass–based core nursing training for undergraduate nursing students was approved by the institutional review board (IRB no. MNUIRB-200326-BM-004-02) at a national university in Korea. Informed consent was obtained prior to obtaining the pretest data, and participants were told that they could stop participating anytime they wanted.

**Statistical Analysis**

Quantitative statistical data analysis was conducted using SPSS (version 25.0; IBM Corp). Mean, SD, frequency, and percentage were calculated for the demographic data, observation data, usability, and learning satisfaction survey. Paired 2-tailed t tests were used to compare outcome measures preintervention and postintervention, and an independent t test was conducted to identify between-groups differences. Pearson correlation analysis was conducted to determine the association between variables. For the qualitative data, all responses were reviewed and coded to identify common themes that were frequently reported.

**Results**

**Quantitative Findings**

The mean age of the study participants was 22.70 years, and 63% (19/30) were female. Approximately two-thirds of participants (22/30, 73%) reported possessing a moderate level of competency in core nursing skills, and approximately 1 in 10 (3/28, 11%) had previous experience with AR (Table 2).
Table 2. Demographic characteristics of study participants (N=30).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>22.70 (1.39)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11 (37)</td>
</tr>
<tr>
<td>Female</td>
<td>19 (63)</td>
</tr>
<tr>
<td><strong>Academic grade, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>4 (13)</td>
</tr>
<tr>
<td>Fair</td>
<td>18 (60)</td>
</tr>
<tr>
<td>Poor</td>
<td>8 (27)</td>
</tr>
<tr>
<td><strong>Satisfaction with clinical placement, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>21 (70)</td>
</tr>
<tr>
<td>Moderate</td>
<td>9 (30)</td>
</tr>
<tr>
<td>Low</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Core nursing skill competency, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>8 (27)</td>
</tr>
<tr>
<td>Fair</td>
<td>22 (73)</td>
</tr>
<tr>
<td>Poor</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Previous experience with augmented reality, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (11)</td>
</tr>
<tr>
<td>No</td>
<td>25 (89)</td>
</tr>
</tbody>
</table>

Participants were given 2 hours of open lab for self-practice of 2 core nursing skills. The number of practice attempts varied between 5 and 9. Full usage of the smart glasses during the self-practice open lab was observed and recorded. Participants used smart glasses in their practice as little as 2 and as many as 6 times (Table 3).

Table 3. Number of practice attempts and smart glass use.

<table>
<thead>
<tr>
<th>Categories</th>
<th>Range</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Practice attempts (total), n</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>2-6</td>
<td>3.30 (0.952)</td>
</tr>
<tr>
<td>Administration of intradermal injection</td>
<td>2-5</td>
<td>3.73 (0.944)</td>
</tr>
<tr>
<td>Total</td>
<td>5-9</td>
<td>7.03 (1.25)</td>
</tr>
<tr>
<td><strong>Practice attempts wearing smart glasses, n</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>0-3</td>
<td>1.83 (0.747)</td>
</tr>
<tr>
<td>Administration of intradermal injection</td>
<td>0-3</td>
<td>1.70 (0.651)</td>
</tr>
<tr>
<td>Total</td>
<td>2-6</td>
<td>3.53 (0.973)</td>
</tr>
</tbody>
</table>

Regarding self-reported usability of the smart glass–based self-practice program, the highest score was obtained for question 11 (perceived interest) with a mean of 9.50 (SD 0.86). Question 5 (screen resolution) scored the lowest with a mean of 7.20 (SD 2.02). The degree of difficulties experienced with devices was rated with a mean of 3.83 (SD 2.73) (Table 4).
Table 4. Results of 16-item usability test (N=30).

<table>
<thead>
<tr>
<th>Item</th>
<th>Range</th>
<th>Usability, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ease of use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. How convenient do you think the smart glass–based core nursing education program is?</td>
<td>3-10</td>
<td>8.10 (1.58)</td>
</tr>
<tr>
<td>2. Was the initial education regarding the device and usage appropriate?</td>
<td>5-10</td>
<td>8.77 (1.46)</td>
</tr>
<tr>
<td>3. Was the text information presented on the screen easy to read?</td>
<td>3-10</td>
<td>7.27 (2.26)</td>
</tr>
<tr>
<td>4. Was the picture information presented on the screen clearly understood?</td>
<td>4-10</td>
<td>8.17 (1.90)</td>
</tr>
<tr>
<td>5. Was the resolution of the screen good?</td>
<td>4-10</td>
<td>7.20 (2.02)</td>
</tr>
<tr>
<td>6. Did you have any difficulties because of errors that occurred during the performance?</td>
<td>1-10</td>
<td>3.83 (2.73)</td>
</tr>
<tr>
<td>7. Was the progression speed adequate?</td>
<td>5-10</td>
<td>8.63 (1.22)</td>
</tr>
<tr>
<td>8. Was the location of the information on the smart glass appropriate? Consistent? Easy to see?</td>
<td>3-10</td>
<td>8.53 (1.85)</td>
</tr>
<tr>
<td>9. Was it convenient to operate the smart glass?</td>
<td>6-10</td>
<td>8.40 (1.48)</td>
</tr>
<tr>
<td><strong>Usefulness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Did the pictures and text information shown help you perform core basic nursing skills?</td>
<td>6-10</td>
<td>9.07 (1.05)</td>
</tr>
<tr>
<td>11. Was this type of educational program interesting?</td>
<td>7-10</td>
<td>9.50 (0.86)</td>
</tr>
<tr>
<td>12. Did you expect better scores using the smart glass training program?</td>
<td>6-10</td>
<td>8.90 (1.21)</td>
</tr>
<tr>
<td>13. Did you have a better understanding of core basic nursing techniques using augmented reality?</td>
<td>5-10</td>
<td>8.77 (1.48)</td>
</tr>
<tr>
<td>14. Would you recommend the smart glass–based core nursing education program to other friends?</td>
<td>3-10</td>
<td>8.70 (2.00)</td>
</tr>
<tr>
<td>15. Do you think smart glass core nursing education will be useful in clinical practice in the future?</td>
<td>4-10</td>
<td>8.77 (1.61)</td>
</tr>
<tr>
<td>16. Are you willing to use a smart glass for other core nursing skills in the future?</td>
<td>5-10</td>
<td>8.87 (1.57)</td>
</tr>
</tbody>
</table>

The overall score for learning satisfaction was 9.00 (SD 0.72). The participants gave the highest rating to “It was an interesting learning experience” (mean 9.60, SD 0.68) and the lowest rating to “It was more effective than lecturer-based education” (mean 7.43, SD 1.81) (Table 5).

Table 5. Results of 7-item learning satisfaction score (N=30).

<table>
<thead>
<tr>
<th>Item</th>
<th>Range</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It was an interesting learning experience.</td>
<td>8-10</td>
<td>9.60 (0.68)</td>
</tr>
<tr>
<td>2. Educational goals of this program were well-achieved.</td>
<td>7-10</td>
<td>9.30 (0.88)</td>
</tr>
<tr>
<td>3. It was a meaningful learning experience.</td>
<td>8-10</td>
<td>9.47 (0.73)</td>
</tr>
<tr>
<td>4. It was more effective than lecturer-based education.</td>
<td>3-10</td>
<td>7.43 (1.81)</td>
</tr>
<tr>
<td>5. I actively engaged in learning.</td>
<td>7-10</td>
<td>9.27 (0.91)</td>
</tr>
<tr>
<td>6. I felt satisfied with the educational program overall.</td>
<td>7-10</td>
<td>9.23 (0.90)</td>
</tr>
<tr>
<td>7. I hope to use this educational program for other subjects.</td>
<td>3-10</td>
<td>8.73 (1.46)</td>
</tr>
<tr>
<td>Learning satisfaction score (total)</td>
<td>N/A4</td>
<td>9.00 (0.72)</td>
</tr>
</tbody>
</table>

aN/A: not applicable.

Paired 2-tailed t tests were used to analyze differences between preintervention and postintervention competency of students on 2 nursing skills. Statistically significant improvement was achieved in both the skills after intervention (P<.001) as mean scores increased from 7.23 (SD 1.17) to 8.90 (SD 0.85) and 6.17 (SD 1.64) to 8.50 (SD 0.97), respectively (Table 6).
The Pearson correlation test was conducted and identified statistically significant negative correlations between the number of practice attempts wearing smart glasses and performance time ($r = -0.666$, $P < .001$). There was a statistically significant positive correlation between the number of practice attempts wearing smart glasses and learning satisfaction ($r = 0.404$, $P = .03$) (Table S1 in Multimedia Appendix 1). An independent $t$ test revealed statistically significant gender differences for usability scores (ease of use, $P = .049$) and previous experience with devices (ease of use, $P = .02$; usefulness, $P = .002$) (Table S2 in Multimedia Appendix 1).

Qualitative Findings

**Overall Experience of the Smart Glass–Based Skill Training Program**

In general, the majority of students found smart glass–based skill training interesting (13/30, 43%) and convenient (8/30, 27%). About one in three participants (8/30, 27%) did not find significant benefits of using smart glasses for self-practice, and one participant reported, “It was interesting at first, but previous text based learning fits better for me.” Resistance to learning new technology was revealed, with participants saying, “I think I had to make more effort to learn about the devices.”

With regard to smart glasses, a large number of participants reported some degree of discomfort. There were touch sensor–related issues (9/30, 30%), specifically, “The touch sensor was too sensitive.” Others complained about the smart glass screen, and participants said, “Small sized text and low resolution caused eyestrain.”

Generally, participants responded that this smart glass–based self-training has educational benefits. Some participants found increased engagement in learning with new technology, saying “I was fascinated by the smart glasses and practice became more interesting using it.” Participants responded to the effectiveness of visualized information, improving their memory of educational content (n=7). Moreover, timely provision of information was found to have significant positive benefits (n=8): “Assisted by timely provided information, accurate and seamless practice was ensured using smart glasses.”

**Perceived Easiness**

Overall, the participants considered smart glass–based training to be very intuitive. Two out of three (20/30, 67%) reported immediate adaptation to smart glasses, with one participant saying “It was quite straightforward, I figured out how it works right away.” One-third of participants expressed the need for additional instructions, with one saying “I got confused with device, especially the touch pad on the glasses did not make sense for me.”

**Recommendations**

Several participants provided feedback regarding areas that needed further improvement. In terms of the smart glasses, participants raised the following issues: (1) touch sensor not working properly while wearing latex gloves, (2) glasses easily fogging while wearing a mask, (3) pain of double-layering glasses for people with poor eyesight, and (4) discomfort due to heavy weight and heat after a period of time (about 15 minutes). Regarding the training program content, participants reported tediousness of the simple text and image, saying “I expected something more entertaining like games.”

**Discussion**

**Principal Findings**

We explored the perceived usability and feasibility of smart glass–based self-practice among undergraduate nursing students. In general, the findings indicate that the participants had a greater degree of interest in this new device. Although some participants showed resistance to learning about the device, most students were pleased with having new educational methods to assist in their self-practice. This is closely linked to the characteristics of the study population. Recent advances in computing technology have transformed education, and the current generation is accustomed to this continuous change [26].

The findings of this study revealed the positive effects of smart glasses on engaging students in self-practice. Like self-practice, where an active learning attitude is essential, smart glasses could certainly provide a learner-centered education platform, allowing learning at an individual’s own pace without restrictions of time and supervisors [31]. This learner-centered approach enables students to make the best use of learning materials. As a matter of fact, participants who showed high levels of learning satisfaction used the smart glasses more frequently. This indicates that active participation is closely linked to the attractiveness of education strategies, which would eventually lead to learning satisfaction. Knowing that implementation of smart glasses induced students’ interest in skill practice, thoughtful consideration is required for nursing faculty members, who should make efforts to identify applicable areas where this technology can be used.
The findings of this study indicate greater improvement in perceived competency of performing blood transfusions. One possible explanation is variability in individual skills. Blood transfusion requires not only skillful performance but also complex procedures that involve multiple confirmation process (eg, physicians’ orders, blood continuants, lab examination results, monitoring patients for side effects) [32] that frequently cause low levels of competency among undergraduate nursing students. Thus, by following guidance provided via smart glasses, students may find the tasks easier to complete. In addition, students would be better equipped with more complete knowledge regarding the step-by-step processes of blood transfusion, leading to increased competency.

In terms of number of uses, there was a positive correlation with learning satisfaction and a negative correlation with time consumed on performance completion. In addition, participants responded to educational benefits, as a timely graphical image assisted in improving their memory of the correct sequences. This suggests that the use of smart glasses has great potential to boost students’ abilities for task completion. This is in line with previous studies on AR smart glasses, which assist health professionals in enabling simultaneous performance of multiple tasks [28,33]. One possible explanation is better cognitive performance due to greater efficacy in information confirmation provided via the glass screen and easy recollection of graphic-based guidance. Similarly, fast-tracking (shortening) the link between knowledge acquisition and actual practice or even tightly coupling them concurrently could expand individuals’ existing abilities. Although usage frequency is closely related to students’ preferences for this kind of learning, cumulative evidence would easily induce active engagement.

Several responses involved feedback that needs further consideration for the use of smart glasses to practice skills in nursing education, including low resolution, lack of visibility due to small-sized text, light smudging, perceived heaviness, severe condensation when wearing masks, and pain and discomfort for users wearing eyeglasses. Smart glasses have been considered for clinical implementation such as medical remote collaboration; thus, this is crucial information for future studies. Tasks are (1) determining the optimal size of text for users with poor eyesight, (2) identifying colors that cause light smudging, and (3) comparing and selecting smart glasses that are less likely to cause these issues. For example, the recently developed Google Glass may overcome some of these drawbacks with its advanced display, customizable hard case (lighter version without lenses or version with a thicker and solid frame), and lightweight form factor [34].

Findings of learning satisfaction outcomes revealed relatively lower scores on the item: “It was more effective than lecturer-based education.” This indicates a limitation of the smart glass–based self-practice program. Although students’ practice was assisted by the smart glasses, it could not sufficiently replace lecturer-based education. This implies the need for additional strategies to meet the educational needs of nursing skill training. Integration of prior educational strategies could effectively reinforce the current version of smart glass–based education.

The diverse features of smart glasses would more effectively replace previous strategies used for self-practice in nursing education. First, self-practice with video recording with self-feedback or peer feedback, the effectiveness of which was well established in a previous review study [35], could well be administered using smart glasses in a simpler and more convenient manner. Second, a demonstration from the lecturer can also be delivered via a smart glass guidance system. Inserting recorded videos or a series of photos in a GIF for demonstration could well guide students’ acquisition of nursing skills. Lastly, consideration for aligning procedural steps with multimodal feedback, such as notification timer, sound, and vibration effect, is needed. There is evidence that gamification contributes to teaching and learning in nursing education [36], and these features have a high potential to immerse learners in self-training.

We conducted further statistical analysis (Tables S1 and S2 in Multimedia Appendix 1) to identify the potential influence of various user characteristics such as age, gender, and previous experience with devices. Interestingly, female participants and participants with no previous experience with AR devices reported better usability of the current smart glass–based training program. Previously, males were believed to be more willing to use and adapt more quickly to new technologies [37], while other studies observed no gender differences [38,39]. The findings of this study partially align with those of a recent study by Drin, Alamaki, and Soumala [40], which reported greater interest among females toward new technology. Novelty effects might be related to the lower usability scores of participants with previous experience; this may be related to prior experience negatively affecting attitudes toward the present experience [41]. Another possible explanation is that students’ perceptions of the current smart glass–based training program might be influenced by their perception of the program itself. Since this study was intended to promote self-practice for nursing skills, a passive attitude toward training was reflected. Regardless of gender, age, and previous device experience, students’ willingness and active attitude result in greater educational benefits. Further investigation regarding influencing factors on the user’s perception toward smart glasses and their applications for education would offer a more comprehensive understanding for future developers.

Limitations

This study was not without limitations. First, although this was a pilot study focusing on usability and feasibility, the small sample size restricted the interpretation of some of the results. In addition, it is not possible to fully elucidate the effectiveness of the smart glass–based training program. Examining usability and feasibility, we did not thoroughly compare the effectiveness of the smart glass–based training program to other existing training programs that are prevalent in nursing education (eg, smartphone video recording of self-practice). Given the finding from this study that smart glasses can be a useful education strategy, more thoroughly demonstrating the effectiveness with future research would encourage faculties to actively incorporate such devices into their education plans. Lastly, it is questionable whether the Vuzix Blade is the best device for nursing skills training, as new smart glasses are continuously released in this...
growing market. Thus, future research using a variety of smart
glasses with differing specifications that reflect factors that caused discomfort and inconvenience in this study would offer valuable information for educators considering the use of smart glasses. Employing and comparing various AR presentation types (eg, 3D content, data visualization, virtual characters) and AR augmentation techniques (eg, multimodal, physical feedback, sound augmentation) are worthy of further investigation to elucidate optimal smart glasses–based practices.

**Conclusion**
The findings of this study suggest the use of smart glasses was a useful educational strategy for assisting self-practice of skills in nursing education. Given the benefits of timely information and hands-free operation (hands free from holding a device), participants reported positive experiences in general, including a high level of interest and appreciation for the convenience of this training program. Participants who had favorable views of this technology-enhanced education were more likely to report greater learning satisfaction, which shows great potential in transforming a previously passive attitude to an active one. Future revision reflecting the feedback from this study would effectively foster a high level of skill competency among undergraduate nursing students, engaging students in active learning and reducing the burden on faculty members.

**Acknowledgments**
This research was supported by a grant (20012234) of Regional Customized Disaster-Safety R&D Program funded by the Ministry of the Interior and Safety (Korea). This work was supported by a National Research Foundation of Korea (NRF) grant funded by the Korean government (No. NRF-2019R1G1A1006737 and No. NRF-2018R1D1A1B07048247).

**Conflicts of Interest**
None declared.

**Multimedia Appendix 1**
Snapshots of the image guide for intradermal injection, snapshots of the image guide for blood transfusion, Pearson correlation analysis among study variables, and difference of usability score (ease of use and usefulness) by gender and previous experience of augmented reality.

[DOCX File, 2121 KB - jmir_v23i3e24313_app1.docx ]

**References**
5. Korean Accreditation Board of Nursing Education-Evaluation core basic nursing skill items. Seoul: Korean Accreditation Board of Nursing Education (KABONE); 2017. URL: http://www.kabone.or.kr/ [accessed 2020-06-20]


**Abbreviations**

API: application programming interface
AR: augmented reality
KABONE: Korean Accreditation Board of Nursing Education
NRF: National Research Foundation of Korea
XR: extended reality
Assessment of Diagnostic Competences With Standardized Patients Versus Virtual Patients: Experimental Study in the Context of History Taking

Maximilian C Fink1, MSc; Victoria Reitmeier1, Dr med; Matthias Stadler2,3, Dr phil; Matthias Siebeck1,3, Prof Dr, MME (D); Frank Fischer2,3, Prof Dr; Martin R Fischer1, Prof Dr, MME (Bern)

1Institute for Medical Education, University Hospital, LMU Munich, Munich, Germany
2Department of Psychology, Ludwig-Maximilians-Universität München, Munich, Germany
3Munich Center of the Learning Sciences, Ludwig-Maximilians-Universität München, Munich, Germany

Corresponding Author:
Maximilian C Fink, MSc
Institute for Medical Education
University Hospital, LMU Munich
Pettenkoferstraße 8a
Munich, 80336
Germany
Phone: 49 089 4400 57428
Email: maximilian.fink@yahoo.com

Abstract

Background: Standardized patients (SPs) have been one of the popular assessment methods in clinical teaching for decades, although they are resource intensive. Nowadays, simulated virtual patients (VPs) are increasingly used because they are permanently available and fully scalable to a large audience. However, empirical studies comparing the differential effects of these assessment methods are lacking. Similarly, the relationships between key variables associated with diagnostic competences (ie, diagnostic accuracy and evidence generation) in these assessment methods still require further research.

Objective: The aim of this study is to compare perceived authenticity, cognitive load, and diagnostic competences in performance-based assessment using SPs and VPs. This study also aims to examine the relationships of perceived authenticity, cognitive load, and quality of evidence generation with diagnostic accuracy.

Methods: We conducted an experimental study with 86 medical students (mean 26.03 years, SD 4.71) focusing on history taking in dyspnea cases. Participants solved three cases with SPs and three cases with VPs in this repeated measures study. After each case, students provided a diagnosis and rated perceived authenticity and cognitive load. The provided diagnosis was scored in terms of diagnostic accuracy; the questions asked by the medical students were rated with respect to their quality of evidence generation. In addition to regular null hypothesis testing, this study used equivalence testing to investigate the absence of meaningful effects.

Results: Perceived authenticity (1-tailed $t_{81}=11.12; P<.001$) was higher for SPs than for VPs. The correlation between diagnostic accuracy and perceived authenticity was very small ($r=0.05$) and neither equivalent ($P=.90$) nor statistically significant ($P=.32$). Cognitive load was equivalent in both assessment methods ($t_{82}=2.81; P=.003$). Intrinsic cognitive load (1-tailed $r=-0.30; P=.003$) and extraneous load (1-tailed $r=-0.29; P=.003$) correlated negatively with the combined score for diagnostic accuracy. The quality of evidence generation was positively related to diagnostic accuracy for VPs (1-tailed $r=0.38; P<.001$); this finding did not hold for SPs (1-tailed $r=0.05; P=.32$). Comparing both assessment methods with each other, diagnostic accuracy was higher for SPs than for VPs (2-tailed $t_{85}=2.49; P=.01$).

Conclusions: The results on perceived authenticity demonstrate that learners experience SPs as more authentic than VPs. As higher amounts of intrinsic and extraneous cognitive loads are detrimental to performance, both types of cognitive load must be monitored and manipulated systematically in the assessment. Diagnostic accuracy was higher for SPs than for VPs, which could potentially negatively affect students’ grades with VPs. We identify and discuss possible reasons for this performance difference between both assessment methods.
Introduction

Performance-Based Assessment With Standardized Patients and Virtual Patients

Since the turn of the millennium, performance-based assessment has become a mandatory part of medical licensure examinations in various countries [1], complementing traditional assessment formats, such as text vignettes, with methods including standardized patients (SPs) and simulated virtual patients (VPs). SPs have been used for performance-based assessment in health care since the 1960s [2]. However, VPs have only recently become more widely employed in this domain [3].

The term SPs refers to (trained) actors or real former patients who act as if they display symptoms of a disease [4]. Usually, students encounter several SPs in assessment settings to reliably measure clinical variety [5]. Performance is then scored by a trained faculty member or the SPs themselves using a rating scheme. Although we will elaborate on the specific features used for this assessment method later, it should be noted here that organizing an assessment with SPs is relatively resource intensive [6].

VPs are a type of computer simulation and typically include an authentic model of a real-world situation that can be manipulated by the participant [7]. VPs can use avatars or realistic videos with SPs as stimuli and offer varying degrees of interaction [8]. Moreover, assessment through VPs can take place automatically, and a recent study showed that such an automatic assessment corresponds well to ratings from clinician-educators [9]. The production of authentic VPs can frequently produce considerable costs above $10,000 [10]. Although the initial production of VPs is often more resource intensive than organizing SPs, this assessment method is then permanently available and fully scalable to a large audience.

Next, we summarize a conceptual framework. This framework provides, on the one hand, a precise operationalization of diagnostic competences. On the other hand, the framework includes a research agenda that summarizes essential moderators of performance that should be examined systematically in research on simulation-based assessment.

A Framework for the Assessment of Diagnostic Competences With Simulations

The framework developed by Heitzmann et al [10] to facilitate diagnostic competences with simulations operationalizes diagnostic competences in assessment settings as a disposition. This disposition encompasses the components of diagnostic knowledge, diagnostic quality, and diagnostic activities. Diagnostic knowledge includes conceptual and strategic knowledge [11]. Conceptual knowledge encompasses concepts and their relationships. Strategic knowledge comprises possible avenues and heuristics in diagnosing. Diagnostic quality consists of components’ diagnostic accuracy and efficiency that can serve as major outcome measures in empirical studies. Diagnostic activities entail the actions of persons assessed during the diagnostic process, such as evidence generation by asking questions in history taking. The framework proposes that context is an important moderator in assessment. Therefore, more research on the effects of the assessment methods SPs and VPs seems to be warranted. A meta-analysis on simulation-based learning of complex skills [12] added to this framework that authenticity should also be explored as an important moderator in assessment and learning. Similarly, a meta-analysis on instructional design features in simulation-based learning indicated that certain types of cognitive load could be detrimental to performance [13]. Therefore, it could be fruitful to explore the relationship between cognitive load and diagnostic competences within SP and VP assessments.

Perceived Authenticity and Diagnostic Competences With SPs and VPs

There is a multitude of conceptualizations of authenticity. In our study, we focus on perceived authenticity [14] because this concept can be assessed entirely internally by learners’ judgment. Other related concepts such as thick authenticity [15] and fidelity [16] can, at least to some extent, also be determined externally.

According to a factor analysis by Schubert et al [14], perceived authenticity—sometimes also called presence—comprises the facets of realness, involvement, and spatial presence. Realness describes the degree to which a person believes that a situation and its characteristics resemble a real-life context [14]. Involvement is defined as a feeling of cognitive immersion and judgment that a situation has personal relevancy [17]. Spatial presence denotes the feeling of physical immersion in a situation [14]. SPs are considered highly authentic because they are carefully trained to realistically portray symptoms and allow for natural interactions [18]. Empirical studies support this claim, reporting high values of perceived authenticity for SPs [19,20]. VPs also received rather high perceived authenticity scores in empirical studies [21] but lacked some of the features that may make SPs particularly authentic, such as high interactivity in oral conversations. Thus, VPs could potentially evoke lower perceived authenticity than SPs. Findings on the effect of authenticity on diagnostic competences are mixed. On the one hand, it has been argued that higher authenticity is associated with higher engagement and better performance [22]. On the other hand, literature reviews [23,24] that compared the relationship between perceived authenticity and clinical performance in simulation-based learning only reported minimal effects of authenticity. In addition, an empirical study [25] showed that above a certain threshold, further increases in perceived authenticity do not improve diagnostic accuracy.
Cognitive Load and Diagnostic Competences With SPs and VPs

Cognitive load theory posits that performance can be inhibited through high situational demands that stress working memory and attention [26]. The cognitive load consists of the following 3 different facets [27]: Intrinsic load results from the interplay between certain topics and materials and the assessed person’s expertise. Extraneous load is created exclusively by characteristics of the assessment environment that strain memory and attention without being necessary for performance. Germane load refers to the cognitive load created through the assessed person’s cognitive processes, including schema construction and abstraction. Intrinsic and extraneous cognitive loads are considered additive and can inhibit performance in complex tasks [27]. Germane load, however, is theorized to bolster performance [27]. A few primary studies from medical education have already contrasted the cognitive load of different assessment methods and reported their relationship with diagnostic competences. Dankbaar et al [28] demonstrated that intrinsic and germane cognitive loads were higher for a group learning emergency skills with a simulation game than for a group learning with a text-based simulation. Extraneous load did not differ between these groups, and none of the groups differed in performance. Haji et al [29] compared surgical skills training with less complex and more complex simulation tasks. The total cognitive load was higher in the more complex simulation than in the less complex simulation, and cognitive load was negatively associated with performance. As a result of these findings, we can conclude that SPs and VPs generally do not differ in different facets of cognitive load if the assessment methods are of equal complexity, and the main characteristics related to the facets are similar. The literature summarized earlier also shows that intrinsic and extraneous cognitive loads are negatively associated with diagnostic competences.

Assessment Method and Diagnostic Competences

Before we discuss diagnostic accuracy and evidence generation—2 important aspects of diagnostic competences—it should be noted that diagnostic competences are only a part of the broader concept of clinical reasoning. Clinical reasoning emphasizes the process of diagnosing and encompasses the full process of making clinical decisions, including the selection, planning, and reevaluation of a selected intervention [30]. In line with the conceptual framework by Heitzmann et al [10] for facilitating diagnostic competences, diagnostic accuracy denotes the correspondence between the learner’s diagnoses and the solutions determined by experts for the same cases. According to this framework, evidence generation (ie, actions related to the gathering of data in a goal-oriented way) is also an important quality criterion for the diagnostic process and a crucial aspect of diagnostic competences.

Diagnostic Accuracy

Currently, there are only a few studies in the health care domain that contrast assessments using VPs and SPs directly in one experiment. Edelstein et al [1] investigated assessments with SPs and computer-based case simulations in advanced medical students using a repeated measures design. A moderate positive correlation was found between diagnostic accuracy in the two assessment formats that used different cases. Guagnano et al [31] examined SPs and computer-based case simulations in a medical licensing exam. Participants first completed the computer-based case simulations and then completed the SPs. The two assessment methods correlated positively with each other. Hawkins et al [32] compared the assessment of patient management skills and clinical skills with SPs and computer-based case simulations in a randomized controlled trial. Participating physicians completed both assessment methods, and a positive correlation of diagnostic accuracy with both assessment methods was reported. Outside the health care domain, a meta-analysis of studies from different domains reported a robust modality effect for students in problem-solving tasks. Students who solved problems presented in the form of illustrations accompanied by text were more successful than students who solved problems presented merely in text form [33]. Similarly, it seems reasonable to assume that one assessment method could lead to higher diagnostic accuracy than the other assessment method because of its different characteristics. The described findings from the health care domain tentatively indicate that SPs and VPs could result in relatively equivalent diagnostic accuracy. Such a finding would contradict the modality effect reported in other domains.

Evidence Generation

Comparable empirical studies on evidence generation for SPs and VPs are lacking. Nevertheless, we can assume that the quality of evidence generation should be higher for SPs than for VPs. The main reason for this is that students can ask questions of SPs more quickly orally than by selecting questions from a menu of options with VPs. Apart from this difference in evidence generation between the 2 assessment methods, the relationships between evidence generation and diagnostic accuracy are interesting. The relationship between the quantity of evidence generation and diagnostic accuracy is relatively complex. The ideal amount of evidence generation may depend strongly on the case difficulty, the diagnostic cues contained in the evidence, and learner characteristics. For these reasons, the framework by Heitzmann et al [10] for facilitating diagnostic competences argues that the sheer quantity of evidence generation is not a dependable quality criterion for the diagnostic process. However, the quality of evidence generation is hypothesized by Heitzmann et al [10] to be a rather dependable quality criterion for the diagnostic process. This agrees with the literature, as we know from studies on SPs using observational checklists that the quality of evidence generation is positively associated with diagnostic accuracy [34]. Moreover, one study with specialists in internal medicine and real patients demonstrated that asking specific questions in history taking correlated positively with clinical problem solving [35].

Study Aim, Research Questions, and Hypotheses

We aim to compare the perceived authenticity, cognitive load, and diagnostic competences in SPs and VPs. We also aim to examine the relationships of perceived authenticity, cognitive load, and quality of evidence generation with diagnostic accuracy. Thus, we address the following 3 research questions: To what extent does perceived authenticity differ across the 2
assessment methods, and how is it associated with diagnostic accuracy (RQ1)? We hypothesize that SPs induce higher perceived authenticity than VPs (H1.1). Moreover, we expect to be able to demonstrate with equivalence tests for correlations (given in the Statistical Analyses section) that perceived authenticity is not associated meaningfully with diagnostic accuracy (H1.2). Next, is cognitive load equivalent for SPs and VPs, and how is it related to diagnostic accuracy (RQ2)? We assume to find equivalent cognitive load for SPs and VPs (H2.1). Moreover, we expect that intrinsic and extraneous loads are negatively related to diagnostic accuracy (H2.2-H2.3). To what extent are the diagnostic competences components diagnostic accuracy, quantity of evidence generation, and quality of evidence generation equivalent or differ for SPs and VPs, and how are they related to each other (RQ3)? We hypothesize that SPs and VPs evoke equivalent diagnostic accuracy (H3.1). In addition, we assume that the quantity of evidence generation is higher for SPs than for VPs (H3.2). We also expect that the quality of evidence generation is positively related to diagnostic accuracy (H3.3).

Methods

Participant Characteristics and Sampling Procedures

A sample of 86 German medical students (with a mean age of 26.03 years, SD 4.71) made up the final data set. This sample consisted of 63% (54/86) females and 37% (32/86) males. Medical students in years 3-6 of a 6-year program with a good command of German were eligible. Medical students in years 3-5 (44/86, 51%) were considered novices, as they were still completing the clinical part of the medical school. Medical students in year 6 (42/86, 49%) were regarded as intermediates as they had passed their second national examination and worked full time as interns in a medical clinic or practice. We provide a detailed overview of participant characteristics across all conditions and a CONSORT (Consolidated Standards of Reporting Trials)-style diagram of participant flow in Multimedia Appendix 1.

We collected data from October 20, 2018, to February 20, 2019, in the medical simulation center of the University Hospital, LMU Munich. We recruited participants via on-campus and web-based advertising. Participants were randomly assigned to conditions by the first author by drawing a pin code to log in to an electronic learning environment without knowing the condition assigned to the pin. In the final data collection sessions, the conditions were filled by the first author with random participants from specific expertise groups (novices vs intermediates). This procedure was applied to achieve a comparable level of expertise in all conditions. As expected, the proportion of participants from different expertise groups did not differ across conditions ($\chi^2 = 0.2; P = .99$).

Research Design

The study used a repeated measures design with assessment method (SPs vs VPs) as the key factor. In addition, we varied the between-subjects factor case group (CG) order and assessment method order. In total, students encountered 6 different cases. We provide an overview of the experiment in Table 1. Details of the succession through cases and medical content in the experimental conditions are provided in Table 2. We attempted to ensure similar topics and difficulty for both CGs by conducting an expert workshop and adapting cases based on the experts’ feedback as part of creating the experimental materials.

Table 1. General overview of the experiment.

<table>
<thead>
<tr>
<th>Part of the experiment</th>
<th>Activity or test</th>
<th>Duration (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretest</td>
<td>Briefing</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Conceptual knowledge test</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>Strategic knowledge test</td>
<td>40</td>
</tr>
<tr>
<td>Break</td>
<td>—a</td>
<td>10</td>
</tr>
<tr>
<td>Assessment phase I (cases 1-3)</td>
<td>VPs^b or SPs^c</td>
<td>70</td>
</tr>
<tr>
<td>Break and change of modality</td>
<td>—</td>
<td>5</td>
</tr>
<tr>
<td>Assessment phase II (cases 4-6)</td>
<td>VPs or SPs</td>
<td>70</td>
</tr>
<tr>
<td>Posttest and debriefing</td>
<td>Working memory test</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>End-debriefing</td>
<td>5</td>
</tr>
</tbody>
</table>

^aNo activity or test takes place.

^bVP: virtual patient.

^cSP: standardized patient.
Table 2. Succession through cases and medical content in the experimental conditions\(^{a,b}\).

<table>
<thead>
<tr>
<th>Cases</th>
<th>Condition 1A</th>
<th>Condition 1B</th>
<th>Condition 2A</th>
<th>Condition 2B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>CG(^c) A (SPs(^d))</td>
<td>CG B (VPs(^e))</td>
<td>CG B (SPs)</td>
<td>CG A (VPs)</td>
</tr>
<tr>
<td>4-6</td>
<td>CG B (VPs)</td>
<td>CG A (SPs)</td>
<td>CG A (VPs)</td>
<td>CG B (SPs)</td>
</tr>
</tbody>
</table>

\(^{a}\)Case group A: (1) pulmonary embolism with lymphoma, (2) congestive heart failure with atrial fibrillation, and (3) hyperventilation tetany caused by a panic attack.

\(^{b}\)Case group B: (1) pulmonary embolism with coagulation disorder, (2) community-acquired pneumonia, and (3) hypertrophic obstructive cardiomyopathy.

\(^{c}\)CG: case group.

\(^{d}\)SP: standardized patient.

\(^{e}\)VP: virtual patient.

**Procedure and Materials**

Participants completed a pretest of conceptual knowledge and strategic knowledge at the beginning of the experiment. Afterward, participants took part in the assessment phase, solving the first 3 cases with SPs and the next 3 cases with VPs or vice versa. All cases were drafted by a specialist in general practice and evaluated positively by an expert panel. The cases were not adapted from real clinical cases but based on cases from textbooks and symptoms reported in guidelines. A short familiarization phase preceded each assessment phase and included a motivational scale. For all cases in both assessment methods, assessment time was held constant at 8 minutes and 30 seconds for history taking and 5 minutes for writing up a diagnosis for the case in an electronic patient file. At the end of the experiment, participants were debriefed. A more detailed overview of the procedure can be found in Multimedia Appendix 2.

Assessment with SPs was conducted in a simulated emergency room. All SPs were (semi-) professional actors who were financially compensated; most had previous experience working in an SP program. All SPs were extensively trained by an acting coach and a physician, memorized their symptoms and scripts, and were not aware of their patient’s diagnosis. Participants first received prior information (eg, electrocardiogram and lab results) and presentation of the chief complaint for each case. Next, participants formulated and asked questions independently, and the SPs responded. The interaction was recorded on a video. After each case, the participants completed a patient file, including measures of diagnostic accuracy and other scales. A screenshot of this assessment method is provided in Figure 1.

The assessment with the VPs was carried out in a simulated assessment environment in a computer room. First, participants received prior information and a video with a chief complaint for each case. The participants then selected questions independently from a menu with up to 69 history-taking questions. The VP’s answer was streamed as a video, including a recorded response by an actor. After each case, the participants completed a patient file, including a measure of diagnostic accuracy and other scales. A screenshot of this assessment method is provided in Figure 1.

The VPs, patient file, and other measures were implemented in the electronic assessment environment CASUS [36]. The questions provided for the VPs were based on a structural and topical analysis of history-taking forms by Bornemann [37] and are displayed in Multimedia Appendix 3. According to this analysis, physician questions in history taking can fall under the 5 categories of main symptoms, prior history, allergies and medication, social and family history, and system review. Participants with SPs received empty history-taking forms for all cases and time to formulate possible history-taking questions during the familiarization phase, at which point participants in the VPs only read all questions from the menu. Without this additional structuring support in the SP condition, the participants in the VP condition would have received additional support in the form of a list of questions in the menu.
Figure 1. History-taking with standardized patients and virtual patients.

Measures and Covariates

Perceived Authenticity

Perceived authenticity was operationalized as a construct with the 3 dimensions of realness, involvement, and spatial presence [14]. All 3 authenticity scales used a 5-point scale ranging from (1) disagree to (5) agree and were taken from multiple validated questionnaires [14,38-40]. The items were slightly adapted to simulation-based assessment and are included in Multimedia Appendix 4. A combined score for all 3 dimensions was built by calculating the mean. This scale achieved a reliability of Cronbach $\alpha=.88$.

Cognitive Load

The cognitive load scale by Opfermann [41] used in this study assessed the extraneous cognitive load with 3 items and germane and intrinsic cognitive loads with 1 item each. A 5-point scale from (1) very easy, (2) rather easy, (3) neutral, (4) rather hard,
to (5) very hard was used. The scale is included in Multimedia Appendix 4. A combined score for all 3 facets was built by calculating the mean. This scale achieved a reliability of Cronbach α=.88.

Motivation, Diagnostic Knowledge, and Other Control Variables

We assessed motivation as a control variable because it could differ between assessment methods and potentially affect performance. The expectancy component of motivation was assessed with a 4-item, 7-point scale adapted from Rheinberg et al [42]. The motivation expectancy scale ranged from (1) strongly disagree to (7) strongly agree. The value component of motivation was measured with a 4-item, 5-point scale based on a questionnaire by Wigfield [43]. The motivation value scale ranged from (1) strongly disagree to (5) strongly agree. The full scales are provided in Multimedia Appendix 4. Diagnostic knowledge was also measured in this study but not later taken into account in the analyses because it was similar in VPs and SPs because of the repeated measures design. We measured diagnostic knowledge using a conceptual and strategic knowledge test. Both types of knowledge have been identified as predictors of clinical reasoning [44]. The maximum testing time was set to 40 minutes per test. More details on both diagnostic knowledge tests are reported in Multimedia Appendix 4. Apart from this, demographic data were collected, including participants’ sex, age, and expertise (year of medical school).

Diagnostic Competences

Diagnostic Accuracy

Diagnostic accuracy was assessed based on the answer to the prompt “Please choose your final diagnosis after history taking” from a long menu containing 239 alternative diagnoses. Two physicians created a coding scheme for scoring diagnostic accuracy in all cases (Multimedia Appendix 4). To do that, the physicians rated all 239 alternative diagnoses for all cases and resolved the disagreements until they reached full agreement. One of the physicians was a specialist in general practice who also drafted the cases. The other physician was a board-certified doctor familiar with medical assessment through her dissertation. The latter physician, who is also the second author of this paper, then scored diagnostic accuracy based on the coding scheme: 1 point was allocated for the designated correct answer, 0.5 point for a partially correct answer, and 0 point for an incorrect answer. Due to having only 1 rater to score the diagnostic accuracy with the comprehensive coding scheme, a reliability estimate cannot be reported. However, this is also not necessary because the exact diagnostic accuracy score for all selectable diagnoses included in the electronic assessment environment was determined upfront in the coding scheme.

Evidence Generation

The second author classified the quality of evidence generation by determining the essential questions relevant for the correct diagnosis for each VP case (the coding scheme is given in Multimedia Appendix 4). This process took part before looking at the experimental data. All solutions were discussed with a specialist in general practice, and all disagreements were resolved. Student assistants transcribed all utterances recorded in the videos of the SP encounters, and the electronic assessment environment stored all selected questions during the VP encounters. The R scripts automatically classified the log data from the VPs using the coding scheme. Student assistants had no medical background and were trained by the second author to code the transcripts from the SP encounters. This task mainly implied recognizing the intent of history-taking questions and linking them, if possible, to the most similar question in the coding scheme. After training the raters, 20% of this complex and extensive SP data were coded by 2 raters to check interrater agreement. This data set encompassed SP data from 18 of the 86 participants of our study with all three SP cases in which the participants took part. Fleiss κ=0.74 demonstrated that agreement was substantial, and the rest of the data were coded by the same raters individually. The score for quantity of evidence generation corresponded to the total number of questions posed for each case. To calculate the score for quality of evidence generation for each case, we counted the number of relevant questions posed and divided this score by the number of relevant questions that could potentially be posed.

Scale Construction

Diagnostic accuracy and evidence generation scales for each assessment method and combining the 2 methods were built by calculating the mean of the included cases. Case 1 in CS A was excluded from all analyses because of high difficulty (mean diagnostic accuracy 0.05, SD 0.18).

Statistical Analyses

This study answers the proposed research questions using traditional null hypothesis significance testing (NHST) and equivalence testing. In contrast to NHST, equivalence testing can be used to investigate “whether an observed effect is surprisingly small, assuming that a meaningful effect exists in the population” [45]. For this type of test, first, the smallest effect size of interest, that is, the threshold for a meaningful effect, is specified based on the literature. The null hypothesis that the effect is more extreme than the smallest effect size of interest is then investigated. To do this, 2 separate 1-sided tests (TOST; eg, t tests) are conducted [46]. These tests examine whether the observed effect is more extreme than the specified smallest effect size of interest. If both 1-sided tests are significant, the null hypothesis that there is a meaningful effect that is more extreme than the smallest effect size of interest is rejected. Thus, equivalence is supported. For more convenient reporting, only the t test with a higher P value is reported. In cases in which equivalence cannot be supported, NHST is performed for follow-up analyses.

All statistical analyses were performed using R version 3.6.1 [47]. The TOST procedure and the corresponding package TOSTER [45] were used to conduct the equivalence tests. In all statistical analyses, the alpha level was set to 5%: 1-tailed tests were used where applicable. The Bonferroni-Holm method [48] was used to correct P values for multiple comparisons in post hoc and explorative tests.

For all equivalence tests, the smallest effect size of interest was determined based on the discussed literature. For H1.2 and related post hoc tests, the smallest effect size of interest was set...
to be more extreme than \( r = \pm 0.20 \), which corresponds to the effect size of small but meaningful correlations typically encountered in the social sciences [49]. For H2.1 and related post hoc tests, a meaningful effect was determined as an effect of Cohen \( d = 0.35 \). This effect size lies between a small effect (Cohen \( d = 0.20 \)) and a medium effect (Cohen \( d = 0.50 \)) [49] and occurs frequently in the social sciences. For H3.1, we determined that a meaningful effect exists in the case of a difference of \( \pm 0.125 \) points in diagnostic accuracy. This was based on supposing a pass cutoff of 0.50 for diagnostic accuracy (ranging from 0 to 1) and setting 4 equal intervals for the hypothetical passing grades A-D.

**Power Analysis**

We conducted a priori power analysis for dependent samples \( t \) tests (H1.1 and H3.2). This power analysis was based on a small to medium effect of Cohen \( d = 0.30 \), 2-tailed testing, an error probability of 5%, and 80% power, resulting in a targeted sample size of 90 participants. Moreover, we carried out a priori power analyses for 1-tailed correlations with \( r = \pm 0.25 \), an error probability of 5%, and 80% power (H2.2-H2.3 and H3.3). This power analysis resulted in a planned sample size of 95 participants. A post hoc power analysis for the main equivalence test (H3.1) with 86 participants, the observed effect of Cohen \( d = 0.26 \), and an error probability of 5% resulted in a power of 78%. All power analyses were conducted using G*Power software [50].

**Results**

**Descriptive Statistics and Analysis of Control Variables**

Descriptive statistics are provided in Table 3. The perceived authenticity variables were rated as very high for SPs and relatively high for VPs. Cognitive load variables were reported to be moderate in both assessment methods. The average diagnostic accuracy was medium. The quantity of evidence generation was higher for SPs than for VPs. The quality of evidence generation was medium for both assessment methods. Motivational variables were rated rather highly for both SPs and VPs. A post hoc comparison showed that the value aspect of motivation was higher for SPs than for VPs (2-tailed \( t_{83} = 2.89; P = .01; \) Cohen \( d = 0.31 \)), whereas the expectancy aspect did not differ between assessment methods (2-tailed \( t_{83} = 0.44; P = .66; \) Cohen \( d = 0.05 \)). Participants demonstrated slightly above medium performance on the conceptual and strategic knowledge tests. Multimedia Appendix 5 provides an additional visualization of the results using boxplots and bee swarm plots.
Table 3. Descriptive statistics.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Both methods, mean (SD)</th>
<th>SPs(^a), mean (SD)</th>
<th>VPs(^b), mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived authenticity(^c)</td>
<td>3.62 (0.67)</td>
<td>4.02 (0.67)</td>
<td>3.23 (0.84)</td>
</tr>
<tr>
<td>Realness(^c)</td>
<td>3.71 (0.79)</td>
<td>4.13 (0.74)</td>
<td>3.28 (1.07)</td>
</tr>
<tr>
<td>Involvement(^c)</td>
<td>3.82 (0.66)</td>
<td>4.03 (0.73)</td>
<td>3.61 (0.83)</td>
</tr>
<tr>
<td>Spatial presence(^c)</td>
<td>3.35 (0.80)</td>
<td>3.89 (0.83)</td>
<td>2.80 (1.05)</td>
</tr>
<tr>
<td>Cognitive load(^c)</td>
<td>2.88 (0.61)</td>
<td>2.88 (0.74)</td>
<td>2.90 (0.69)</td>
</tr>
<tr>
<td>Intrinsic load(^c)</td>
<td>3.18 (0.68)</td>
<td>3.20 (0.78)</td>
<td>3.14 (0.80)</td>
</tr>
<tr>
<td>Extraneous load(^c)</td>
<td>2.84 (0.65)</td>
<td>2.82 (0.79)</td>
<td>2.87 (0.76)</td>
</tr>
<tr>
<td>Germane load(^c)</td>
<td>2.74 (0.76)</td>
<td>2.73 (0.88)</td>
<td>2.76 (0.84)</td>
</tr>
</tbody>
</table>

Diagnostic competences

<table>
<thead>
<tr>
<th></th>
<th>Both methods, mean (SD)</th>
<th>SPs(^a), mean (SD)</th>
<th>VPs(^b), mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic accuracy(^d)</td>
<td>0.46 (0.18)</td>
<td>0.51 (0.28)</td>
<td>0.41 (0.24)</td>
</tr>
<tr>
<td>Quality of evidence generation(^d)</td>
<td>22.26 (4.88)</td>
<td>29.01 (8.03)</td>
<td>17.34 (4.21)</td>
</tr>
<tr>
<td>Quality of evidence generation(^d)</td>
<td>0.40 (0.11)</td>
<td>0.37 (0.18)</td>
<td>0.43 (0.13)</td>
</tr>
</tbody>
</table>

Control variables

<table>
<thead>
<tr>
<th></th>
<th>Both methods, mean (SD)</th>
<th>SPs(^a), mean (SD)</th>
<th>VPs(^b), mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motivation expectancy aspect(^e)</td>
<td>5.07 (0.91)</td>
<td>5.10 (0.88)</td>
<td>5.05 (1.08)</td>
</tr>
<tr>
<td>Motivation value aspect(^c)</td>
<td>4.44 (0.51)</td>
<td>4.54 (0.54)</td>
<td>4.34 (0.67)</td>
</tr>
<tr>
<td>Conceptual knowledge(^d)</td>
<td>0.65 (0.14)</td>
<td>—(^f)</td>
<td>—</td>
</tr>
<tr>
<td>Strategic knowledge(^d)</td>
<td>0.66 (0.15)</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

\(^a\)SP: standardized patient. 
\(^b\)VP: virtual patient. 
\(^c\)Scale range: 1-5. 
\(^d\)Scale range: 0-1. 
\(^e\)Scale range: 1-7. 
\(^f\)Knowledge was assessed before taking part in SPs and VPs.

Perceived Authenticity and Diagnostic Accuracy (RQ1)

A paired sample t test demonstrated that in line with hypothesis H1.1, perceived authenticity was considered higher for SPs than VPs in terms of the combined score (1-tailed t\(_{81}=11.12\); P<.001; Cohen d=1.23). Post hoc tests showed that this was also the case for realness (t\(_{80}=8.83\); P<.001; Cohen d=0.98), involvement (t\(_{81}=4.60\); P<.001; Cohen d=0.51), and spatial presence (t\(_{79}=10.65\); P<.001; Cohen d=1.19). Our expectation in H1.2 was that perceived authenticity would not be meaningfully associated with diagnostic accuracy. The TOST procedure for correlations showed that the relationship between diagnostic accuracy and the combined perceived authenticity score (r=0.05; P=.09) was outside the equivalence bounds of a meaningful effect of r=±0.20. Post hoc equivalence tests demonstrated that this also holds for the relationship of diagnostic accuracy with realness (r=0.03; P=.66), involvement (r=0.07; P=.11), and spatial presence (r=0.05; P=.08). Reanalyzing these correlations with regular 1-tailed NHST tests also yielded nonsignificant results for the combined score (P=.32), realness (P=.39), involvement (P=.28), and spatial presence (P=.33). These results mean that there is neither evidence for the absence of meaningful correlations nor evidence for significant correlations. These inconclusive findings may stem from the lack of statistical power because of the relatively small sample size [45].

Cognitive Load and Diagnostic Accuracy (RQ2)

We hypothesized in H2.1 that we would find equivalent cognitive load scores for SPs and VPs. Equivalence testing with the TOST procedure for paired samples indicated that for both assessment methods, the scores for combined cognitive load (t\(_{82}=2.81\); P=.003) were significantly within the equivalence bounds of an effect of Cohen d=0.35. Adjusted post hoc equivalence tests showed that this is also the case for intrinsic load (t\(_{82}=−2.47\); P=.008), extraneous load (t\(_{82}=2.55\); P=.01), and germane load (t\(_{82}=2.64\); P=.01). We expected in H2.2-H2.3 to uncover negative correlations between diagnostic accuracy and intrinsic cognitive load and extraneous load. As assumed, intrinsic cognitive load (1-tailed r=−0.30; P=.003) and extraneous load (1-tailed r=−0.29; P=.003) correlated negatively with the combined score for diagnostic accuracy. Adjusted explorative follow-up analyses showed that germane load (r=−0.25; P=.010) and the total score for cognitive load
(r = −0.31; P = .004) also correlated negatively with the combined score for diagnostic accuracy.

Assessment Method and Diagnostic Competences (RQ3)

Diagnostic Accuracy

In H3.1, we hypothesized finding equivalent diagnostic accuracy scores for SPs and VPs. H3.1 was first examined by applying a paired samples TOST procedure. According to our data, we cannot reject hypothesis H3.1 that a difference in diagnostic accuracy of at least ±0.125 points (1 grade) exists between the 2 assessment methods (t_{85}=−0.60; P=.28). A follow-up 3-way mixed design analysis of variance demonstrated that neither the CG order nor the assessment method order (F_{3,82}=2.49; P=.12; η^2=0.03, respectively, F_{3,82}=0.02; P=.88; η^2=0.01) had a significant effect on diagnostic accuracy. The assessment method itself, however, had a significant main effect (F_{3,82}=6.30; P=.01; η^2=0.07), indicating that diagnostic accuracy was higher for SPs than for VPs. The finding that diagnostic accuracy was higher for SPs than for VPs also corresponds to the result of a paired sample t test (2-tailed t_{85}=2.49; P=.01; Cohen d=0.27).

Evidence Generation

H3.2 that students display an increased quantity of evidence generation with SPs than with VPs was supported (1-tailed t_{85}=12.26; P<.001; Cohen d=1.47). However, in an explorative follow-up analysis, we found no evidence that the quantity of evidence generation was related to diagnostic accuracy (1-tailed r=0.11; P=.15). This finding holds equally for SPs (r=−0.09; P=.76) and VPs (r=−0.10; P=.82). Moreover, H3.3 that the quality of evidence generation is positively related to diagnostic accuracy in both assessment methods was not supported (1-tailed r=0.18; P=.05). Corrected post hoc analyses showed, however, that the quality of evidence generation was positively related to diagnostic accuracy for VPs (r=0.38; P<.001); this finding did not hold for SPs (r=0.05; P=.32). Additional post hoc exploratory analyses revealed that the quality of evidence generation was higher for VPs than for SPs (2-tailed t_{85}=−2.47; P=.02; Cohen d=0.29).

Discussion

Principal Findings

With regard to perceived authenticity, our results showed that SPs and VPs achieved high scores on all 3 dimensions of realness, involvement, and spatial presence. Despite this high level of perceived authenticity in both assessment methods, perceived authenticity was higher for SPs than for VPs on all 3 dimensions. This finding is in line with the literature, which has long claimed that SPs achieve a very high level of perceived authenticity [18-20]. Other studies on perceived authenticity have so far focused on comparing formats such as SPs, video presentations, and text vignettes and different levels of authenticity within VPs [21]. Our study extends this literature by directly comparing SPs and VPs with respect to 3 frequently used perceived authenticity variables. This comparison seems particularly relevant, as both assessment formats are becoming increasingly popular. Our findings on the relationship between perceived authenticity and diagnostic accuracy are mixed. The equivalence test on correlations was not significant; therefore, we could not confirm the hypothesis that perceived authenticity is not meaningfully associated with diagnostic accuracy. However, a regular correlation between perceived authenticity and diagnostic accuracy that was calculated afterward was close to 0. Taken together, these findings of nonequivalence and nonsignificance indicate that we did not have sufficient power to draw a conclusion [45]. Nevertheless, we have found some indication that the correlation between perceived authenticity and diagnostic competences is rather small. This finding is in accordance with literature reviews [23,24], which reported small correlations between perceived authenticity and performance.

With regard to cognitive load, we found that the combined score is equivalent for SPs and VPs that use the same clinical cases. This finding substantiates the literature suggesting that cognitive load depends mainly on task complexity [29]. Moreover, the fact that the extraneous load was equivalent for SPs and VPs indicates that user interaction through a software menu does not substantially increase cognitive load. This finding is important because decreasing the cognitive load by allowing for user input using natural language processing [21] is still highly expensive. Our study also adds to the literature that the level of cognitive load is similar in SPs and VPs as assessment methods if the different types of cognitive load are systematically controlled for during the design process. In addition, we demonstrated that intrinsic and extraneous cognitive loads correlate negatively with diagnostic accuracy. The finding on intrinsic cognitive load corroborates that the interplay between materials and the assessed person’s expertise is associated with performance. The finding on extraneous cognitive load shows that unnecessary characteristics of the assessment environment can strain memory and attention and be detrimental to performance in assessment settings. Together, these findings fit well with the literature, which has repeatedly reported negative effects of intrinsic and extraneous cognitive loads on complex problem solving in medical education [27] and other domains [51]. Our study unveils that a negative relationship between intrinsic and extraneous cognitive loads and performance in a simulation-based measure of diagnostic competences already shows when overall cognitive load is medium on average.

Our study found no evidence that diagnostic accuracy was equivalent for SPs and VPs. In contrast, higher diagnostic accuracy was achieved for SPs than for VPs. The small number of studies comparing both assessment methods so far [1,31,32] have reported medium correlations, not taking into account different case content or testing time. Using the TOST procedure as a novel methodological approach, our study contributes to the literature by finding that grading was not equivalent, as participants received a better hypothetical grade when the simulation-based assessment was administered with SPs than with VPs. On the one hand, we cannot rule out that this finding may be explained by additional support from the actors in the SP assessment. To avoid and mitigate such an effect, actors were trained by an acting coach and a physician, memorized their symptoms and scripts, and did not know the diagnosis of.
their case. Moreover, student assistants screened all SP assessments, and no additional systematic support by actors was discovered. On the other hand, this finding can be explained by the lower appraisal of motivational value and the lower quantity of evidence generation reported for VPs. Participants solving VP cases may thus have been less engaged and may have collected a smaller number of important diagnostic cues that supported their diagnostic process.

Contrary to our expectations, the quality of evidence generation was not positively correlated with the combined diagnostic accuracy score. Closer inspection of the data revealed that the quality of evidence generation was positively correlated with diagnostic accuracy in VPs. This confirmed relationship is in line with the theoretical assumptions of Heitzmann et al [10]. In SPs, however, the quality of evidence was not correlated with diagnostic accuracy. This finding contradicts the theoretical assumptions of Heitzmann et al [10] and empirical results from studies using observational checklists with SPs [34] and real patients [36]. There are 2 explanations for these conflicting findings. First, the quality of evidence generation was, as an exploratory follow-up $t$ test indicated, higher in VPs than in SPs. This higher quality of evidence generation could have been caused by a slightly different process of history taking in both assessment methods. Participants working with VPs selected questions from a menu. In contrast, participants working with SPs formulated questions during history taking freely. Second, VPs could have offered additional support to assessed persons who displayed a low quality of evidence generation, whereas VPs reacted in a completely standardized way to all assessed persons.

Limitations

One methodological limitation of our study might be the low statistical power for the analysis of hypothesis H1.2 and related post hoc analyses that addressed the relationship between the perceived authenticity variables and diagnostic accuracy. This lack of statistical power can primarily be attributed to our investigation of whether a correlation of $r = 0.20$ or more extreme exists. As recommended by Lakens [46], the smallest effect size of interest was selected based on findings from the literature. Specifying the smallest effect size of interest to be larger would have increased power but not have contributed findings from a valuable equivalence test to the literature. This is the case because the literature already assumes a small effect size [23,24].

One theoretical limitation of the study is that the results on perceived authenticity may not generalize without restrictions to other related concepts of authenticity. Shaffer et al [15] argue that thick authenticity consists of four different aspects. An authentic task, situation, or material should (1) exist in real life, (2) be meaningful, (3) allow the learner to engage in professional activities of the discipline, and (4) be conducted rather similar in instruction and assessment. The authors assume that thick authenticity can only be achieved when all aspects of authenticity are adequate and that VPs could potentially achieve similar authenticity to SPs. Hamstra et al [16] proposed distinguishing fidelity using the terms physical resemblance and functional task alignment. The authors report weak evidence for the relationship between physical resemblance and performance, and strong evidence for the relationship between functional task alignment and performance. In our study, the concepts of thick authenticity and fidelity were not measured for two reasons. First, these concepts can, to some extent, only be judged externally by experts. Second, the repeated measures design of the study forced us to keep aspects such as thick authenticity, physical resemblance, and functional task alignment as similar as possible in SPs and VPs. Nevertheless, we believe that the relationship between different authenticity concepts and diagnostic competences still requires further research. Future studies should attempt to untangle the relationship between different authenticity concepts and diagnostic competences by measuring these systematically.

Conclusions

Our findings on the relationship between perceived authenticity and diagnostic accuracy contribute to the debate on the costs and benefits of perceived authenticity in performance-based assessments. These results relativize the importance of perceived authenticity in assessment. Increasing the perceived authenticity of assessment methods above a certain necessary threshold and thus raising their costs [23] does not seem to be of much benefit. Such spending could potentially squander a large share of the medical education budget [52] that could be put to more valuable use. Our results on cognitive load highlight its importance as a process variable in assessment settings. Performance-based assessment should thus attempt to reduce extraneous load and control for intrinsic load to measure performance in a standardized way that is still close to clinical practice [53].

Finally, the findings on diagnostic competences have some practical implications if VPs are used as an alternative to SPs in assessment. In particular, we found that VPs could lead to lower diagnostic accuracy scores than SPs, which could, in turn, negatively affect students’ grades. There are 2 different mechanisms that could explain this finding: assessment with SPs could overestimate true performance or assessment with VPs could underestimate true performance. In accordance with SPs overestimating performance, we could not rule out additional support from the actors. In fact, the low, nonsignificant correlation between the quality of evidence generation and diagnostic accuracy in SPs, together with the higher diagnostic accuracy in SPs, could indicate that actors provided some additional support (eg, to participants who displayed low quality of evidence generation). Careful training [54] and screening thus seem to be of great importance to avoid additional support from actors during SP assessment to match the high level of standardization that VPs provide. The mechanism of possible underestimation of performance with VPs could be substantiated by the lower motivational value and quantity of evidence generation discovered for VPs. We suggest taking the following measures: students could be motivated additionally in VP assessment by more interactive environments (eg, using natural language processing) or providing automated elaborated feedback directly after the assessment. Moreover, the assessment time can be extended when menu-based VPs are used in practice. This way, the quantity of evidence generation could be raised to a level similar to that in the SP assessment.
Acknowledgments

The authors would like to thank Hannah Gerstenkorn, who developed the case vignettes. In addition, the authors would like to thank Ana Maria Semm, Renke Biallas, Jessica Feichtmayr, and Johannes Kissel, who assisted in conducting the study and analyzing the data, and Keri Hartman for proofreading. Finally, the first author (M Fink) would like to thank Larissa Kaltefleiter for her advice. This work was funded by the German Research Association (Deutsche Forschungsgemeinschaft; project number FOR2385).

Authors' Contributions

M Fink wrote the first draft of the manuscript, took part in conducting the study, and conducted data analysis and visualization. VR took part in conducting the study and provided feedback and editing. M Stadler conducted data analysis and visualization and provided feedback and assisted with editing. M Siebeck conceptualized and designed the study, provided feedback and editing, and acquired funding. FF conceptualized and designed the study, provided feedback and editing, and acquired funding. All authors approved the final manuscript for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Participant characteristics across all conditions and CONSORT (Consolidated Standards of Reporting Trials)–style diagram of participant flow.

[DOCX File, 55 KB - jmir_v23i3e21196_app1.docx]

Multimedia Appendix 2

Overview of the experimental procedure and simulation phases.

[DOCX File, 22 KB - jmir_v23i3e21196_app2.docx]

Multimedia Appendix 3

Table containing the questions provided with all virtual patients. These questions were allocated to the five history-taking categories of main symptoms, prior history, allergies and medication, social and family history, and system review.

[DOCX File, 27 KB - jmir_v23i3e21196_app3.docx]

Multimedia Appendix 4

Authenticity scales, cognitive load scales, coding scheme for diagnostic accuracy, coding scheme for the quality of evidence generation, motivation scales, and details of the diagnostic knowledge tests.

[DOCX File, 33 KB - jmir_v23i3e21196_app4.docx]

Multimedia Appendix 5

Boxplots and bee swarm plots for authenticity, cognitive load, and clinical reasoning variables for standardized patients and virtual patients.

[DOCX File, 73 KB - jmir_v23i3e21196_app5.docx]

References


37. Bornemann BM. Documentation forms of internal medicine and surgery for history taking and the physical examination for the medical training of students in Germany: An analysis of content and structure. Diss. München: Institut für Didaktik und Ausbildungsforschung in der Medizin der Ludwig-Maximilians-Universität München; 2016. URL: https://edoc.ub.uni-muenchen.de/19166/1/Bornemann_Barbara.pdf [accessed 2021-02-16]


Abbreviations

CG: case group
**NHST:** null hypothesis significance testing

**SP:** standardized patient

**TOST:** 2 separate 1-sided test

**VP:** virtual patient

---

©Maximilian C Fink, Victoria Reitmeier, Matthias Stadler, Matthias Siebeck, Frank Fischer, Martin R Fischer. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 04.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.

Please cite as:
Fink MC, Reitmeier V, Stadler M, Siebeck M, Fischer F, Fischer MR
Assessment of Diagnostic Competences With Standardized Patients Versus Virtual Patients: Experimental Study in the Context of History Taking
J Med Internet Res 2021;23(3):e21196
URL: https://www.jmir.org/2021/3/e21196
doi:10.2196/21196
PMID:33661122
Linguistic Analysis of Online Communication About a Novel Persecutory Belief System (Gangstalking): Mixed Methods Study

Andrew Lustig1,2*, MD, MSc; Gavin Brookes3*, PhD; Daniel Hunt4*, PhD

1Department of Psychiatry, Faculty of Medicine, University of Toronto, Toronto, ON, Canada
2Centre for Addiction and Mental Health, Toronto, ON, Canada
3ESRC Centre for Corpus Approaches to Social Science, Department of Linguistics and English Language, Faculty of Arts and Social Sciences, Lancaster University, Lancaster, United Kingdom
4School of English Studies, Faculty of Arts, University of Nottingham, Nottingham, United Kingdom

*all authors contributed equally

Abstract

Background: Gangstalking is a novel persecutory belief system whereby those affected believe they are being followed, stalked, and harassed by a large number of people, often numbering in the thousands. The harassment is experienced as an accretion of innumerable individually benign acts such as people clearing their throat, muttering under their breath, or giving dirty looks as they pass on the street. Individuals affected by this belief system congregate in online fora to seek support, share experiences, and interact with other like-minded individuals. Such people identify themselves as targeted individuals.

Objective: The objective of the study was to characterize the linguistic and rhetorical practices used by contributors to the gangstalking forum to construct, develop, and contest the gangstalking belief system.

Methods: This mixed methods study employed corpus linguistics, which involves using computational techniques to examine recurring linguistic patterns in large, digitized bodies of authentic language data. Discourse analysis is an approach to text analysis which focuses on the ways in which linguistic choices made by text creators contribute to particular functions and representations. We assembled a 225,000-word corpus of postings on a gangstalking support forum. We analyzed these data using keyword analysis, collocation analysis, and manual examination of concordances to identify discursive and rhetorical practices among self-identified targeted individuals.

Results: The gangstalking forum served as a site of discursive contest between 2 opposing worldviews. One is that gangstalking is a widespread, insidious, and centrally coordinated system of persecution employing community members, figures of authority, and state actors. This was the dominant discourse in the study corpus. The opposing view is a medicalized discourse supporting gangstalking as a form of mental disorder. Contributors used linguistic practices such as presupposition, nominalization, and the use of specialized jargon to construct gangstalking as real and external to the individual affected. Although contributors generally rejected the notion that they were affected by mental disorder, in some instances, they did label others in the forum as impacted/affected by mental illness if their accounts if their accounts were deemed to be too extreme or bizarre. Those affected demonstrated a concern with accumulating evidence to prove their position to incredulous others.

Conclusions: The study found that contributors to the study corpus accomplished a number of tasks. They used linguistic practices to co-construct an internally coherent and systematized persecutory belief system. They advanced a position that gangstalking is real and contested the medicalizing discourse that gangstalking is a form of mental disorder. They supported one another by sharing similar experiences and providing encouragement and advice. Finally, they commiserated over the challenges of proving the existence of gangstalking.
Gangstalking is a novel persecutory belief system whereby those affected believe they are being followed, stalked, and harassed by a large number of people, often numbering in the thousands [1,2]. In contrast to traditional forms of stalking that are usually organized by a single person [3], those affected by gangstalking are unable to identify a single person responsible for their persecution and experience it as a widely distributed and coordinated effort of co-conspirators. People who identify as affected by gangstalking self-identify as targeted individuals.

Although specific experiences of gangstalking vary between those affected, the various expressions of this polythetic belief system include a number of common elements. In particular, the campaign of harassment that affected individuals perceive is frequently experienced as an accretion of innumerable individually benign acts such as people clearing their throat, muttering under their breath, or giving dirty looks as they pass on the street. Perceived as deliberate, connected, and malicious, intense distress is experienced as a cumulative effect of these acts over a prolonged period. Individuals affected by gangstalking are frequently unable to pinpoint a clear motive for the harassment, which is a further source of perplexity and distress. They frequently describe that the apparent goal is to make them appear mentally ill, to cause them to be discredited and disbelieved, and sometimes to encourage or precipitate their eventual suicide.

Interest in gangstalking is increasing over time and the popular press reports the activities of those affected with growing frequency [4-7]. As shown in Figure 1, the popularity of the Google search term gangstalking has increased steadily over the past decade [8]. When targeted individuals present to clinical attention, they are frequently diagnosed with psychotic illnesses and the gangstalking is conceptualized as a persecutory delusional system by psychiatric professionals. The gangstalking belief system is similar to some other well-established persecutory delusional belief systems, such as the Truman Show delusion [9], where those affected believe that their lives are surreptitiously being continuously recorded and produced into a reality television show and that everyone or nearly everyone they come into contact with is complicit in the deceit. As with many stigmatized beliefs [10,11], individuals affected by gangstalking reject the psychiatric formulation of their condition and turn elsewhere for support.

Targeted individuals congregate in online fora where they can speak openly of their concerns, flesh out their ideas, and comment on each other’s experiences. These fora are a nonclinical environment where those affected may express their beliefs more openly and transparently without the fear of being disbelieved or labeled as may be the case in clinical settings. The internet has become an important source of health information [12]. In addition to providing a platform for those affected to find support, online fora may also serve as a crucible where people flesh out, develop, and linguistically and rhetorically construct the gangstalking phenomenon. It may also serve as a medium of transmission of the ideas as with other belief systems [13]. This study aims to describe how users of an internet forum about gangstalking construct, support, and contest the gangstalking belief system. It also seeks to describe how they use language to navigate social relationships within the context of the forum and as part of these processes.

Delusions are defined as fixed beliefs that are not amenable to change in light of conflicting evidence [14]. An alternative definition is that delusions are beliefs that are demonstrably untrue or not shared by others and which are not ordinarily accepted by other members of the person’s culture or subculture [15]. However, attempts to precisely define delusions have proven problematic and debate and controversy persist [16], with some authors suggesting that pinning down delusions definitively may be an impossible task [17]. For example, superstitious beliefs resemble delusions and are widely held among people who are not affected by mental illness [18]. Other belief systems such as astrology, tarot, and parapsychology also resemble delusional belief systems, yet people endorsing these belief systems are not usually classified as experiencing delusions. Although there are widely accepted hypotheses regarding a biological underpinning of delusions, to date there is insufficient evidence to support a clear mechanistic explanation of them [19]. Moreover, the content of delusions varies across place and time and appears to be heavily influenced by prevalent cultural trends and symbols [20].

For these reasons, we regard persecutory belief systems and their variants such as conspiracy theories, overvalued ideas, and idiosyncratic belief systems as being socially constructed [21,22]. One of the key tenets of social constructionism is that knowledge is sustained by social processes [23]. This view holds that it is through discourse that certain, dominant ways of viewing and understanding particular phenomena come to be regarded as truth, at the expense of other perspectives [24]. It is on this basis (ie, through discourse) that certain psychological or embodied experiences come to be understood and treated within a society as being either normal or pathological and, by extension, those who experience that phenomenon as either healthy, ill, or even deviant. In this paper, we adopt a social constructionist approach to understanding the roles that language, discourse, and other social processes play in constructing the gangstalking phenomenon.
Figure 1. Relative frequency of "gangstalking" as a Google search term.

Methods

The methodology adopted in this study can be described as corpus-based discourse analysis. Corpus linguistics is largely a methodology (but also a field of research) which involves using computational techniques to examine recurring linguistic patterns in large, digitized bodies of authentic language data. Discourse analysis is an approach to text analysis which focuses on the ways in which linguistic choices made by text creators contribute to particular functions and representations. The approach to corpus-based discourse analysis employed in this study is derived from that described at length by Hunt and Brookes [25] in a previous analysis of mental health–related discourse in online fora.

This approach relies on a combination of 3 techniques from corpus linguistics: keyword analysis, collocation analysis, and manual examination of concordances. The first 2 techniques are quantitative methods that use statistical techniques to sift through a large body of text (known as a corpus) to identify, respectively, words and word combinations that are notable due to their high frequency or statistical salience [26]. The third technique, concordancing, is essentially a way of viewing the corpus data that allows users to inspect all instances of a given word, word string, or collocational pairing in the corpus—in context—and, if it is desired, to access the original corpus texts in their entirety. Concordancing facilitates more qualitative analysis of the patterns in a corpus. In this study, it is used to follow up the identification of keywords and collocational pairing, with the ensuing qualitative analysis trained on identifying the wider discursive and rhetorical practices that the keywords and collocates signal and through which the forum users construe their relationships, identity, and experiences.

To obtain source texts for our corpus of forum interactions about gangstalking, we used Google to identify support groups for people experiencing gangstalking. We then focused on the largest gangstalking forum on the internet in terms of number of users, threads, and posts. The forum used to construct the study corpus is organized into topics, each one of which has an accompanying discussion which forms a thread. We used Python 3.0 code to extract 420 complete threads (225,936 words; see Table 1). The data collected included all threads posted between July 17, 2020, and September 2, 2020 (the date of collection). Some threads that were posted and subsequently deleted by their authors were not available for analysis. This was the case for 80 of the 500 threads we sought to extract, which left 420 threads for analysis. The forum requires posters to successfully solve a CAPTCHA before posting to prove they are human and not a bot.

All of the data used in our analysis were posted on a public forum, available to any internet user without having to subscribe or log into the forum. The forum permits users to contribute anonymously with a pseudonymous username that is not linked to their offline identities. Our examination of the forum posts constitutes what Eysenbach and Till [27] refer to as passive
analysis. The institutional research ethics board at The Centre for Addiction and Mental Health reviewed the proposed study design and opined that it did not require formal approval.

To help preserve contributors’ anonymity, we term this corpus the gangstalking internet corpus. At the time of data collection, the gangstalking forum that we sampled had a total of approximately 14,000 (exactly 13,598) members. To ensure that forum members’ identities are protected as far as is possible, no usernames or references to any other personally identifying information will be reproduced in the data extracts cited in this paper.

Our analysis began by using version 8 of the corpus analytical software WordSmith Tools [28] to identify keywords in the study corpus. Keywords are words that occur in the study corpus with a statistically marked frequency when compared with a reference corpus, which usually represents a norm or benchmark for the type of language under study [29]. As our reference corpus, we elected to use the spoken component of the updated British National Corpus [30]—an 11-million-word corpus of conversational British English sampled between 2012 and 2016. This reference corpus was also used by Hunt and Brookes [25], who demonstrated its utility for identifying keywords which signal discursive and rhetorical practices in the context of online fora.

Keyness was measured using a combination of the log-likelihood and the log ratio statistic [31]. Log-likelihood is a confidence measure. The higher the log-likelihood value assigned to a keyword, the smaller the probability that the (statistically marked) observed frequency of that word has arisen due to chance or a sampling error, for example. Log ratio, by contrast, is an effect size measure. The higher the log ratio score assigned to a particular keyword, the larger the observed difference is between its frequencies in the analysis corpus and the reference corpus. We stipulated that keywords should have a log-likelihood score of 15.13, indicating a confidence level of 99.99%. We also specified that a word had to be present in at least 2.5% of forum posts (ie, 69 posts out of 2749) in order to be identified as a keyword. We then ranked the resulting keywords using the log ratio statistic [32]. We set a minimum log ratio of 1.5 for a word to be included as a keyword. A log ratio of 1.5 means that the word is 2.25 times as frequent in the study corpus as in the reference corpus.

After identifying keywords, we grouped them into thematic and semantic categories. We began with the categories defined by Sheridan et al [2] in their content analysis of self-defined gangstalking-affected individuals’ accounts of their subjective experiences of the phenomenon and modified them to capture the themes that emerged from our keyword list.

Following keyword categorization, we extracted collocates of a select number of keywords of interest, in order to examine the wider linguistic contexts within which those words tended to occur in the forum posts. This step takes us beyond the solitary items in the keyword output and begins to move toward understanding the meanings and functions of words in context; as Firth [33] puts it, “you shall know a word by the company it keeps.” In this way, collocate analysis can identify the meanings and associations that affected individuals attribute to different aspects of gangstalking. We defined collocates as words occurring within 5 words to the left or right of the search word (this is the default in WordSmith Tools and had been found to be productive for corpus-based discourse studies, eg, by Hunt and Brookes [25]; Tables 2 and 3). Collocation was measured and ranked using the cubed version of the mutual information (MI) statistic (MI³). The MI³ statistic highlights collocational pairings whose frequency is marked (ie, higher than would be expected given the frequencies of the constituent words and the size of the corpus overall). It is useful for corpus-based discourse analysis, as it favors high-frequency collocational pairings which are thereby particularly well established in the discourse [34]. For analyses of computer-mediated communication, this offers the practical advantage that it does not place undue emphasis on infrequent collocates that are typos or spelling errors.

Finally, keywords and collocational pairings of interest were subjected to manual discourse analysis using concordance output and, where beneficial, based on entire forum posts and those which precede and follow them in the threads. As noted, the objective of this stage of the analysis was to identify the discursive and rhetorical practices through which the forum contributors construed the gangstalking phenomenon and their experiences of it.

### Table 1. Profile of the gangstalking internet corpus.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Gangstalking corpus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total threads sampled</td>
<td>420</td>
</tr>
<tr>
<td>Total posts</td>
<td>2749</td>
</tr>
<tr>
<td>Mean posts per thread</td>
<td>6.54</td>
</tr>
<tr>
<td>Total words</td>
<td>225,836</td>
</tr>
<tr>
<td>Mean words per post</td>
<td>82.1</td>
</tr>
</tbody>
</table>

https://www.jmir.org/2021/3/e25722

J Med Internet Res 2021 | vol. 23 | iss. 3 | e25722 | p.333

(page number not for citation purposes)
Table 2. Top 5 collocates of gangstalking (5 left/5 right), ranked by MI3.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Collocate</th>
<th>Frequency</th>
<th>MI3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>the</td>
<td>107</td>
<td>16.59</td>
</tr>
<tr>
<td>2</td>
<td>and</td>
<td>66</td>
<td>14.74</td>
</tr>
<tr>
<td>3</td>
<td>that</td>
<td>41</td>
<td>13.70</td>
</tr>
<tr>
<td>4</td>
<td>you</td>
<td>31</td>
<td>12.38</td>
</tr>
<tr>
<td>5</td>
<td>are</td>
<td>25</td>
<td>12.09</td>
</tr>
</tbody>
</table>

aMI3: cubed version of the mutual information (MI) statistic.

Table 3. Top 5 lexical collocates of gangstalking, ranked by MI3.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Collocate</th>
<th>Frequency</th>
<th>MI3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>people</td>
<td>14</td>
<td>10.32</td>
</tr>
<tr>
<td>2</td>
<td>believe</td>
<td>12</td>
<td>11.53</td>
</tr>
<tr>
<td>3</td>
<td>think</td>
<td>12</td>
<td>10.77</td>
</tr>
<tr>
<td>4</td>
<td>One</td>
<td>11</td>
<td>10.37</td>
</tr>
<tr>
<td>5</td>
<td>Real</td>
<td>11</td>
<td>12.04</td>
</tr>
</tbody>
</table>

aMI3: cubed version of the mutual information (MI) statistic.

Results

Study Analysis Overview

As described in the previous section, we began our analysis by obtaining keywords from our corpus of gangstalking forum threads. We modified Sheridan and James [1] initial 24 thematic categories of the gangstalking experience to 9 aggregate keyword categories (Table 4): (1) conceptions of gangstalking, (2) social and interpersonal concepts, (3) conceptualizations of the individual, (4) mental and psychological processes, (5) epistemic indicators, (6) extent of conspiracy, (7) technological affordances employed in gangstalking, (8) words pertaining to the internet, and finally, (9) grammatical words were categorized together. Some words were assigned to multiple categories. For example, the polysemous word state can refer to a state of mind. It can also refer to a nation or political community. For this reason, it was placed in 2 categories.

Table 4. Keyword categories.

<table>
<thead>
<tr>
<th>Thematic/lexical category</th>
<th>Associated keywords ranked by log ratio score (frequencies [n] in brackets)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conceptions of gangstalking</td>
<td>Gangstalking (380), gangstalkers (148), perps (113), gangstalked (83), stalked (99), stalking (347), targeted (183), target (146), program (95), TI (144), evil (91), control (195), situation (88)</td>
</tr>
<tr>
<td>Social and interpersonal concepts</td>
<td>Harassment (161), victim (137), gang (278), torture (141), other (152), power (111), involved (130), against (181), social (101), anyone (225), help (223), group (127)</td>
</tr>
<tr>
<td>Conceptualizations of the individual</td>
<td>Victim (137), individuals (98), individual (104), human (110), life (345), person (275), someone (298), myself (115)</td>
</tr>
<tr>
<td>Mental and psychological processes</td>
<td>Fear (120), mental (128), state (102), believe (352), experience (121), crazy (110), mind (276)</td>
</tr>
<tr>
<td>Epistemic indicators</td>
<td>Evidence (128), information (129), believe (352), happening (94), real (190), reason (126), seem (83), seems (100)</td>
</tr>
<tr>
<td>Extent of conspiracy</td>
<td>Government (200), public (120), police (176), state (102), law (115), using (130), world (240)</td>
</tr>
<tr>
<td>Technological affordances</td>
<td>Technology (131), video (91)</td>
</tr>
<tr>
<td>Internet related</td>
<td>https (411), www (242), com (271), lol (72), post (121)</td>
</tr>
<tr>
<td>Grammatical</td>
<td>etc (167), its (235), themselves (114), become (90), may (188), am (335), being (600), by (795), their (851), also (415), most (293), without (131), will (741), since (122), case (92)</td>
</tr>
</tbody>
</table>

aTI: targeted individuals.
Lexicalizing Gangstalking

The keywords belonging to the category Conceptions of gangstalking illustrate that those affected employ various lexical choices for constructing gangstalking in their forum posts. Comparing raw frequencies, it is most commonly referred to as gangstalking, which occurs 380 times in the corpus, and stalking, which occurs 347 times. Gangstalking is the gerund form of gangstalk, a portmanteau of gang and stalk. The word is a neologism. It is not included in standard English language dictionaries and indeed is absent from the updated Spoken British National Corpus, which served as our reference corpus for the keyword analysis above. Gangstalking is sometimes lexicalized as the bigram gang stalking in our corpus (n=142 occurrences). The words stalking (n=347) and harassment (n=161) were also used.

The term gangstalking served several different functions in our corpus. In some instances, it serves as a progressive verb. In other instances it is used as a gerund or as a present participle and functions as an adjective. For example:

**LIL WAYNE IS GANGSTALKING AND HARASSING ME**

The gangstalking scumbags at the bottom of the hierarchy are usually exploited and disrespected endlessly.

But they still play the childish gangstalking games.

While the first of these examples demonstrates that gangstalking is conceived of as a process similar to harassment (and, in this case, perpetrated by a famous musician), examples 2 and 3 demonstrate the way in which the existence of gangstalking is frequently represented as presupposed and uncontroversial. That is, the use of gangstalking as a descriptor of people or games functions as an existential presupposition; the use of gangstalking in this way presupposes it is. This implies that gangstalking is a valid and real concept.

The determiner the is the most frequent collocate of gangstalking in our corpus, occurring in the L1 position (ie, immediately to the left of gangstalking) a total of 47 times in the corpus. Lexicalizing gangstalking with the definite article the frames it entirely as an entity external to the affected individual. Moreover, use of the definite article indicates the verbal, as opposed to the nominal, gerund which conceptualizes a specific and actualized situation that is marked as identifiable [35]. The forum serves as a site of discursive contest between 2 competing worldviews. According to one, the concerns about gangstalking reside within the affected individual as part of a medicalizing discourse. In this paradigm, the experience of gangstalking may be regarded as a chemical imbalance or psychological disturbance. The countervailing view, by contrast, adopts a credulous persecutory discourse and posits that the difficulty is entirely due to the thoughts and behavior of malevolent others located outside of the affected individual. Use of the determiner the anticipates this contest and supports the latter view, which is a minority discourse in psychiatric practice, but the majority in this corpus.

Below are several examples of this construction.

Satan is definitely at work when it comes to the gangstalking and he is using technology as well as gang stalking perps as human vessels to get his will accomplished.

Even I filed complaints to Federal, provincial, and other organizations, the gangstalking increases.

The gangstalking was heavy. Every day. Every minute of the day. I still didn’t know what it was. I thought it was bullying, and I “”deserved“” it for being different.

These comments speak about affected individuals’ concern that the phenomenon is widespread, insidious, and centrally coordinated. Much like the use of gangstalking as a presupposition, these examples also demonstrate how gangstalking is represented as taking place regardless of the affected individual’s perceptions. This is achieved through the linguistic process of nominalization, in which the process of gangstalking is presented as a noun (the gangstalking). In the second extract above (ie, Even I filed complaints ...), for instance, it is not that the affected individual perceives that the gangstalking is becoming more intense or that they are being gangstalked more frequently, rather their post expresses the seemingly objective fact that their gangstalking has increased, once again presenting the phenomenon as incontrovertible.

Representations of the gangstalking phenomenon invariably include references to the perpetrators of the conspiracy as well as affected individuals. In the gangstalking community, the victims are usually known as targeted individuals. TI occurred 144 times in the data, targeted 183 times, and individuals 98 times, while targeted individual and targeted individuals occurred a total of 86 times. Among those affected, the perpetrators of gangstalking are known as perps. That word occurred 113 times in the corpus.

The next most frequent collocate of gangstalking is the coordinating conjunction and, which occurs most commonly in the R1 position (ie, directly following the node).

I have gangstalking and direct energy weapons/remote neural monitoring happening to me.

Can confirm Iran not exempt from gangstalking and very advanced mind control technologies.

This gangstalking, and chronic chemical poisonings, have taken a toll on my health.

Undoubtedly, these Government stalking worthless punks could not afford nice cars, lavish homes, and domestic fees, if they were not gangstalking and research people’s brains 24/7.

As these examples attest, forum contributors use the conjunction to situate the gangstalking behavior within a matrix of similar persecutory and malicious behaviors. In this manner, members of this community construct gangstalking as an individual phenomenon that is intertwined with broader national and international conspiracies. This includes 14 references to “direct energy weapons” and 69 references to voice to skull (V2K) communication technologies. As an online phenomenon, this may also increase contact between individuals who experience
gangstalking as an aspect of a persecutory delusion and members of internet conspiracy cultures more generally.

Consistent with this claim, the most frequent keyword in our analysis was https, appearing 411 times across 140 of the comments. It was used in the context of URLs, pointing readers to other resources on the internet that commenters used to emphasize and elaborate on their ideas. This speaks to the hyperlinked and connected nature of the internet and online communities but also to the nature of gangstalking as a belief system that has been popularized and shared through the networked communication of the web.

Several of the keywords highlighted interpersonal themes. This demonstrates that the gangstalking belief system is based on malicious interpersonal interactions. Affected individuals identify themselves as victim (n=137) and use the term gang (n=278) to describe their tormentors. The words someone (n=298) and anyone (n=225) are used to describe people involved in the conspiracy. Both are indefinite pronouns and allow for doubt about who they are describing. This may speak to the inchoate nature of the belief system in which those affected are certain that they are being targeted even if they cannot always precisely pinpoint whom by.

Figures of Authority
One of the keyword categories pertains to the broad reach of the conspiracy. These words identify powerful state actors. Almost without exception, those affected cannot identify a single person or agent who is responsible for their persecution. Some affected individuals construe the gangstalking as being retribution for a minor slight or altercation in the past. However, they speak of agents of symbolic authority such as government (n=200), police (n=176), and state (n=102) as either having an organizing role or at least permitting and encouraging the persecution.

Gangstalking definitely is coming from government, but it is using the private sector to avoid detection.

The government has been using this technology to target specific people and also experimentally torture some people.

Since police is involved in this, there is very little we can do about it and suing them won’t help but don’t let that deter you.

I have a history of being stalked by the police so, no, I don’t ask them for help.

This formulation frames gangstalking as a process that is occurring outside the affected individual. However, throughout the corpus, contributors also refer to the alternative view that gangstalking may be a psychological process. The keywords believe, mental, mind, and experience all draw attention to the epistemological and ontological challenges faced by those affected: what is really happening and how can one be sure? For example:

Do you actually believe in this?
They will not believe you. It would be crazy to believe us without evidence.

Also, describing gangstalking will often sound completely illogical - people will not believe the government would spend that much time or money on a person.

Individuals affected by gangstalking express concern about being able to demonstrate the veracity of their experiences. Evidence occurs 128 times in the corpus. It most frequently occurs with the collocates collect (MI=15.41) and gather (MI=14.18). Those affected post about the need, the challenges, and the potential benefits of accumulating sufficient evidence to conclusively demonstrate the veracity of the belief system:

If you are not presenting some form of evidence to skeptics, you are wasting your time.

It sounds like you have the opportunity to gather evidence and confirmation this is happening.

Faced with the risk of being disbelieved, being portrayed as mentally ill is a central concern of those affected. A common theme running through their accounts is that the very purpose of the campaign is to discredit and stigmatize them by making them appear chronically mentally ill. For example, the adjective crazy occurs 110 times in the corpus with almost all instances pertaining to their concerns about being labeled as mentally ill and stigmatized:

Yeah it’s they ritual to drive you crazy so you act weird so they can put you as crazy person so nobody will listen to the abuse.

The trick is to be subtle so you don’t come across as crazy or threatening.

I was told at the beginning they would make me look crazy or lying so no one would believe it.

Throughout the corpus, individuals impacted by gangstalking deal with the possibility and the assertion that they are affected by mental illness. Throughout the corpus, those impacted deal with this tension and the possibility that they are affected by mental illness by representing craziness as the intended outcome of gangstalking that they are actively resisting. Accordingly, those affected rarely acknowledge that they have mental illness. However, in some cases posters posit that other forum members do.

You guys are actually insane...

Hey man you need serious mental help.

In other instances, posts note that it is actually the perpetrators of gangstalking that are affected by mental illness:

Most Government gangstalkers dispatched to you, have severe psychological problems, and are afflicted with a serious mental illnesses.

It is not your fault for being gang stalked. Since stalkers have mental illness or personality disorder that fuels this behaviour.

In this manner, references to mental illness in the community serve to insulate the majority of its members from the contention that they themselves are affected by delusions. Mental illness is seen as a characteristic of perps rather than targeted
individuals or is attributed to a small number of community members whose experiences are dismissed as too extreme.

The frequent use of the word *seem* (n=83) and its variations, *seems* (n=100), *seemed* (n=24), and *seemingly* (n=13), could be viewed as reflecting uncertainty relating to aspects of affected individuals’ accounts of their gangstalking experiences. However, tellingly, these linguistic markers of uncertainty did not reflect any uncertainty relating to the legitimacy of gangstalking itself. Rather, the forum members used *seem* and its related forms to hypothesize about the nature of their own or others’ gangstalking experiences, as well as to theorize about its effects on them as individuals. As the next example demonstrates particularly well, such hypothetical scenarios tend to err on the side of the gangstalking explanation for the experiences being described, thereby arguably bolstering the legitimacy of the phenomenon.

> ...what *seemed* to be the same man, although I couldn’t get a good look at him.

> *It seems* like once I feel a great level of peace, they come around to bring me down.

> *Seems* like you are being gangstalked by an actual gang.

**Discussion**

It is well established that online social support confers mental health benefits upon patients [36,37]. However, the contested nature of gangstalking makes the role of this forum more ambiguous. On the one hand, the forum offers a platform for those affected by gangstalking to be heard and believed, in some instances without the stigma of being labeled as mentally ill. On the other hand, in some instances the forum may serve to further reinforce a maladaptive belief system, drawing those affected further into an echo chamber or down the rabbit hole of conspiracy, reinforcing previously held beliefs and discouraging them from seeking treatment.

Our analysis identified a lexicon comprising words that are highly salient to members of the gangstalking community, many of which are likely to be unfamiliar to outsiders. This includes words like *gangstalking* itself, as well as words that label the various actors in the gangstalking universe including *targeted individuals* and *perp*. In addition, contributors use specialized vocabulary to describe technological affordances such as V2K to describe “voice to skull” technologies to broadcast sounds into the minds of those affected. In addition to its communicative function, using these words serves to validate and legitimize forum contributors as members of the community [38].

The data depict the forum as a site of ontological discursive contest between 2 opposing worldviews about the nature of gangstalking. In one, it is seen as a widespread, crowdsourced system of persecution involving many members of the community, the government, police, and other figures of symbolic authority. The countervailing view is that it is a product of mental disorder and a figment of affected individuals’ imaginations. The linguistic practices in this corpus show that *gangstalking* is lexicalized in various ways that take its existence as given. In addition to constructing and representing coordinated harassment as an objective state of affairs, the nominalization of *gangstalking* also obscures the agent of the harassment and the party affected by it. Contributors use *seem* and its variants to hedge and capture a sense of uncertainty. Further, though gangstalking includes a core set of beliefs [1,2], individual expressions of the belief system vary from person to person. The term *gangstalking* allows forum contributors with varying experiences to have a common nomenclature to refer to their experiences for the purposes of exchanging stories and support with alike others. Moreover, it might be argued that the label *gangstalking* provides the forum users with a means with which to confer a sense of symbolic order over a set of otherwise incoherent experiences, in the process perhaps granting them a sense of control over it [39], or at the very least the linguistic apparatus with which to convey their distress and seek out others who are “in the same boat.”

Despite the potential value of labeling and naming a contested phenomenon like gangstalking, it is nevertheless important to note that many of the contributors to this also manifested a concern about being labeled as mentally ill and generally rejected such a formulation. Although the contributors acknowledge that the distress caused by persecution, alienation, and disbelief may be a source of psychological distress and mental disorder, they also reject the formulation that the belief system is itself a product of the mind. However, some descriptions of gangstalking that are deemed too extreme are labeled as pathological by other group members, which implies that these members operate with a vaguely specified gradient along which experiences of gangstalking may be classed as being pathological at one end and not at all pathological on the other.

Our analysis highlighted the interpersonal nature of the belief system and affected individuals’ concern with interpersonal processes. The gangstalking belief system is characterized by malice perpetrated by a vast number of unnamed others. These include private citizens and also official bodies such as police and government.

These results have the potential to inform clinicians interacting with patients who experience persecutory belief systems. Building a therapeutic relationship to enable engagement is the central process in therapy for psychosis [40]. Having a detailed understanding of the belief systems held by people affected by persecutory belief systems may be important in developing empathy and building a therapeutic alliance. Cognitive behavioral approaches to the treatment of persecutory belief systems recommend that clinicians partner with patients to critically evaluate and dispute delusional and other unhelpful beliefs. Doing so requires a detailed understanding of the beliefs and evidence for and against them. Our hope is that this study may be helpful in that regard.

Our study focused on a particular persecutory belief system. However, insights from this work may be applied more broadly to other, related belief systems. This analysis is particularly valuable because it is based on discussions taking place in a nonclinical setting which arguably allows for more candid and authentic communication, alleviating a potential “Hawthorne effect” of data collected in clinical settings.
Online fora such as the one examined here represent popular avenues for health-related support and advice seeking. This is likely the case, to an extent, for all health-related issues. Yet, this is particularly relevant to contested health issues such as gangstalking, whose contested clinical status may result in those affected turning to peers rather than practitioners for advice and social support. For practitioners seeking to learn about the belief systems and (patient) community norms associated with contested health issues, it therefore behooves them to become acquainted with such online peer support contexts and the linguistic routines (and associated discourses) that characterize the interactions that take place within them.

Acknowledgments
The following individuals merit thanks for providing helpful comments: David Chartash, David Gratzer, Jason Joannou, Erene Stergiopoulos, Albert Wong, and Juveria Zaheer.

Conflicts of Interest
None declared.

References
5. Weinberger S. Mind Games New on the Internet: a community of people who believe the government is beaming voices into their minds. They may be crazy, but the Pentagon has pursued a weapon that can do just that. The Washington Post. 2007 Jan 14. URL: https://tinyurl.com/s7ndk9uk [accessed 2020-10-21]

©Andrew Lustig, Gavin Brookes, Daniel Hunt. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 05.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Toward a Multivariate Prediction Model of Pharmacological Treatment for Women With Gestational Diabetes Mellitus: Algorithm Development and Validation

Carmelo Velardo1,2, PhD; David Clifton1,2, DPhil; Steven Hamblin1, PhD; Rabia Khan1, PhD; Lionel Tarassenko1,2, DPhil; Lucy Mackillop1,3,4, MA

1Sensyne Health, plc, Oxford, United Kingdom
2Department of Engineering Science, University of Oxford, Oxford, United Kingdom
3Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom
4Nuffield Department of Women’s Reproductive Health, University of Oxford, Oxford, United Kingdom

Corresponding Author:
Carmelo Velardo, PhD
Sensyne Health, plc
Schrodinger Building
Heatley Road
Oxford, OX4 4GE
United Kingdom
Phone: 44 0330 058 1845
Email: carmelo.velardo@sensynehealth.com

Abstract

Background: Successful management of gestational diabetes mellitus (GDM) reduces the risk of morbidity in women and newborns. A woman’s blood glucose readings and risk factors are used by clinical staff to make decisions regarding the initiation of pharmacological treatment in women with GDM. Mobile health (mHealth) solutions allow the real-time follow-up of women with GDM and allow timely treatment and management. Machine learning offers the opportunity to quickly analyze large quantities of data to automatically flag women at risk of requiring pharmacological treatment.

Objective: The aim of this study is to assess whether data collected through an mHealth system can be analyzed to automatically evaluate the switch to pharmacological treatment from diet-based management of GDM.

Methods: We collected data from 3029 patients to design a machine learning model that can identify when a woman with GDM needs to switch to medications (insulin or metformin) by analyzing the data related to blood glucose and other risk factors.

Results: Through the analysis of 411,785 blood glucose readings, we designed a machine learning model that can predict the timing of initiation of pharmacological treatment. After 100 experimental repetitions, we obtained an average area under the receiver operating characteristic curve of 0.80 (SD 0.02) and an algorithm that allows the flexibility of setting the operating point rather than relying on a static heuristic method, which is currently used in clinical practice.

Conclusions: Using real-time data collected via an mHealth system may further improve the timeliness of the intervention and potentially improve patient care. Further real-time clinical testing will enable the validation of our algorithm using real-world data.

(J Med Internet Res 2021;23(3):e21435) doi:10.2196/21435

KEYWORDS
gestational diabetes mellitus; mobile health; machine learning; algorithms

Introduction

Background

Gestational diabetes mellitus (GDM), defined as glucose intolerance with onset or first recognition during pregnancy [1], increases the risk of morbidity in women and newborns. Successful management of GDM reduces maternal hyperglycemia and perinatal morbidity. Having a pregnancy complicated by GDM is associated with a risk of developing type 2 diabetes in the long term for women [2] and, later in life,
for the offspring [3]. Standard clinical management for GDM is lifestyle advice and pharmacological treatment [4,5].

The increased prevalence of GDM [6], combined with limited resources available to the National Health Service (NHS) [7], is challenging the optimal delivery of care to women with GDM in the NHS.

GDM is usually diagnosed after 24 weeks of pregnancy, providing only a short intervention period (typically around 10 weeks) to influence perinatal outcomes. Therefore, timely identification of the need for pharmacological treatment is very important.

In current clinical practice, blood glucose (BG) data are provided by women in the form of paper-based diaries that are brought to clinics for clinician review. Decisions regarding GDM management therefore occur only during these reviews.

**Benefits of Mobile Health**

Access to real-time data recorded in electronic diaries could enable between-clinic recognition of patterns in the data and allow midwives to adjust medication in a timely fashion so that women have more chance of tighter control of their BG readings, facilitating improved clinical outcomes for the woman and her baby.

Mobile health (mHealth; ie, internet-linked mobile devices to monitor patients’ health) is well placed to facilitate this type of care and provide health care providers access to a larger and richer set of data on which to base their clinical decisions [8].

The use of mHealth by women with GDM can simplify their daily routine and has been shown to provide an easy and acceptable way of collecting, storing, and analyzing their data to aid personal decision making [9,10].

Digitally monitored BG can also provide additional benefits to clinicians by enabling real-time reviews and customized feedback. Furthermore, using the collected data could lead to the development of algorithms for the early identification of the need for pharmacological treatment, allowing earlier intervention, more frequent reviews, and potentially improved outcomes.

Some studies have successfully used baseline characteristics to predict the need for pharmacological treatment or maternal outcomes. Among these studies, factors such as glucose tolerance test results, maternal age, maternal BMI, ethnicity, and previous pregnancy history were identified as predictors of the requirement for pharmacological therapy [11-16].

**Prediction of Pharmacological Treatment**

Barnes et al [12] analyzed a cohort of 3317 women with GDM to predict pharmacological treatment using variables from electronic patient records. The authors validated their model using data from different time periods (eg, 1992-2004 and 2005-2015) and multiple clinics (Bankstown-Lidcombe Hospital Diabetes Centre and Liverpool Hospital Diabetes Centre). Their algorithm was capable of a positive predictive value of 87.6%, negative predictive value of 69.9%, sensitivity of 93%, specificity of 99.4%, and the area under the receiver operating characteristic curve (AUC) value of 0.712 (95% CI 0.693-0.731). This study makes use of variables at diagnosis, such as the oral glucose tolerance test and glycated hemoglobin (HbA1c) results, to predict the need for pharmacological treatment. In contrast to our study, the authors do not include operational, real-time BG readings, which may be fundamental to obtain better predictions.

Data collected by mHealth platforms (an example is given in Figure 1) will enable the design of algorithms for the identification of women at risk (stratification) and the early detection of required pharmacological treatment (prediction). By using machine learning (ML) to analyze data, it will be possible to provide real-time feedback to women and clinicians and allow the development of decision-supported processes for the titration of medication therapy for hyperglycemia.
This paper aims to describe the application of ML techniques to real-world data collected with an mHealth app to predict future medication events. This study compares how the predictive algorithm performs against standard heuristic techniques currently employed in NHS trusts and provides initial insights on future lines of work that will improve the existing model.

**Methods**

**Data Collection**

The GDm-Health system (Sensyne Health, plc) was used in research and clinical practice settings, and at the time of writing, it is currently routinely used for clinical practice in 35 NHS trusts.

The GDm-Health system was used to track (1) BG readings and (2) adherence to medications prescribed by health care professionals. Using the GDm-Health app, participants entered their readings, tagged them with information identifying the meal (eg, prebreakfast, postlunch, etc) and recorded information concerning the dose of any medication taken. Whenever enabled, wireless transfer from Bluetooth-enabled BG monitors was used; as an alternative (eg, if there were issues with the wireless transfer or use of a noncompatible meter), manual input of BG readings was also employed.

The analysis was performed on fully anonymized data based on established partnerships with these trusts.

For the analysis in this paper, one source of data was an implementation study that included data from (1) John Radcliffe Hospital, Oxford University Hospitals (OUH) NHS Foundation Trust, and (2) Royal Berkshire Hospital, Royal Berkshire Hospitals (RBH) NHS Foundation Trust.

This implementation study was performed by the Institute of Biomedical Engineering at the University of Oxford and OUH.

Data from the research implementation were collected for the period January 2016 to January 2019 for OUH and September 2014 to September 2019 for RBH.

A second larger set of data was generated by the anonymized data set collected and curated by Sensyne Health, plc, via the GDm-Health system. Anonymization was performed according to guidelines [17] and using a publisher (Privitar, London, United Kingdom).

Both data sets were analyzed in anonymized form. Anonymization included the removal of identifiable information (eg, given name, family name, NHS number) and transformation of sensitive information (eg, date of birth was transformed into age in years). In both instances (research and production implementation), the systems were used for clinical management.
of women with GDM; therefore, this analysis corresponds to a retrospective, secondary care–based cohort study of women with GDM using the GDm-Health system (Figure 2 describes the data flow that contributed to the data set used for the analysis).

Figure 2. Data collection and anonymization flow. NHS: National Health Service; OUH: Oxford University Hospitals; RBH: Royal Berkshire Hospitals.

Pregnant women with GDM used the GDm-Health app to track pre- and postprandial BG. All women with GDM during the monitoring period were included in the analysis. Women with type 1 and type 2 diabetes and Maturity onset diabetes of the young (MODY) were excluded from the analysis.

GDM was diagnosed using a variety of methods, including the International Association of Diabetes and Pregnancy Study Groups criteria [18] and the National Institute for Health and Care Excellence 2010 guidelines [19]. Clinical management included hospital-based follow-up in antenatal clinics and remote monitoring of BG readings using the GDm-Health app. Monitoring and management of patients varied across sites and included management via diet alone, metformin, insulin, or a combination of the above.

Analysis
To develop an algorithm that could predict women in need of pharmacological treatment, we identified 2 subgroups of interest: the diet–diet group and the diet–drug group. Women belonging to the first group did not have any prescribed medication; therefore, they remained on lifestyle-based therapy throughout their pregnancy. Those belonging to the second group transitioned from lifestyle-based therapy to pharmacological treatment (metformin and/or insulin). We identified patients as belonging to this group when not taking any medication for at least 14 days from the first day of use of the GDm-Health system. If participants initiated pharmacological treatment before the cutoff period (2 weeks), they were excluded from the analysis as they would have initiated pharmacological treatment too early.

By aligning data from all involved women to their respective delivery date allows us to plot the average BG values regardless of their meal tag and their standard error per day up to delivery. Figure 3 shows the plot of the average BG per day up to the delivery date, and at the same time it shows the number of readings used to compute the statistics of the previous. One can observe how both averages decrease toward the delivery date, suggesting that treatment is successful in both groups. However, the average BG value for those in the diet–drug group was higher than that in the diet–diet group. This result points to the importance of the BG value in deriving features to distinguish women belonging to these 2 groups.
**Figure 3.** Graph (a) shows the average and SE of blood glucose values per day corresponding to the 2 groups. Graph (b) indicates how many readings per day were used to obtain the average in (a). In both cases, the number of days on the x-axis refers to the number of days to delivery. For the period where the number of readings is high, 100 to 5 days to delivery, which roughly corresponds to the last 3 months, the average of the blood glucose values for the 2 groups is clearly different.

**Clinical Variables**

To train a model that is capable of recognizing women belonging to one of the 2 specified groups (diet–diet and diet–drug), we trained an ML algorithm over a set of features (predictors) to be extracted from the training periods associated with the 2 groups.

A list of relevant predictors, informed by clinicians, was drawn up to summarize the monitoring period extracted from the data of each group. Wherever possible, this set of predictors was extended by considering the average and SD of variables over the monitoring period to capture the level and variability of each.
Table 1 lists the set of predictors used for our analysis, together with a detailed explanation of their nature, including the time and the way in which they were recorded. The majority of predictors describe the BG level at different times of the day (eg, prebreakfast, postdinner); 2 identify a consecutive alerting situation (eg, 3 days with high readings at the meal tag in a row), and 2 describe demographics of the patient (age and BMI).

**Table 1.** Description of predictors used in this study.

<table>
<thead>
<tr>
<th>Feature</th>
<th>How it was expanded</th>
<th>When it was recorded</th>
<th>How it was recorded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast readings</td>
<td>Mean, SD, min(^a), max(^b), linear regression coefficient</td>
<td>Recordings were made according to the GDM(^c) management plan each participant discussed with their health care professional</td>
<td>BG(^d) data were recorded by participants through the GDm-Health mobile app developed to help mothers-to-be to keep track and manage their BG throughout their pregnancy</td>
</tr>
<tr>
<td>Lunch readings</td>
<td>Mean, SD, min, max, linear regression coefficient</td>
<td>Recordings were made according to the GDM management plan each participant discussed with their health care professional</td>
<td>BG data were recorded by participants through the GDm-Health mobile app developed to help mothers-to-be to keep track and manage their BG throughout their pregnancy</td>
</tr>
<tr>
<td>Evening meal readings</td>
<td>Mean, SD, min, max, linear regression coefficient</td>
<td>Recordings were made according to the GDM management plan each participant discussed with their health care professional</td>
<td>BG data were recorded by participants through the GDm-Health mobile app developed to help mothers-to-be to keep track and manage their BG throughout their pregnancy</td>
</tr>
<tr>
<td>All readings (regardless of prandial tag)</td>
<td>Mean, SD, min, max, linear regression coefficient</td>
<td>Recordings were made according to the GDM management plan each participant discussed with their health care professional</td>
<td>BG data were recorded by participants through the GDm-Health mobile app developed to help mothers-to-be to keep track and manage their BG throughout their pregnancy</td>
</tr>
<tr>
<td>Raised 3-day prebreakfast</td>
<td>Variable indicating the number of prebreakfast alerts in a 3-day consecutive period</td>
<td>Recordings were made according to the GDM management plan each participant discussed with their health care professional</td>
<td>BG data were recorded by participants through the GDm-Health mobile app developed to help mothers-to-be to keep track and manage their BG throughout their pregnancy</td>
</tr>
<tr>
<td>Raised 3-day postprandial</td>
<td>Variable indicating the number of alerts in a 3-day consecutive period for each postprandial meal</td>
<td>Recordings were made according to the GDM management plan each participant discussed with their health care professional</td>
<td>BG data were recorded by participants through the GDm-Health mobile app developed to help mothers-to-be to keep track and manage their BG throughout their pregnancy</td>
</tr>
<tr>
<td>BMI</td>
<td>BMI at the time of booking</td>
<td>Data were recorded at the first encounter with the health care professional</td>
<td>BMI is a derived variable from weight and height. Both these variables were recorded at the time of booking</td>
</tr>
<tr>
<td>Age</td>
<td>Age at the time of booking</td>
<td>Data were recorded at the first encounter with the health care professional</td>
<td>Variable derived, for privacy reasons, from the date of birth recorded at booking. Recorded as age in number of months</td>
</tr>
<tr>
<td>Ethnicity risk factor</td>
<td>Asian, Chinese, Pakistani, Bangladeshi, and other ethnicities considered at risk for GDM</td>
<td>Data were recorded at the first encounter with the health care professional</td>
<td>Data were manually recorded by the health care professional</td>
</tr>
<tr>
<td>Risk factors</td>
<td>Previous GDM, high BMI, family history of diabetes, previous large-for-gestational-age baby, ethnicity, polyhydramnios, glycosuria, macrosomia, missed OGTT(^e), unable to take OGTT, polycystic ovaries</td>
<td>Data were recorded at the first encounter with the health care professional</td>
<td>Data were manually recorded by the health care professional</td>
</tr>
</tbody>
</table>

\(^a\)min: minimum.  
\(^b\)max: maximum.  
\(^c\)GDM: gestational diabetes mellitus.  
\(^d\)BG: blood glucose.  
\(^e\)OGTT: oral glucose tolerance test.

Data collected were first analyzed at the population level. BG data distributions were inspected, and sensible (data-driven) thresholds were established to filter out readings that considered outliers. BG monitoring is highly affected by how the test is
performed and the experience level of the user. Therefore, inconclusive tests can lead to skewed BG values that are not representative of the real BG levels, and such outliers must be identified and removed to avoid bias in the training data. For the BG level, the 95th percentile of all population data was selected as the cutoff threshold, and values above this level were excluded from the data set as outliers.

As we cannot assume that our analysis would be unaffected by missing data (eg, we cannot guarantee that data are missing entirely at random), variables with missing data were imputed by substituting each missing feature with the values of the population mean for that characteristic.

Development of an ML Model

Figure 4 shows the learning tasks considered. BG metrics and medication information were available on the GDm-Health platform. Medications are prescribed by health care professionals and are collected and available on the GDm-Health platform as self-reported information by women. Both the type of medication and its dosage were captured in the platform; however, only a binary representation (medication/no medication) was used during the analysis. For the diet–drug group, the training period considered corresponded to the week before the first medication was administered. For the diet–diet group, as it was challenging to identify a clear event and to train over a range of data that represent the whole predelivery monitoring period, a randomly selected week was chosen from all the available ones. For the diet–drug group, we excluded from the training week one day before the start of medication, whereas there was no need for a gap day for the diet–diet group.
Figure 4. For both (a and b) training and (c and d) validation, summary features are computed on 1 week’s data and a label is assigned according to the group the data belong to (diet–drug and diet–diet). During training, (a) for women with a medication prescription (diet–drug), the week before the first medication dosage is considered for training. A 1-day gap between the training week and the medication event is maintained. (b) For women with no medication prescription (diet–diet), a random week is selected among all those available. During validation, (c) for women in the diet–drug group, we used a similar approach to training and computed the features on the week before the first day of medication (leaving a 1-day gap before the medication event). (d) For women in the diet–diet group, instead, we considered each week available for testing as an independent sample on which to perform a prediction.

Validation was performed similarly to the training for the diet–drug group, that is, based on features computed from the week before the medication event. For the diet–diet group, all available nonoverlapping weeks were independently considered.

For each of these, a set of features was generated with the appropriate label for the diet–diet group.
To develop the statistical model, we trained a logistic regression model on training data and tested the output of the training model on the held-out validation data.

We repeated this experiment on 100 different random permutations of the main data set between training and validation data using a 70% training and 30% validation split. At each iteration, to avoid biasing the algorithm toward the overrepresented class (diet–diet), this was randomly downsampled to the number of women in the underrepresented class (diet–drug). The validation set was not downsampled, thereby retaining within it the class imbalance that would be observable in real data. Before training, a lasso feature selection step was performed on the training data and predictors deemed important to this step were selected and used for training the algorithm. The lasso MATLAB (MathWorks) function was used with its alpha parameter set to 0.75 (corresponding to elastic net regression) and using 5-fold cross-validation.

At each iteration, a different set of women would compose the training and testing set, thus training is performed on subjects who do not contribute data to the testing set.

The results of the test were evaluated by computing the receiver operating characteristic curve (ROC), which plots the false-positive rate (FPR) against the true-positive rate (TPR). The AUC was also computed to permit the comparison of different models and to provide a summary of the performance of the algorithm. From the 100 repeated experiments, a summary description of the ROC and AUC was obtained by calculating percentiles at 5%, 50%, and 95%, providing the median ROC curve and CIs at 5% and 95%, respectively.

To compute the ROC curves, risk groups were defined automatically by the perfcurve function (MATLAB 2019a) by varying the value of the decision threshold over the range of values from 0 to 1 produced by the logistic regressor. Finally, comparison with the standard of care was evaluated by visualizing the performance of the current methodology against the ROC curve. The current clinical heuristic states that treatment should be considered if 3 or more consecutive BG readings of the same meal tag are over the designated threshold.

Results

Data Description

Data from 12 trusts were collected from women being monitored using the GDm-Health platform during 2019 (Sensyne Health plc data set) and from the Oxford University research data set between 2014 and 2015. A total of 3029 women were included in our data set at the time of analysis. After excluding data from women with incomplete demographic information (eg, missing weight and height) and excluding data from women with insufficient BG data (eg, women with fewer than 36 BG readings in the first week of use), data from 1789 women were analyzed. After further reduction and classification into one of the 2 groups of interest for our analysis (diet–diet and diet–drug), the remaining group of women (Figure 5) provided 411,785 BG readings (mean 230, SD 181), of which 160,812 were tagged as breakfast readings, 117,887 as lunch readings, and 133,086 as evening meal readings.

Figure 5. Consort diagram describing the data selection flow. Final groups are identified by the colored boxes.
Among the 1789 patients, 39.12% (700/1789) women required pharmacological treatment during their pregnancy, whereas the remaining group was managed only through diet adjustments.

**Analysis**

The results of the analysis outlined in the Methods section are summarized in Figure 6.

**Figure 6.** Experimental results. (a) ROC curves depicting the 5th and 95th centiles out of 100 repetitions of the classification experiment. (b) Histogram showing the distribution of area under the curve values for all 100 experiments. (c) Top 10 variables out of 100 repeated experiments. (d) Precision-recall curve depicting the 5th and 95th centiles out of 100 repetitions of the classification experiment. (a) Performance of the 3-day heuristic. Each dot represents a different run out of 100 repetitions. Although straightforward to implement, the average performance of the heuristic does not provide the possibility of customizing the algorithm to specific needs, such as increasing the true-positive rate at the expense of a higher false-positive rate. AUC: area under the curve; ROC: receiver operating characteristic.

The ROC and AUC results of repeated experiments are shown in Figure 6. Figure 6 also shows the results of the lasso feature selection with the top 14 (top 10 in bold) and summarizes the number of times each was deemed relevant. Figure 6 summarizes the precision-recall curves. Results from the repetition of the validation step are described by the 5%, 50%, and 95% ROC values percentiles; these provide the median ROC curve and corresponding CIs, and the same is done for the precision-recall curves in Figure 6.

The histogram of AUC values drawn from the ROC curves is centered around a median value of 0.80, which supports the potential for clinical evaluation of the proposed algorithmic approach.

To evaluate the distribution of scores for a given model, we selected one close to the median performance shown in Figure 6, 0.80 AUC. The selected model operates with 4 features (mean of all BG values, mean of all prebreakfast BG values, max of all postbreakfast BG values, and raised 3-day prebreakfast). Figure 7 shows the distribution of scores for the 2 classes and demonstrates how the model can distribute scores for both classes, although an overlap is presented around the decision boundary. For completeness, additional figures showing the distribution of feature values are shown in the Multimedia.
Appendix 1 for true positive, true negative, false positive, and false negative.

To compare performance with the standard of care, we evaluated the algorithm against the 3-day heuristic currently used in the trusts, considering that treatment should be considered when 3 or more consecutive BG readings of the same meal tag are over the designated threshold.

**Figure 7.** Distribution of scores from a model close to median performance (area under the curve 0.80). The model uses 4 features to perform its function. Although scores for the diet–diet group are clearly distributed on the left-hand side of the graph, the diet–med group presents higher variability.

As shown in **Figure 6**, the current heuristic performance is fixed to an area and is nonconfigurable. However, the proposed ML-based approach can make use of a different threshold (eg, to classify differently the score of 0 to 1 output by the logistic regression), thus allowing a change in the operating point of the system and allowing for a larger TPR at the expense of a slightly larger FPR. For example, from **Figure 6**, we could aim at 80% TPR by increasing our FPR by 20%, thus providing the possibility to the system to identify more women in need of medications, at the added cost of few women who will probably be screened by midwives and identified as false positives.

**Discussion**

The increased prevalence of GDM [6] and limited resources available to the NHS [7] pose a problem to the already burdened antenatal care services.

Predicting the need for pharmacological treatment could likely benefit women diagnosed with GDM by improving glycemic control, thereby leading to improved perinatal outcomes and avoiding complications such as large-for-gestational-age newborns or c-sections. Digital health technology such as GDm-Health can provide the real-time monitoring required to collect dense, longitudinal data sets and enable the delivery of clinical decisions quickly and efficiently to patients. Algorithms derived from real-world data obtained from GDm-Health could help midwives to optimize their clinical decision making and allow interventions, including medication, to be delivered earlier.

**Conclusions**

In this study, we have used ML on a large, anonymized data set from a population affected by GDM to design an algorithm capable of detecting the need for pharmacological treatment.

The strength of our study lies in the use of a large, multisite, real-world data set to validate our results. Predictors selected by our ML algorithm match most of the predictors included in the state of the art [11-16] and are enhanced by the use of risk factors and other demographic information available as part of routinely collected data by GDm-Health.

The logistic algorithm employed was experimentally tested against LightGBM and Random Forest algorithms. However, when applied to the same features and methodology, these comparator algorithms did not significantly improve AUC performance (both reporting a median of 0.81 AUC).

The aggregated results of the trained logistic regression models achieved an average AUC of 0.80, which is significant to justify future work to evaluate and validate this algorithm in real clinical settings.

Some of the limitations of this study are very common to other mHealth systems, including the challenge of user-reported data such as medication and BG data, which may be inaccurate or missing. However, in the case of GDm-Health data, user retention and user adherence have been very high, with only 4% of profiles being excluded because of complete disengagement with the system (117 women with no readings).

Given the longitudinal nature of this data set (ie, from 2014 to 2019) and the heterogeneous nature of each trust, women at each trust could have been subject to different clinical
management processes, adding to the complexity of the ML task.

Nevertheless, we demonstrate that our algorithm predicts the requirement for pharmacological therapy, and we show the superiority of our approach against a heuristic currently employed in clinical settings.

The very likely future introduction of ML algorithms to aid the work of health care professionals and to support patients coping with their conditions requires the validation of the technology using real-world data sets such as the one provided by GDm-Health. We intend to clinically validate the performance of the algorithm further by evaluating its real-time performance on a data set used for clinical operations. To that end, we will first pursue a posthoc analysis on a subset of data not used to design the algorithm and then deploy an implementation of the algorithm alongside GDm-Health to monitor its real-time performance (ie, predictions performed on a daily basis on updated BG daily readings) against decisions performed by health care professionals. Finally, repeated validation and postmarket evaluation strategies will be employed to continuously validate the algorithm against clinical decision making made by health care professionals.

Future work may include new analyses of the GDm-Health data set to include other variables that might identify a change in clinical patient management (eg, including the trust name as a predictor), considering variable lengths of predictive windows (eg, computing features at 2, 3, or 4 weeks before a medication event), or considering the problem as a time-to-event prediction (via Cox proportional hazards, etc).

Acknowledgments

The authors would like to thank all members of the TREAT-GDM research team, the patients who participated in the study, and those who had used the GDm-Health system. A special thanks to Ian Gallen for his invaluable contributions. The team acknowledges the support of Roberto Liddi, Rodrigo Jazinski, Michael Griffiths, Anna Muszkiewicz, James Farrant, Manoj Krishnamoorthy, and Darren Gibb.

Authors’ Contributions

CV performed the analysis and wrote the first draft. LM, CV, LT, and DC contributed to the study methodology. All the authors contributed to revising and finalizing the paper.

Conflicts of Interest

Sensyne Health, plc, acquired the rights of the GDm-Health system from the University of Oxford, and it is the company that develops, maintains, and commercializes the GDm-Health system for the management of GDM. LM was supported by the National Institute for Health Research Oxford Biomedical Research Centre and works part time for Sensyne Health, plc. CV works for Sensyne Health, plc, and is a visiting lecturer in the Department of Engineering Science, University of Oxford. LT, DC, and PW work part time or consult for Sensyne Health, plc.

Multimedia Appendix 1

Error analysis of true positives, true negatives, false positives, and false negatives for a given selected model.

References


Abbreviations

AUC: area under the receiver operating characteristic curve
BG: blood glucose
FPR: false-positive rate
GDM: gestational diabetes mellitus
mHealth: mobile health
ML: machine learning
NHS: National Health Service
OUH: Oxford University Hospitals
RBH: Royal Berkshire Hospitals
ROC: receiver operating characteristic curve
TPR: true-positive rate
Original Paper

The Perceived Impact and Usability of a Care Management and Coordination System in Delivering Services to Vulnerable Populations: Mixed Methods Study

Rubina Rizvi1, PhD, MD; Courtney VanHouten1, MA; Tiffani J Bright1, PhD; Mollie M McKillop1, PhD; Shira Alevy1, MEd; David Brotman1, MS; Megan Sands-Lincoln1, MPH; Jane Snowdon1, PhD; Barbie J Robinson2, MPP, JD; Carolyn Staats2, AB; Gretchen P Jackson1, PhD, MD; William J Kassler1, MPH, MD

1IBM Watson Health, Cambridge, MA, United States
2Department of Health Services, Sonoma County, Santa Rosa, CA, United States

Corresponding Author:
Rubina Rizvi, PhD, MD
IBM Watson Health
75 Binney St
Cambridge, MA, 02142
United States
Phone: 1 952 237 7660
Email: rubina.rizvi@ibm.com

Abstract

Background: People with complex needs, such as those experiencing homelessness, require concurrent, seamless support from multiple social service agencies. Sonoma County, California has one of the nation’s largest homeless populations among largely suburban communities. To support client-centered care, the county deployed a Care Management and Coordination System (CMCS). This system comprised the Watson Care Manager (WCM), a front-end system, and Connect 360, which is an integrated data hub that aggregates information from various systems into a single client record.

Objective: The aim of this study is to evaluate the perceived impact and usability of WCM in delivering services to the homeless population in Sonoma County.

Methods: A mixed methods study was conducted to identify ways in which WCM helps to coordinate care. Interviews, observations, and surveys were conducted, and transcripts and field notes were thematically analyzed and directed by a grounded theory approach. Responses to the Technology Acceptance Model survey were analyzed.

Results: A total of 16 participants were interviewed, including WCM users (n=8) and department leadership members (n=8). In total, 3 interdisciplinary team meetings were observed, and 8 WCM users were surveyed. WCM provided a central shared platform where client-related, up-to-date, comprehensive, and reliable information from participating agencies was consolidated. Factors that facilitated WCM use were users’ enthusiasm regarding the tool functionalities, scalability, and agency collaboration. Constraining factors included the suboptimal awareness of care delivery goals and functionality of the system among the community, sensitivities about data sharing and legal requirements, and constrained funding from government and nongovernment organizations. Overall, users found WCM to be a useful tool that was easy to use and helped to enhance performance.

Conclusions: WCM supports the delivery of care to individuals with complex needs. Integration of data and information in a CMCS can facilitate coordinated care. Future research should examine WCM and similar CMCSs in diverse populations and settings.

(J Med Internet Res 2021;23(3):e24122) doi:10.2196/24122

KEYWORDS
vulnerable population; managed care; data integration; advanced technologies; usability; mixed methods study
**Introduction**

**Background**

Providing comprehensive services to vulnerable populations is a complex task requiring effective and efficient collaboration and resource alignment among various safety net agencies [1,2]. Care management processes are often complicated when such organizations operate in information silos. These processes often involve agencies such as health care, law, housing, and law enforcement, which tend to work independently and lack effective, seamless communication across agencies [3]. To mitigate this growing challenge, synchronization of agencies at different levels is required to successfully provide holistic, client-centered care in an effective and timely manner. These existing silos could be further addressed by using technology as a common platform, which could serve as a reliable information repository for data aggregation, reporting, and exchange. Currently, limited evidence exists about the use, benefits, and shortcomings of social management tools built on advanced technologies.

Sonoma County is a large county in California, with over 500,000 residents [4] and a disproportionately large homeless population compared with similarly sized communities [5]. The 2019 Sonoma County Homeless Census and Survey Comprehensive Report [6] suggested that approximately 3000 homeless people live primarily in vehicles (29%) and emergency shelters (25%); on streets (24%); and in various other shelters (22%), such as tents, transitional housing, or abandoned buildings [6]. This homeless crisis has been intensified by natural disasters, most recently the Kincaid Fire (October 23 to November 6, 2019), which threatened more than 90,000 structures and burned 77,758 acres, resulting in evacuations throughout Sonoma County [7]. This critical situation was recognized by the Sonoma County department leadership and increased the need for a solution that could help address the existing gaps by providing holistic, client-centered care for the county’s residents with complex needs. In 2017, the board of supervisors established a 3-step approach for achieving their objectives by implementing the Accessing Coordinated Care and Empowering Self-Sufficiency (ACCESS) [8] initiative to identify the most vulnerable residents and provide them with coordinated services. In efforts to establish a rapid response, the interdepartmental multidisciplinary team (IMDT) was created to coordinate cross-departmental services. The IMDT mainly comprises personnel from each social service department and eligibility specialists, who were hands-on Watson Care Manager (WCM) users, and leaders and executives from programs and services participating in the ACCESS initiative, who engaged indirectly with the WCM system and its output but were not hands-on users. Sonoma County partnered with International Business Machines (IBM) to develop a Care Management and Coordination System (CMCS) to support the IMDT [9].

The primary objective of the CMCS is to successfully refer vulnerable residents to the services they need most and foster data sharing and collaboration among diverse care professionals to optimize service delivery. The CMCS tool consists of 2 components: Connect360 and WCM. Connect360 is an integrated data hub that receives data from participating agencies and generates a comprehensive, client-specific record as a single data source. These agencies include housing, human services, justice, child support services, substance use disorders, mental health, medical services, aging, and independence. WCM is the front-end interface (our study focus) that displays the consolidated client record to care providers. Using WCM, IMDT members actively enter, aggregate, and render up-to-date information, which enables them to develop integrated care plans for vulnerable clients (Figure 1) [3].

**Figure 1.** The front-end interface of Watson Care Manager.
Objectives
The purpose of this study is to evaluate the user-facing component of WCM to better understand its usability and perceived impact on service delivery processes at the Sonoma County Department of Health and Human Services (SC DHHS). We aimed to examine the role and perceived benefit of using WCM in case management, identify factors facilitating or impeding the use of WCM, and understand user acceptance of WCM with regard to perceived usability and ease of use of WCM.

Methods

Study Design
A mixed methods study, including observations, interviews, and surveys, was conducted at SC DHHS in December 2019. Purposive sampling was employed to recruit 2 sets of participants from SC DHHS: (1) WCM end users, which included eligibility specialists, and representatives from various government, law enforcement, and community agencies and (2) department leadership, which included individuals serving in an executive or management capacity.

Data Collection
The IMDT meetings were observed by four research team members (RR, CV, TB, and MS) with diverse backgrounds. The semistructured interview guides included questions focused on job role, initiation of client contact, client burden of care, client interaction and engagement, WCM use, and interview demographics. The interview guides used for WCM users and department leadership are included in Multimedia Appendices 1 and 2, respectively. Interviews were conducted on-site and over telephone; all were audio recorded, transcribed verbatim, and saved using a Health Insurance Portability and Accountability Act–compliant app Otter (version 2.1.17) [10]. Before each interview, the WCM tool was used during these meetings, and an example of the summary home page of the front-end interface is shown in Figure 1. In total, 3 IMDT meetings were observed; each meeting lasted approximately 3 hours, and field notes were taken by each observer. The WCM tool was used during these meetings, and an example of the summary home page of the front-end interface is shown in Figure 1.

Interviews were conducted with 8 WCM users and 8 department leadership members. Of the 16 interviews, 13 were conducted in person and 3 were conducted over the telephone. Interviews with WCM users lasted for an average of 60 min; the longest interview lasted approximately 130 min. Department leadership interviews averaged approximately 40 min, whereas one leadership interview with 2 individuals lasted for 140 min. The study participant characteristics are aggregated and summarized in Table 1.

Table 1. Descriptive characteristics of Watson Care Manager users and department leadership (N=16).  

<table>
<thead>
<tr>
<th>Participants</th>
<th>Value, n (%)</th>
<th>Age (years), range</th>
<th>Age (years), mean (SD)</th>
<th>Gender (female), n (%)</th>
<th>Education (master’s degree or higher), n (%)</th>
<th>Technology skills (intermediate skill level or higher), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WCM users (n=8)</td>
<td>8 (50)</td>
<td>31-62</td>
<td>47 (13.2)</td>
<td>6 (75)</td>
<td>5 (63)</td>
<td>7 (88)</td>
</tr>
<tr>
<td>Department leadership (n=8)</td>
<td>8 (50)</td>
<td>42-58</td>
<td>51.6 (6.2)</td>
<td>5 (63)</td>
<td>6 (75)</td>
<td>N/A b</td>
</tr>
</tbody>
</table>

aWCM: Watson Care Manager.

bN/A: not applicable.

Analysis of the transcripts resulted in a list of codes. For reporting purposes, we included only the top 10 most frequently applied codes stemming from the analysis of 3 transcript sources (Multimedia Appendix 4).

The most granular-level codes were grouped as follows: (1) WCM role and function in care management practices with subthemes of data centralization and streamlined workflows (eg, shared decision making and information aggregation), (2) process influencing factors having subthemes of facilitators and barriers (eg, community demographics and data privacy), and (3) usability and satisfaction with subthemes overall usability and specific tool functionalities (eg, interaction with the interface and alerts; Figure 2).
Figure 2. The 3 unifying supraordinate themes and the corresponding subthemes. WCM: Watson Care Manager.

Unifying Theme: WCM Role and Function in Care Management Practices
Observations of IMDT meetings consistently suggested that WCM was used as the main tool for data review, both by leaders and users. WCM provided IMDT team members with an opportunity to have a collaborative team discussion about a client’s status and review the data before the IMDT meeting. Despite its advantages, it was observed that 2 WCM users continued to reference paper copies of case information as a supplemental resource for facilitating updates and discussion. Slight differences were observed between department leadership and WCM users. Leadership primarily discussed the positive impact WCM had on employees and department operations, whereas users tended to discuss the impact of WCM in the context of facilitating daily task accomplishments, establishing client rapport, and strengthening existing relationships. Despite these differences, these interviews revealed a praxis-based approach whereby descriptions of task achievement were used to illustrate how WCM supported larger goals. Analysis of all the observations and interviews revealed 2 principal themes of use: (1) data management and centralization and (2) streamlined agency communication.

Subtheme: Data Management and Centralization
Both program leaders and hands-on users repeatedly referenced the role of WCM as a data management tool to centralize client information and serve as a platform to reliably retrieve and store client information. In addition to progress-related updates, WCM helped users to stay up to date on short-term, practical tasks such as taking clients to probation or court hearings, delivering public transit vouchers, or keeping medical follow-up appointments. The following excerpt from the field notes validated how WCM facilitated scheduling a client’s appointment, thereby enhancing task performance efficiency:

During a client presentation, the case manager requested a new medical appointment, and the nurse made the medical appointment instantly. The appointment was scheduled before the conversation was even over. [Observation note]

WCM users routinely retrieved and documented case notes in up to 7 different systems simultaneously before working in WCM. Furthermore, documentation of client interactions in multiple systems was necessary to meet state and federal reporting requirements; however, they did not have a platform to store or share case-specific information such as care plans or client goals:

If Watson didn’t provide that service [providing a platform across multiple systems], I’m doing what I’ve been doing that is, I have seven systems, and I work in those seven systems to gather information. [Participant #6, user]

We also don’t have a place where our care plan is currently living. And so Watson is the only place that the care plan actually lives. The living document. So, I think that is really important. [Participant #6, user]

I use it to go in and see what one of the other team members have already completed when there is something that needs to be done. To make sure that anything that needs to be done for the benefit of the client is being done. [Participant #4, user]

WCM not only helped in care delivery but also helped users maintain their client’s enrollment in government support programs through an alerts feature. Department leadership noted that securing and maintaining such support is integral to helping a client achieve stability but that it can sometimes be a burden on client managers whose clients are often enrolled in several programs with different requirements and renewal terms:

Unifying supraordinate themes

| WCM role and function in care management practices | Process influencing factors | Usability and satisfaction |
| Data management and centralization | Facilitators | Overall system's usability and satisfaction |

Subthemes

| Streamlined workflow and communication | Barriers | Usability related to specific features |
Well, I kind of go back to what I was saying about the alerts. If I missed the alert, and I didn't reach out to the client and inform the client this is upcoming [and] this has to be done, or you will lose the benefit [and] to go through the process of trying to get that benefit reestablished is a lengthy process. So, it helps the client, and it helps me to know that I'm doing my job. [Participant #4, user]

In addition, by aggregating client eligibility information, WCM coordinated multiple application processes, allowing the client to apply for multiple programs at one time. This coordination reduced the cognitive burden on employees and helped reduce unnecessary client effort by avoiding the need to constantly obtain required documentation or navigate multiple application procedures:

A lot of [applications and eligibility] interactions we use Watson Care Manager. We can like coordinate to get verification before my interview [with the client]. So, at the time of the interview begins or the time I meet the client like they can already have everything ready so it's like “here you go. Like I have it and it's more straightforward my end that I can approve them all one time and just collect the application.” [Participant #2, user]

Department leadership interviews echoed the resulting benefits of WCM by rendering data that are streamlined and centralized, serving as a one-stop shop to learn about the client’s current status and to plan out the next steps:

That’s one of the things that everybody has a great help for with Watson, how we use that information, bringing our respective data together, and work in a more coordinated fashion. [Participant #15, department leadership]

Subtheme: Streamlined Workflow and Communication
Streamlined workflow and communication emerged as common subthemes, from interviews of both leaders and hands-on users. WCM played an essential role in effective and efficient communication not only within the agency but also between other agencies. More specifically, agencies related to health care, housing, and justice were able to communicate across silos to address time-sensitive client needs. Examples included understanding a client’s current health status and making timely health care appointments, ascertaining the availability of housing spaces based on individual needs, and verifying the parole status of the client. Observations noted up-to-date exchange of information between WCM users from different agencies, resulting in a comprehensive, timely care delivery plan that prioritizes clients’ needs and avoids potential adverse repercussions:

Client released from jail to the crisis residential unit and needs mental health services but refuses. Group discussion around options, pathways – how to get client to seek mental health. Probation officer reminded the criticality of client’s compliance with receiving mental health treatment since it was one of the conditions of his parole. [Observation note]

During interviews, both WCM users and department leadership discussed how WCM use and IMDT meetings facilitated real-time discussions among the pertinent care providers from the representative agency, enabling more informed, shared, and efficient decision making. Both users and department leadership highlighted specific descriptions of how case managers and other client specialists were able to advocate for their clients. Users also shared their prior experiences before the introduction of WCM and described operating in silos and on different information technology systems. They described the benefit of provisioning a holistic, client-centered approach with a common shared platform with specific case examples:

We could all talk about how the client is doing within the shelter. And so the [parole officer and shelter manager] worked with her on a plan...and everything got better from there. We can have a shared understanding. [Participant #6, user]

Effects on communication and coordination led to changes in workflow processes, and they were described by one user as follows:

A lot of [applications and eligibility] interactions we use Watson Care Manager. We can like coordinate to get verification before my interview [with the client]. So, at the time of the interview begins or the time I meet the client like they can already have everything ready so it’s like, here you go. Like I have it and it's more straightforward my end that I can approve them all one time and just collect the application. [Participant #2, user]

In addition to integrating data and alerts from multiple agencies, WCM facilitated cross-program collaboration by providing a shared vocabulary. This common language and shared context fostered mutual understanding among agencies:

I mean we've spent many hours talking about like really silly things but like things that are weirdly fundamental for, like, one government agency talking to another like, what does date of admission mean? What does it mean to the jail, what does it mean to behavioral health? Are we tracking the right date of admission?... oh my god what a headache to have a conversation but at the same time, like us, understanding that one person's definition of this thing is radically different from someone else's is important. [Participant #6, user]

Unifying Theme: Process Influencing Factors
Facilitators and barriers influencing the implementation and use of WCM were primarily identified through participant interviews from both executives and the hands-on users of WCM. During interviews, factors that shaped engagement with WCM were described.

Subtheme: Facilitators Influencing WCM Implementation and Use
WCM users from the IMDT and department leadership discussed opportunities to expand WCM to additional groups of clients in other US counties, apart from Sonoma County. The
IMDT attendees acknowledged the benefits and value of WCM and provided examples of how performance improvement enabled client success.

...so, it helps the client, and it helps me to know that I'm doing my job. [Participant #4, user]

It's just everything's there in your fingertips and you just might have to scroll down a little bit, but everything there...my success rate is so much more...ultimately that's what matters so like improving care, [I am] pretty satisfied with it. [Participant #2, user]

Department leadership described their viewpoint on the role of WCM in facilitating a collaborative environment. It was valuable in helping their transformation toward a client-centered culture. They also discussed WCM’s flexibility, which enabled diverse departmental participation and improved care coordination. Multiple agencies recognized the value of WCM’s role in streamlining care delivery and facilitating efficiency. Finally, this environment indicated a strong and widespread commitment to collaboration and willingness to participate in WCM use:

Our ability to show that [WCM] is effective helps us advocate for and leverage your resources. If they see it as successful then they are willing to put more resources into it. [Participant #15, department leadership]

This work that you’re [WCM] doing, and what has been accomplished thus far with Watson - I think is groundbreaking, and really has great potential to go to scale. [Participant #15, department leadership]

In addition, users and department leadership highlighted the unique aspects of Sonoma County that may have contributed to WCM’s success in their client population. Notably, the manageable, medium-sized county with active community-based agency participation facilitated and maximized WCM’s utility and resulting outcomes:

I think Sonoma is in a very good place in that we’re medium sized county and we, we have a lot of community-based organizations that work with us are already under contract and so it's probably more possible in Sonoma County than anywhere to be successful. [Participant #9, department leadership]

Subtheme: Barriers Influencing WCM Implementation and Use

Currently, there is a lack of awareness and knowledge about how the ACCESS initiative operates. Barriers exist and impede its widespread adoption across other counties within California:

...so I think we have work to do, and a lot of that will be about outreach! [Participant #9, department leadership]

The concerns around data privacy and security and the complexity of legal requirements also present implementation challenges. Although leadership expressed the desire to participate in the ACCESS initiative, they expressed concerns about meeting strict federal and state reporting requirements on data sharing in addition to their struggle in identifying appropriate funding streams:

You know, we have these really, really, strict policies on our data, so we've been able to do some match where we've been able to get some cohort data and then match it against our system, but we haven't been able to into the universal system and you know that's been a little frustrating. [Participant #9, department leadership]

In user interviews, participants discussed the possibilities of using WCM for simple data organization and commented that they had fewer data systems and necessary log-in requirements:

I have like nine systems...that I use on a frequent basis. And then I have to use the additional two or three, four programs...So, with that and then I have to use Watson Care Manager because there's not much integration with that so I have to do three different systems with my case notes, so you have three different IDs and passwords you have to log in and I have like 12. [Participant #2, user]

One user, however, voiced concern about duplicate efforts and manual tasks required when WCM was not able to retrieve all client-related data from various resources. They suggested that improved integration was needed to make the processes more efficient:

So, while at the moment it isn't frustrating or feeling like an extra piece of work...it's just the system is not set up right now. [Participant #3, user]

Unifying Theme: Usability and Satisfaction (Users’ Perspective)

Users’ perception of WCM was analyzed based on data from observations, user interviews, and surveys. Perspectives on usability, including both PU and ease of use, and satisfaction are presented in Table 2.
Table 2. Responses from the Technology Acceptance Model survey.

<table>
<thead>
<tr>
<th>Variable and TAM&lt;sup&gt;a&lt;/sup&gt; survey questions&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Reported TAM score, median (minimum-maximum)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PU&lt;sup&gt;c&lt;/sup&gt;</strong></td>
<td></td>
</tr>
<tr>
<td>Enables me to accomplish tasks more quickly than other products</td>
<td>4 (3-7)</td>
</tr>
<tr>
<td>Improves my job performance</td>
<td>5 (3-7)</td>
</tr>
<tr>
<td>Increases my productivity</td>
<td>4.5 (2-7)</td>
</tr>
<tr>
<td>Enhances my effectiveness on the job</td>
<td>4.5 (3-7)</td>
</tr>
<tr>
<td>Makes it easier to do my job</td>
<td>4.5 (3-7)</td>
</tr>
<tr>
<td>I have found WCM&lt;sup&gt;d&lt;/sup&gt; useful in my job</td>
<td>5 (3-7)</td>
</tr>
<tr>
<td>Median PU</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td><strong>PEOU&lt;sup&gt;e&lt;/sup&gt;</strong></td>
<td></td>
</tr>
<tr>
<td>Learning to operate was easy</td>
<td>4.5 (2-7)</td>
</tr>
<tr>
<td>Easy to get to do what I want it to do</td>
<td>5 (3-6)</td>
</tr>
<tr>
<td>Interaction is clear and understandable</td>
<td>5 (3-7)</td>
</tr>
<tr>
<td>Flexible to interact with</td>
<td>5.5 (2-7)</td>
</tr>
<tr>
<td>Easy for me to become skillful</td>
<td>6 (2-7)</td>
</tr>
<tr>
<td>I found WCM easy to use</td>
<td>5 (2-7)</td>
</tr>
<tr>
<td>Median PEOU</td>
<td>5 (4.5-6)</td>
</tr>
<tr>
<td>Overall combined median</td>
<td>5 (4-6)</td>
</tr>
</tbody>
</table>

<sup>a</sup>TAM: Technology Acceptance Model.
<sup>b</sup>The Technology Acceptance Model version used in this study had 12 questions, 6 assessing perceived usefulness and 6 assessing perceived ease of use, and they were scored on a 7-point Likert scale where 1=extremely disagree and 7=extremely agree.
<sup>c</sup>PU: perceived usefulness.
<sup>d</sup>WCM: Watson Care Manager.
<sup>e</sup>PEOU: perceived ease of use.

**Subtheme: Overall Perceived Usability and Satisfaction**

Overall, WCM users found the system to be well suited for their needs, serving as a one-stop shop for users by providing them with client-related data under one coherent platform. Users described WCM as being able to reliably house client information and provide easy access to relevant, time-sensitive information. Most importantly, WCM did not simply replicate previously existing electronic or paper forms but dynamically supported client care delivery by providing access to the latest data on client status and progress-related updates. Interviews also indicated the agility of WCM in allowing for rapid customization and the creation of a tool personalized according to their preferences.

TAM surveys were completed by WCM users and, on average, took 10 to 15 min (Table 2).

User feedback also suggested that WCM was not being used to its full potential and that specific WCM features were underused. WCM users suggested that additional individualized training might allow for better optimization of WCM capabilities:

...it's almost like having a Ferrari, and only knowing how to drive a Ford. [Participant #4, user]

**Subtheme: Usability Related to Specific Features**

The alerts feature was one characteristic of the tool that was valuable to WCM users. A benefits coordinator used the alerts feature to notify managers about programs for which their client was eligible, to set reminders for application deadlines, or to notify regarding benefits renewal dates. Users described the alerts as valuable reminders that helped them monitor and maintain their clients’ enrollment and avoid coverage gaps. Department leadership interviews also expressed agreement on the benefits of the alert feature. Leadership noted that securing and maintaining such support is integral to helping a client achieve stability but is often a burden on client managers whose clients are often enrolled in several programs with different requirements and renewal terms:

Oh, yeah, I have one thing that I can put up as why Watson Care Managers are so needed is to share the information piece, and the alerts, put on that front page of the summary page. [Participant #2, user]

Users also mentioned 2 other features that they thought were useful. Both the summary (with demographics) page and the availability of a clients’ picture facilitated with their tasks by providing succinct, identifiable, and useful data:
Findings from observations, interviews, and the TAM survey indicated that users found WCM to be well suited for their needs. A high level of PU (PU=5) and PEOU (PEOU=5) was indicated as a result of the TAM survey, and WCM was considered a reliable and useful tool that was easy to use and helped improve participants’ overall productivity.

It should be noted that some WCM users indicated concern about the lack of interface optimization, such as unnecessary clicking and scrolling. The few users that reported this were not familiar with the system, which influenced their ability to efficiently perform tasks. This feedback was further supported by the median TAM score of 4 (with a minimum-maximum value of 3-7), especially for the responses around accomplishing tasks quicker:

*Part of it’s about learning to use the system and part of it’s about minimizing clicks...* [Participant #6, user]

**Discussion**

**Principal Findings**

Provision of effective, holistic, client-centered care for vulnerable populations presents a complex challenge requiring substantial collaboration and careful coordination. This study provides unique insights into how a technology solution serves as an essential anchoring tool in a case management model. It enables data consolidation across agencies under one platform and serves as a common communication channel. The tool cultivated an environment of shared decision making and strengthened relationships among agencies.

The CMCS data hub, comprising WCM and Connect360, helped to retrieve and consolidate data in one shared place. It provided case workers with most recent data, such as court dates, benefit eligibility due dates, and doctors’ appointments for clients who often need timely actions. According to users, WCM played a valuable role in addressing the challenges unique to social work with homeless populations where information is often transient, including mobile phone numbers, addresses, and contact information. WCM users and department leadership also provided feedback on barriers, including lack of funding, complex reporting structures, and limited awareness about the ACCESS initiative. Despite these barriers, WCM was perceived as a useful and easy-to-use tool associated with high user satisfaction, as validated by observations, interviews, and TAM responses.

The WCM tool was recognized for its high level of usability and satisfaction. Key features included alerts, information summary page with demographics, the client picture, and the client list page, which served as an index to pull all the client records stratified by priority status. The overall TAM score results and the scores across the 2 dimensions of usefulness and ease of use reinforced findings from the qualitative analysis.

Furthermore, the TAM survey results may suggest a greater likelihood of future use of the WCM tool, consistent with previous literature [14]. No association was observed between the level of interaction, education, and self-perceived skills in the technology when comparing these variables with TAM results (Table 2), which is informative of its high usability as scored consistently across diverse sets of users.

**Limitations**

Although these findings illustrate the capabilities of an advanced technology-based tool (WCM) in enhancing the care delivery processes within a county’s homeless population, the study is not without limitations. These findings focused only on one specific cohort of vulnerable, homeless individuals residing in a single county. We also did not objectively measure the impact of the tool on long-term client outcomes. Instead, the study examined the perceived and observed usability and effects on workflow from the perspectives of program leaders and hands-on users. We did not incorporate client perspectives in this study.

**Conclusions**

This mixed methods study provides a better understanding of the public health impact that social care management tools such as WCM may have on counties in need of care coordination. Future research investigating the impact of WCM on outcomes (eg, social, clinical, and economical) and the value of WCM for additional communities and diverse subpopulations is essential to build upon these existing findings.

**Acknowledgments**

The authors would like to acknowledge the work and dedication of Hannah Helmy, PhD; Linda Low; and Margaret Holly for their contribution to this research.

**Conflicts of Interest**

RR, CV, TB, MM, SA, DB, ML, JS, GJ, and WK are employees of IBM Watson Health.

---

**Multimedia Appendix 1**

Interview guide for Watson Care Manager users.

[PDF File (Adobe PDF File), 55 KB - jmir_v23i3e24122_app1.pdf ]
Multimedia Appendix 2
Interview guide for department leadership.

[PDF File (Adobe PDF File), 39 KB - jmir_v23i3e24122_app2.pdf]

Multimedia Appendix 3
Technology Acceptance Model.

[PDF File (Adobe PDF File), 29 KB - jmir_v23i3e24122_app3.pdf]

Multimedia Appendix 4
Top 10 frequently applied codes stemmed from the analysis of 3 sources of transcripts. ACCESS: Accessing Coordinated Care and Empowering Self-Sufficiency WCM: Watson Care Manager WPC: Whole Person Care.

[PNG File, 700 KB - jmir_v23i3e24122_app4.png]

References
5. Responding to Homelessness in Sonoma County, County of Sonoma, California. 2020. URL: https://sonomacounty.ca.gov/CAO/Homelessness/ [accessed 2020-03-01]

Abbreviations
ACCESS: Accessing Coordinated Care and Empowering Self-Sufficiency
CMCS: Care Management and Coordination System
IBM: International Business Machines
IMDT: interdepartmental multidisciplinary team
PEOU: perceived ease of use
PU: perceived usefulness
SC DHHS: Sonoma County Department of Health and Human Services
TAM: Technology Acceptance Model
WCM: Watson Care Manager
e-Mental Health Program Usage Patterns in Randomized Controlled Trials and in the General Public to Inform External Validity Considerations: Sample Groupings Using Cluster Analyses

Samineh Sanatkar1,2, PhD; Peter Baldwin1, MPsychol, PhD; Kit Huckvale1,2, PhD; Helen Christensen1, PhD; Samuel Harvey1, MBBS, MRCGP, MRCPsych, FRANZCP, PhD

1Black Dog Institute, The University of New South Wales Sydney, Randwick, Australia
2School of Psychiatry, The University of New South Wales Sydney, Randwick, Australia

Corresponding Author:
Samineh Sanatkar, PhD
Black Dog Institute
The University of New South Wales Sydney
Hospital Road
Randwick, 2031
Australia
Phone: 61 9382 4368
Email: s.sanatkar@unsw.edu.au

Abstract

Background: Randomized controlled trials (RCTs) with vigorous study designs are vital for determining the efficacy of treatments. Despite the high internal validity attributed to RCTs, external validity concerns limit the generalizability of results to the general population. Bias can be introduced, for example, when study participants who self-select into a trial are more motivated to comply with study conditions than are other individuals. These external validity considerations extend to e-mental health (eMH) research, especially when eMH tools are designed for public access and provide minimal or no supervision.

Objective: Clustering techniques were employed to identify engagement profiles of RCT participants and community users of a self-guided eMH program. This exploratory approach inspected actual, not theorized, RCT participant and community user engagement patterns. Both samples had access to the eMH program over the same time period and received identical usage recommendations on the eMH program website. The aim of this study is to help gauge expectations of similarities and differences in usage behaviors of an eMH tool across evaluation and naturalistic contexts.

Methods: Australian adults signed up to myCompass, a self-guided online treatment program created to reduce mild to moderate symptoms of negative emotions. They did so either by being part of an RCT onboarding (160/231, 69.6% female) or by accessing the program freely on the internet (5563/8391, 66.30% female) between October 2011 and October 2012. During registration, RCT participants and community users provided basic demographic information. Usage metrics (number of logins, trackings, and learning activities) were recorded by the system.

Results: Samples at sign-up differed significantly in age ($P=.003$), with community users being on average 3 years older (mean 41.78, SD 13.64) than RCT participants (mean 38.79, SD 10.73). Furthermore, frequency of program use was higher for RCT participants on all usage metrics compared to community users through the first 49 days after registration (all $P$ values <.001). Two-step cluster analyses revealed 3 user groups in the RCT sample (Nonstarters, 10-Timers, and 30+-Timers) and 2 user groups in the community samples (2-Timers and 20-Timers). Groups seemed comparable in patterns of use but differed in magnitude, with RCT participant usage groups showing more frequent engagement than community usage groups. Only the high-usage group among RCT participants approached myCompass usage recommendations.

Conclusions: Findings suggested that external validity concerns of RCT designs may arise with regards to the predicted magnitude of eMH program use rather than overall usage styles. Following up RCT nonstarters may help provide unique insights into why individuals choose not to engage with an eMH program despite generally being willing to participate in an eMH evaluation study. Overestimating frequency of engagement with eMH tools may have theoretical implications and potentially impact economic considerations for plans to disseminate these tools to the general public.

(J Med Internet Res 2021;23(3):e18348) doi:10.2196/18348
KEYWORDS

e-mental health; engagement patterns; external validity; randomized controlled trial; community sample

Introduction

Well-designed randomized controlled trials (RCTs) are widely seen as the gold standard for determining treatment efficacy as random assignment to either a treatment or control group allows for the isolation of the treatment effect from both known and unknown confounding factors [1]. Although the importance of RCTs in establishing internal validity is undisputed, researchers have pointed out the external validity concerns of RCTs [2]. These concerns relate to participant selection, attention, retention, researcher contact, and specifics and frequency of data collection—all of which can limit the generalizability of findings to the general public.

Such external validity considerations may be even more justified when considering those RCTs that evaluate e-mental health (eMH) programs, which are designed to deliver effective, scalable mental health care in the community [3-6]. For example, RCTs of eMH programs often selectively recruit from online communities [7] and provide a level of direction for adhering to usage recommendations (eg, reminders) that users in the general public will not encounter, particularly in self-guided eMH programs. These top-down practices affecting user attrition have been described as “push factors” [8]. RCT participants may also be particularly motivated to follow the research protocol and have researcher contact, which likely differs from how the general public experience an eMH program. Furthermore, deterministic approaches to evaluating eMH program effectiveness do not necessarily reflect the ever-changing eMH landscape [5]. As Sieverink and colleagues [9] pointed out, RCTs lack the ability to inform about processes (ie, how behavior evolves between the pre-, post-, and follow-up assessments) or which program components (or combination thereof) contribute to improvements in mental health outcomes. It is therefore pivotal for eMH interventions to show that the treatment effects initially shown in RCTs can translate into real-world benefits in practicable ways.

Despite the need for eMH programs to be applicable to real-world conditions, information on the external validity of eMH treatment outcomes is not widely available. In a recent systematic review of digital interventions addressing comorbid depressive symptoms and substance use, only 1 of the 6 studies examined reported on the comparability of the sample used to the wider population [10]. Similarly, in a review paper of mobile apps promoting physical activity, Blackman and colleagues [11] found that all mobile health intervention studies considered (N=20) reported on treatment effectiveness, but only 4 of these studies reported on how representative the study sample was for the target population.

This problem extends to eMH program design. A considerable body of research examining the effects of different eMH design features on behavioral changes has not addressed the question of how applicable these findings are once the programs are disseminated [3]. Although at least some studies address limitations to the generalization of eMH trial findings, studies examining how or if study protocols influence eMH engagement behaviors are rare. Arguably, whether or not a study protocol influences participant behavior constitutes another important factor in establishing the external validity of eMH findings [4].

One comparison between RCT and real-world uptake was undertaken with moodgym, an eMH program aimed at reducing anxiety and depression. It showed that public registrants were less likely than RCT participants to complete the recommended number of treatment modules [12]. Interestingly, however, symptom reductions over time were comparable between both RCT and community user groups, raising the question of whether a reduced protocol may yield similar benefits.

This short paper attempts to deepen the discussion on the influence of the RCT environment on eMH engagement behavior by presenting engagement patterns of RCT participants and community users of an eMH tool, called myCompass, side by side. Our aim is to explore whether patterns of program engagement differ between RCT participants who receive usage recommendations as part of being involved in an evaluation study versus users in the general community who receive the same usage recommendations only on the myCompass homepage. The goal of this paper is to examine engagement rather than outcomes; therefore, we are presenting cluster analysis findings that help visualize behavioral patterns rather than quantify differences in health and well-being.

Methods

Program Description

The present analyses are based on the first version of myCompass, an eMH program that was available to all Australians between 2011 and 2018. myCompass is hosted and run by the Black Dog Institute, and funded by the Australian Department of Health. Version 1 of this self-guided program offered online mental health resources and activities to address mild to moderate symptoms of depression, anxiety, and stress. Core functionalities of myCompass were the daily tracking and learning activities components. The tracking function allowed users to track up to 3 moods, behaviors, or cognitions (eg, sadness, alcohol consumption, worry) in real time. Users indicated their current states on an interval scale from low (0) to high (10). Another main function of myCompass was learning activities. Learning activities were set of 14 modules which aimed at aiding beneficial behaviors such as goal setting, sleep quality, or managing fear and anxiety. Each module was split into 2 to 3 sessions to promote skill-building exercises over the course of several days and took about 10 to 15 minutes to complete online.

Samples

Our study considered engagement data from 2 distinct samples: (1) an RCT participant sample and (2) a naturalistic community sample of general public users who freely adopted myCompass. All participants and users registered to version 1.0 of myCompass between October 2011 and October 2012. Trial
participants and community users freely registered either to the research study or directly to the myCompass website. Trial recruitment took place through multiple avenues, such as social media posts on Facebook and announcements on the Black Dog Institute volunteer research register [13], while the myCompass website could be found spontaneously through internet search engines. RCT participants and general public users received the same usage recommendations on the myCompass home page of completing at least 2 modules and using the tracking function once a day (see Figure 1). All users, independent of whether or not they were part of the research study, set the frequency of program use reminders in line with their own preferences on the myCompass website. However, only research participants were able contact research staff.

The RCT sample comprised 231 participants allocated to the eMH treatment group for the initial evaluation study of myCompass [13]. Exclusion criteria for entering the study were being younger than 18 or older than 75 years, not possessing an internet-enabled mobile phone, not having access to a computer with internet and email, and showing either minimal or severe symptoms of depression and anxiety as determined by symptom scores on the Depression Anxiety and Stress Scale [14].

The community sample comprised 8391 adults who registered for myCompass on their own accord. Community members needed to provide a valid email address and mobile phone number to verify their willingness to register to the program. As part of the profile setup within the myCompass program, RCT participants and community users alike completed assessments of common mental health symptoms, which formed the basis for tracking recommendations made by the program [13]. If scores indicated severe distress (ie, depression, anxiety, or a stress scores of 8 or higher out of 10) or suicidal ideation, the sign-up process was terminated and individuals were redirected to the Black Dog Institute website with information on how to seek immediate support.

Figure 1. Screenshot of myCompass homepage with usage recommendations.
Measurement of User Engagement
We selected 4 usage metrics to assess user engagement. These were number of logins, number of logged trackings (irrespective of how many items were tracked at any one time), number of learning activities started, and number of learning activities completed.

Statistical Analysis
All analyses were conducted in SPSS version 25 (IBM Corp). Participants using myCompass as part of the RCT and those in the community sample were initially compared using chi-square and t tests. We then conducted 2 two-step cluster analyses to determine distinct usage groups within the RCT participant and community user samples. A two-step cluster analysis allows for the detection of naturalistic (ie, not hypothesis-driven) groupings within a data set by way of examining distances between data points (step 1). Based on these distance calculations, an algorithm (step 2) determines the number of groupings or clusters for each data set. In the current analysis, we selected the log-likelihood distance measure and the Schwarz Bayesian information criterion statistic to determine the most appropriate number of clusters.

Results
Demographic Information
Data were available for 8622 users of myCompass. Table 1 shows the basic demographic information and online engagement behaviors of individuals taking part in the myCompass RCT and those signing up to myCompass via the program’s website. Although both groups had similar gender ratios (RCT: 160/231, 69.6% female; general public: 5563/8391, 66.3% female; P=.30), community users were on average 3 years older than RCT participants (P=.003). Notably, all average access and engagements statistics were higher for RCT participants than for general public users (all P values <.001).

Table 1. Mean, SD, and between-group statistics on demographic information and usage behavior through 49 days (N=8622).

<table>
<thead>
<tr>
<th>Variable</th>
<th>RCTa sample (n=231), mean (SD)</th>
<th>Community sample (n=8391), mean (SD)</th>
<th>F test</th>
<th>P values</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>38.79 (10.73)</td>
<td>41.78 (13.64)</td>
<td>9.07</td>
<td>.003</td>
<td>0.20</td>
</tr>
<tr>
<td>Female (%)</td>
<td>1.70 (0.46)</td>
<td>1.66 (0.47)</td>
<td>1.07b</td>
<td>.30</td>
<td>N/A</td>
</tr>
<tr>
<td>49-day logins (n)</td>
<td>11.26 (15.78)</td>
<td>3.90 (6.91)</td>
<td>229.21</td>
<td>&lt;.001</td>
<td>1.01</td>
</tr>
<tr>
<td>49-day trackings (n)</td>
<td>11.26 (10.42)</td>
<td>2.57 (5.95)</td>
<td>343.48</td>
<td>&lt;.001</td>
<td>1.24</td>
</tr>
<tr>
<td>49-day modc started (n)</td>
<td>1.14 (1.62)</td>
<td>0.53 (0.85)</td>
<td>113.81</td>
<td>&lt;.001</td>
<td>0.71</td>
</tr>
<tr>
<td>49-day mod completed (n)</td>
<td>1.02 (1.53)</td>
<td>0.12 (0.53)</td>
<td>555.85</td>
<td>&lt;.001</td>
<td>1.57</td>
</tr>
</tbody>
</table>

aRCT: randomized controlled trial.
bChi-square statistic.
cmod: modules.

Two-Step Cluster Analyses
A number of RCT participants allocated to the myCompass group did not proceed to register to myCompass (73/231, 31.6%) and therefore did not provide any engagement data. To make the RCT group more comparable to the general public sample (where each person registered to myCompass and provided engagement data), we removed these participants from the sample used for the cluster analysis. Table 2 shows the results of the cluster analysis among RCT participants who were allocated to myCompass for the duration of the 7-week intervention period. The cluster analysis yielded 2 distinct user groups among the RCT participants. Results of a multivariate analysis of variance confirmed significant cluster group differences on all 4 usage variables (all P values <.001; see Table 2), indicating that the clustering procedure was successful in establishing distinct user groups.

The first and larger user group (114/158, 72.2%) were “10-Timers” who logged into their assigned program around 9 times (mean 8.84, SE 2.01) and used myCompass mainly for tracking (mean 7.77, SE 1.83) rather than completing learning activities (mean 0.23, SE 0.21). The second user group (44/158, 27.8%) were “30+-Timers”, who logged into myCompass every other day (mean 36.20, SE 1.71). When the 30+-Timers logged on, they used the program’s tracking function (mean 34.59, SE 1.56) in addition to starting and completing around three learning activities (modules started: mean 3.36, SE 0.19; modules completed: mean 2.67, SE 0.18) over the course of 7 weeks.
Table 2. Cluster analysis groupings of 158 myCompass randomized controlled trial participants’ usage behaviors and multivariate analysis of variance testing of the significant difference between clusters.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Nonstarters (n=73), mean (SE)</th>
<th>10-Timers (n=114), mean (SE)</th>
<th>30+-Timers (n=44), mean (SE)</th>
<th>F test (1, 156)</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>38.79 (10.73)a</td>
<td>37.08 (10.71)</td>
<td>41.40 (8.09)</td>
<td>5.82</td>
<td>.02</td>
</tr>
<tr>
<td>Female (%)</td>
<td>1.70 (0.46)a</td>
<td>1.70 (0.46)</td>
<td>1.66 (0.48)</td>
<td>0.24</td>
<td>.62</td>
</tr>
<tr>
<td>Logins (n)</td>
<td>N/A</td>
<td>8.84 (2.01)</td>
<td>36.20 (1.71)</td>
<td>184.53</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Trackings (n)</td>
<td>N/A</td>
<td>7.77 (1.83)</td>
<td>34.59 (1.56)</td>
<td>214.73</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Modules started (n)</td>
<td>N/A</td>
<td>0.77 (0.22)</td>
<td>3.36 (0.19)</td>
<td>145.22</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Modules completed</td>
<td>N/A</td>
<td>0.23 (0.21)</td>
<td>2.67 (0.18)</td>
<td>156.73</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Table 3 presents the results of the cluster analysis in the general public. Similar to findings among RCT participants, the community sample cluster analysis yielded 2 distinct clusters that differed across all usage variables (all P values <.001). The vast majority of general public users (7681/8391, 91.54%) were “2-Timers” or individuals who entered myCompass approximately twice (mean 2.25, SE 0.17) and used the tracking function once (mean 1.13, SE 0.14). The average module completion near zero in this group (mean 0.03, SE 0.02).

Table 3. Cluster analysis groupings of 8391 myCompass general public users usage behaviors and multivariate analysis of variance testing of the significant difference between clusters.

<table>
<thead>
<tr>
<th>Variables</th>
<th>2-Timers (n=7681), mean (SE)</th>
<th>20-Timers (n=710), mean (SE)</th>
<th>F test (1, 8389)</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>41.70 (13.67)</td>
<td>42.83 (13.33)</td>
<td>4.59</td>
<td>.03</td>
</tr>
<tr>
<td>Female (%)</td>
<td>1.66 (0.47)</td>
<td>1.67 (0.47)</td>
<td>0.08</td>
<td>.78</td>
</tr>
<tr>
<td>Logins (n)</td>
<td>2.25 (0.17)</td>
<td>21.82 (0.16)</td>
<td>13803.55</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Trackings (n)</td>
<td>1.13 (0.14)</td>
<td>18.06 (0.14)</td>
<td>14057.60</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Modules started (n)</td>
<td>0.40 (0.03)</td>
<td>1.98 (0.03)</td>
<td>3145.51</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Modules completed</td>
<td>0.03 (0.02)</td>
<td>1.07 (0.02)</td>
<td>3670.39</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Discussion

This paper presents findings on individual usage behaviors for an Australian eMH tool, either as part of an RCT or as an open-access tool freely adopted by the general public. Exploratory findings reveal that the same number of usage groups emerged in both data sets: a large “lower-intensity” usage group and a smaller “higher-intensity” usage group. However, our findings revealed interesting differences between the 2 data sets that warrant consideration. First, the general community group tended to be older than the RCT group and overall used the eMH program significantly less frequently based on all usage metrics. Of further note, a considerable number of individuals registered to myCompass directly and were not part of the research trial. This could be because participation in a research study is more time intensive, as research volunteers are required to complete psychometric measures in addition to using the eMH tool. It is also possible that only a relatively smaller number of individuals were exposed to the research trial recruitment calls, while a greater number of interested individuals were able to discover the myCompass website using internet search engines.

Second, although the cluster analytical findings revealed 2 behavioral groups across both samples, the magnitude of usage was higher in the RCT sample for both usage groups. For example, the low-usage group in the RCT logged in an average of 9 times, while the low-usage group in the general community logged in only about twice on average. The high-usage group in the RCT sample was, again, not only higher in magnitude (about 35 logins on average as opposed to about 20 logins in the general community), but also proportionally bigger than that in the community sample. Specifically, 27.8% (44/158) of RCT users were identified as frequent users (30+-Timers), whereas only 8.46% (710/8391) of general public users were identified as such (20-Timers). Accordingly, the 30+-Timers RCT group completed the recommended 2 or more learning activities and came closest to the tracking recommendations of 49 logged trackings, whereas the 20-Timers community sample group clearly did not meet the tracking or learning activity recommendations. Thus, only the high-usage RCT group could...
be described as “adhering” to the learning activity recommendations, and no group adhered to the tracking recommendations.

Our findings add weight to Cavanagh’s [4] concerns about external validity in eMH trials, suggesting that inferences about real-world engagement from RCT data should be made with caution. Although sample composition and usage patterns were comparable between the RCT and general community users, generalizing from the RCT sample would have overestimated the magnitude of real-world program engagement. One potential reason for this could be the differing motivation for eMH adoption. In our study, RCT participants seemed to be more motivated to use the eMH program and to use the core functionalities more consistently than were users in the general public. It is possible that, beyond the willingness to participate in mental health research, the aims stated in the Participant Information Statement inadvertently attracted individuals who were interested in the topic of eMH and therefore more motivated to engage with an eMH tool in general and with the activities recommended to them in particular. On the other side of the behavioral spectrum, we uncovered a unique set of participants in the RCT population who were willing to participate in the RCT but did not proceed to register to the online mental health tool (ie, Nonstarters). These participants were not representative of the community population because they did not encounter the eMH tool at all.

Our study is unique in that we contrasted RCT and general public behavioral patterns for the same eMH program during the same time period, maximizing the comparability of users’ eMH experience while minimizing the influence of historical factors. However, some limitations of our analyses warrant consideration. First, our analytic techniques only allowed for a limited number of engagement variables, but many other variables, such as the number of tracking reminders a user sets, could have provided us with a more detailed picture of eMH engagement behavior. Second, we were only able to study those users who actually engaged with the core functionalities of the program repeatedly; therefore, our findings largely reflect individuals motivated to adopt an eMH program. Third, the data reported in this paper were collected between 2011 and 2012 and certainly would have made a timelier contribution then.

Technological advances since this time include improvements in interface design and user experience features, such as chatbots, gamification, and virtual reality [15,16]. However, these relatively more high-tech solutions have yet to be fully integrated into the digital mental health landscape [16]. Thus, we believe that the general knowledge and discussion derived from this analysis, which inspected usage behaviors along common metrics such as logins, module usage, and mood monitoring, still bears relevance today. Fourth, the observed effect may be limited in scope. It is possible that the findings presented in this paper only apply to unguided eMH interventions. Usage patterns may differ for eMH programs that provide therapist assistance, which generally facilitates engagement [17]. Last, we did not examine the significance of differences observed across samples. This short paper focused on eMH engagement rather than outcomes, as our goal for this study was to reignite a discussion of the real-world applicability of eMH engagement data derived from RCT findings.

In summary, our findings suggest that eMH engagement in RCTs likely matches the type of eMH engagement in real-world users, but may overestimate the magnitude of such engagement. This could be an important consideration for eMH researchers, designers, and policy makers, as they implement eMH tools after efficacy is established. We recommend that future eMH trials examine whether participant selection and per protocol instructions affect usage behavior, and if so, that due consideration be given to this in implementation planning. Similarly, those planning a wide-scale rollout of new eMH tools should consider which aspects of the original trial may help in promoting usage and whether similar methods can be used in the real world. Ecological validity in eMH engagement science is also relevant to theoretical investigations of how eMH tools improve individuals’ well-being. Mechanisms of change established in RCTs must be practicable in the real world for eMH to deliver on its promise of effective and scalable mental health care. Ultimately, the goal of improving eMH engagement science is to set realistic expectations of eMH benefits—both health and economic—and understand how to maximize these. The more accurately we can speak to eMH engagement, the more fruitful both eMH science and policy will be going forward.

**Conflicts of Interest**

None declared.

Multimedia Appendix 1
Supplementary figures.

[DOCX File, 81 KB - jmir_v23i3e18348_app1.docx ]

**References**


Abbreviations

eMH: e-mental health
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 20.02.20; peer-reviewed by K Mathiasen, B Lo; comments to author 23.06.20; revised version received 30.09.20; accepted 11.12.20; published 11.03.21.

Please cite as:
Sanatkar S, Baldwin P, Huckvale K, Christensen H, Harvey S

e-Mental Health Program Usage Patterns in Randomized Controlled Trials and in the General Public to Inform External Validity Considerations: Sample Groupings Using Cluster Analyses

J Med Internet Res 2021;23(3):e18348
URL: https://www.jmir.org/2021/3/e18348
doi:10.2196/jmir.22745
PMID:33704070
Commencement of and Retention in Web-Based Interventions and Response to Prompts and Reminders: Longitudinal Observational Study Based on Two Randomized Controlled Trials

Athanasios Andriopoulos1, MSc; Erik M G Olsson1*, PhD; Ylva Hägg Sylvén1, MSc; Jonas Sjöström2, PhD; Birgitta Johansson3, PhD; Louise von Essen1, PhD; Helena Grönqvist1, PhD

1Department of Women’s and Children’s Health, Uppsala University, Uppsala, Sweden
2Department of Informatics and Media, Uppsala University, Visby, Sweden
3Immunology, Genetics and Pathology, Uppsala University, Uppsala, Sweden
*these authors contributed equally

Corresponding Author:
Helena Grönqvist, PhD
Department of Women’s and Children’s Health
Uppsala University
Akademiska sjukhuset
Uppsala, 75185
Sweden
Phone: 46 736236500
Email: helena.gronqvist@khh.uu.se

Abstract

Background: Web-based interventions are effective for several psychological problems. However, recruitment, adherence, and missing data are challenges when evaluating these interventions.

Objective: This study aimed to describe the use patterns during the commencement phase, possible retention patterns (continuation of data provision), and responses to prompts and reminders among participants in 2 randomized controlled trials (RCTs) evaluating web-based interventions.

Methods: Data on use patterns logged in 2 RCTs aiming to reduce symptoms of anxiety and depression among adult patients recently diagnosed with cancer (AdultCan RCT) and patients with a recent myocardial infarction (Heart RCT) were analyzed. The web-based intervention in the AdultCan trial consisted of unguided self-help and psychoeducation and that in the Heart trial consisted of therapist-supported cognitive behavioral therapy. In total, 2360 participants’ use patterns at first log-in, including data collection at baseline (ie, commencement) and at 2 follow-ups, were analyzed. Both the intervention and comparison groups were analyzed.

Results: At commencement, 70.85% (909/1283) and 86.82% (935/1077) of the participants in AdultCan and Heart RCTs, respectively, logged in and completed baseline data collection after receiving a welcome email with log-in credentials. The median duration of the first log-in was 44 minutes and 38 minutes in AdultCan and Heart RCTs, respectively. Slightly less than half of the participants’ first log-ins were completed outside standard office hours. More than 80% (92/114 and 103/111) of the participants in both trials explored the intervention within 2 weeks of being randomized to the treatment group, with a median duration of 7 minutes and 47 minutes in AdultCan and Heart RCTs, respectively. There was a significant association between intervention exploration time during the first 2 weeks and retention in the Heart trial but not in the AdultCan trial. However, the control group was most likely to retain and provide complete follow-up data. Across the 3 time points of data collection explored in this study, the proportion of participants responding to all questionnaires within 1 week from the prompt, without a reminder, varied between 35.45% (413/1165) and 86.82% (935/1077). After 2 reminders, up to 97.6% (165/169) of the participants responded.

Conclusions: Most participants in both RCTs completed the baseline questionnaires within 1 week of receiving the welcome email. Approximately half of them answered questions at baseline data collection outside office hours, suggesting that the time flexibility inherent in web-based interventions contributes to commencement and use. In contrast to what was expected, the intervention groups generally had lower completion rates than the comparison groups. About half of the participants completed the questionnaires without a reminder, but thereafter, reminders contributed to both baseline and follow-up retention, suggesting
they were effective. Strategies to increase commencement of and retention in eHealth interventions are important for the future development of effective interventions and relevant research.

*(J Med Internet Res 2021;23(3):e24590) doi:10.2196/24590*

**KEYWORDS**
log data analysis; use pattern; retention; dropout; attrition; online intervention; online data

**Introduction**

**Background**

Web-based interventions are efficient for mental health problems such as symptoms of anxiety, depression, and posttraumatic stress [1-4], with effects lasting up to 3 years after treatment [5-7]. However, studies evaluating web-based interventions struggle with low use, where some participants never log in or commence the intervention at all [8,9] and where retention rates, that is, the continuation of participant data provision, vary between 17% and 98% [10-13]. The problem of low retention has been continuously reported in relation to web-based interventions and research and has even been discussed in terms of the law of attrition [13]. Although this problem is not unique to eHealth, the complexity of the field makes attrition almost inevitable, and it is thus important to highlight, measure, and discuss its determinants to be able to improve future eHealth interventions and research, for example, regarding usability, efficacy, and increased acceptability [13]. Disease severity [14], symptoms of anxiety [15], technical issues, lack of motivation, time constraints, the complexity of the intervention, low expectations of its efficacy, compatibility with participants’ profiles, and current needs [13,16] have been reported by participants as reasons for noncommencement and low retention [8,17-21]. Demographic variables such as younger age, higher level of education, and female gender are often associated with increased retention in web-based intervention studies [22].

In web-based intervention trials, it is possible to track participants’ activities in the intervention by logging use patterns with high precision, including recording every click a participant makes on the web-based platform when working with the intervention and answering questionnaires [23]. Automatized and standardized reminders via emails or text messages are often used to support retention at low cost and with minimal effort [12]. Previous findings indicate that the majority of participants in randomized controlled trials (RCTs) evaluating a web-based intervention perceived reminders as harmless, well accepted, and useful, but the effectiveness of reminders in increasing retention in this type of intervention has seldom been evaluated systematically [24,25]. Log data could be valuable for analyzing the patients’ use patterns in web-based interventions and their overall utility [26,27].

**Aim and Research Questions**

The overall aim of this study is to describe use patterns of participants in 2 RCTs evaluating web-based interventions aimed at reducing symptoms of anxiety and depression in adult patients with cancer (AdultCan trial [28]) and patients who recently had a myocardial infarction (Heart trial [8]) when (1) logging in to the portal for the first time for completing baseline questionnaires (ie, commencement), (2) completing questionnaires at the first and second follow-ups (ie, retention), and (3) responding to prompts and reminders to fill in questionnaires (ie, responses).

**Research Questions Regarding Commencement**

The research questions regarding commencement were as follows:

- How many potential participants completed the baseline questionnaires and how many left it incomplete?
- Was there a difference in sex or age between those who completed the baseline questionnaires and those who did not?
- How many days after invitation did the participants complete the baseline questionnaires and how many logged in more than once before completing them?
- How long did it take to complete the baseline questionnaires and at what time of the day were the questionnaires completed?

**Research Questions Regarding Retention**

The research questions regarding retention were as follows:

- How long did the participants explore the intervention after randomization and how many completed follow-up 1 and follow-up 2?
- Was there a difference between those allocated to treatment versus those not regarding completion of follow-up questionnaires?
- Was there an association between exploring activity during the first 2 weeks and completion of follow-up questionnaires?

**Research Questions Regarding Prompts and Reminders**

The research questions regarding prompts and reminders were as follows:

- How many participants completed questionnaires at follow-up 1 and 2, respectively, after being prompted to do so, and how many responded to questionnaires at follow-ups 1 and 2, respectively, after being reminded one or two times?

**Methods**

**Design**

The study had a longitudinal and descriptive correlational design and used secondary data analysis. The primary analysis of the efficacy of the interventions has been reported elsewhere [8,28].
Setting

The Uppsala University Psychosocial Care (U-CARE) program has the overarching goal of promoting psychosocial health among patients struck by somatic diseases and their significant others [23].

The 2 RCTs explored in this study, AdultCan [28] and Heart [8], were conducted via the U-CARE portal (hereafter, portal), a secure web portal developed within U-CARE.

In the AdultCan trial, a stepped-care (consisting of 2 steps) web-based intervention was evaluated. The first step, available for 24 months for each participant, consisted of information, psychoeducation, and self-help material including texts, video lectures, discussion forums, and the possibility for participants to ask questions about cancer and its treatment and get answers from experts. Participants still reported anxiety and depression after access to the first step, and after 1, 4, or 7 months, they were offered a second step consisting of 10 weeks of therapist-supported internet-based cognitive behavioral therapy (iCBT) [28]. Log data collected via the portal during the first step of the intervention were analyzed in this study.

In the Heart trial, a web-based intervention consisting of 14 weeks of therapist-supported iCBT, including self-help material, homework assignments, web-based contact with a therapist, and peer support via a discussion forum, was evaluated. The intervention included 10 modules, for example, behavioral activation, cognitive restructuring, exposure, and problem solving. Participants could choose which modules to work with and receive weekly therapist support [8].

Participants

Log data from 1283 participants in the AdultCan trial and 1077 participants in the Heart trial were analyzed. In the AdultCan trial, the inclusion criteria were patients with newly (within 6 months) diagnosed breast, prostate, or colorectal cancer as well as patients with recurrence of colorectal cancer (within 6 months of diagnosis) at 3 hospitals in Sweden. Exclusion criteria were inability to read and understand Swedish, cognitive disability (eg, dementia or psychosis), a constant need for care (Karnofsky score<40), short expected survival (<3 months), severe depression or suicide risk with regard to answers on the Montgomery-Åsberg Depression Rating Scale-Self-Report (MADRS-S) measure, and participation in a competing clinical trial including prostate cancer patients receiving radiotherapy.

In the Heart trial, inclusion criteria were >7 on one or both of the Hospital Anxiety and Depression Scale (HADS) subscales. Exclusion criteria were scheduled for coronary artery bypass surgery; inability to use a computer, internet, email, or mobile phone; unable to read Swedish; expected to live <1 year; anticipated to show poor compliance (eg, substance abuse); self-reported severe depression or suicidal ideation; MADRS-S item 9>3; and participation in another behavioral intervention trial. Detailed information about the methods used in the AdultCan and Heart RCTs is provided elsewhere [8,28]. In this study, participants who provided informed consent and were added to the portal were considered as participants.

Procedure

In both studies, participants who self-reported symptoms of anxiety and/or depression above the cut-off >7 on any of the subscales of the HADS were randomized to either the treatment group or the control group. In the AdultCan trial, those scoring below the cut-off on both subscales were assigned to a reference group that was followed longitudinally. Details of the procedure at commencement and data collection in the AdultCan and Heart trials are presented in Table 1.
Log data from the full duration of the AdultCan and Heart trials.

Data and Data Collection

Log data refers to records of real-time actions performed by each user, and mouse clicks and keyboard strokes are logged as user actions with time stamps. In this study, log data at commencement, during the 2-week period following commencement, and at 2 consecutive follow-up time points within the RCTs AdultCan [28] and Heart [8] were collected via the secure portal developed within U-CARE.

Variables

The variables used to answer the research questions are presented in Table 2.

Table 1. The procedure at commencement and follow-up data collection in AdultCan and Heart trials.

<table>
<thead>
<tr>
<th>Phase, Studies</th>
<th>AdultCan trial</th>
<th>Heart trial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commencement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Eligible persons were informed about the study at a regular hospital visit or by telephone within 6 months after being diagnosed with cancer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• After providing written informed consent, participants received a welcome email with log-in credentials to the portal for baseline questionnaires.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Participants were informed that if all baseline questions were not answered within 24 h, they would have to restart from scratch.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If participants did not complete the 14 baseline questionnaires within 7 days, they received a reminder via SMS and email.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If participants did not complete the baseline questionnaires within 14 days, they received a second reminder via SMS and email.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If participants had still not completed the baseline questionnaires 30 days after the prompt, study personnel contacted them, if possible, by telephone and reminded them to respond to the questionnaires.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Participants scoring above the cut-off on HADS were randomized to the treatment or control group in the portal. The log-in session where a participant is randomized is called the “randomization session.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Participants scoring below the cut-off were assigned to the reference group and were asked to answer questionnaires at selected time points.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Participants randomized to the treatment group got immediate access to the first step of the intervention via the portal.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Retention, prompts, and reminders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Follow-up 1: 2 weeks after randomization, participants were asked to complete 1 (control group) or 2 (treatment group) questionnaires.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Follow-up 2: 1 month after randomization, participants were asked to complete 4 (reference group), 8 (control group), or 10 (treatment group) questionnaires.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• At follow-up 1 and 2 participants were prompted via email and SMS to log in and complete the questionnaires.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If participants did not complete the questionnaires within 7 days after the prompt, they received a first reminder via SMS and email.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If participants did not complete the questionnaires within 12 days after the prompt, they received a second reminder via SMS and email.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aHADS: Hospital Anxiety and Depression Scale.

bMI: myocardial infarction.

Participants logged in to the portal with double authentication, entering username, personal password, and a temporary 5-digit code that they received in an SMS. A log-in session ended when a participant logged out of the portal or was inactive for more than 20 minutes.

In the Heart trial, at the second reminder, participants were offered to use paper forms to answer questionnaires at follow-up 1 and 2, which 27 and 46 participants did at the 2 follow-ups, respectively. Thus, the web-based completion rate is only a part of the total completion rate in the Heart trial.

Data and Data Collection

Log data from the full duration of the AdultCan and Heart trials were collected from April 16, 2013, to April 28, 2017, and were exported from the portal by a system developer. The data were reviewed by a second system developer. In addition, the researchers performed random checks and reviewed any inconsistencies.

Log data refers to records of real-time actions performed by each user, and mouse clicks and keyboard strokes are logged as user actions with time stamps. In this study, log data at commencement, during the 2-week period following commencement, and at 2 consecutive follow-up time points within the RCTs AdultCan [28] and Heart [8] were collected via the secure portal developed within U-CARE.
Table 2. Variables used in the study.

<table>
<thead>
<tr>
<th>Phase and study variables measured</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Commencement</strong></td>
<td></td>
</tr>
<tr>
<td>Participant commencing answering questionnaires at baseline</td>
<td>y/n</td>
</tr>
<tr>
<td>Participant completing answering questionnaires at baseline</td>
<td>y/n</td>
</tr>
<tr>
<td>Time from the welcome email sent from the portal with log-in credentials to participant’s first log-in</td>
<td>d,h:</td>
</tr>
<tr>
<td>Duration of participant first log-in</td>
<td>min:s</td>
</tr>
<tr>
<td>Time of the day when the participant first logged in</td>
<td>h:min</td>
</tr>
<tr>
<td>Day of week when the participant first logged in</td>
<td>Mo-Su</td>
</tr>
<tr>
<td>Whether the participant’s first log-in ended with a click by the participant on the log-out button or if the participant was automatically logged out after being inactive (passive log-out)</td>
<td>y/n</td>
</tr>
<tr>
<td><strong>Retention</strong></td>
<td></td>
</tr>
<tr>
<td>Participant explored the intervention in randomization session (treatment group only)</td>
<td>y/n</td>
</tr>
<tr>
<td>Participant explored the intervention within 14 days after randomization (treatment group only)</td>
<td>y/n</td>
</tr>
<tr>
<td>Length of time the participant explored the intervention within 14 days after randomization (treatment group only)</td>
<td>min:s</td>
</tr>
<tr>
<td>Participant completed all questionnaires at follow-up 1 and 2</td>
<td>y/n</td>
</tr>
<tr>
<td><strong>Response to prompts and reminders</strong></td>
<td></td>
</tr>
<tr>
<td>Number of prompts and/or reminders sent to participants at the 3 data collection time points</td>
<td>0-2</td>
</tr>
</tbody>
</table>

a y/n: yes or no.
b d: day.
c Mo-Su: Monday to Sunday.

The following portal activities were defined as exploring the intervention: any click in the library, forum, chat, diary, FAQ, ask an expert, using the internal message system, and the iCBT program.

Self-reported demographical data were collected at baseline.

**Missing Data**

Missing data were mostly because messages, such as prompts and reminders, from the portal were not logged properly, as a result of a temporary technical error in the early phase after launching the studies. The welcome emails with log-in credentials were erroneously logged for 5 and 7 participants in the respective studies, and reminders to log in to the portal to answer questionnaires at baseline were erroneously or insufficiently logged for 118 and 50 participants from the AdultCan and Heart RCTs, respectively, with missing data as a result. The corresponding figures for the first follow-up were 76 and 19, and for the second follow-up, 112 and 18. In the Heart trial, 68, 24, and 42 participants were not reached by telephone for reminders at baseline, first, and second follow-up, respectively. The country of birth was not reported by one participant. When investigating exploration, 10 participants in the AdultCan trial and 7 in the Heart trial had missing data.

**Statistical Analysis**

Descriptive statistics were used to examine and report all variables. Medians were used when the frequency distributions were skewed. Pearson chi-square test was used to examine potential differences between the numbers of participants exploring the intervention among participants who completed the baseline (completers) and those who did not complete the baseline (noncompleters) in the respective study groups. The Mann-Whitney U-test was used to examine potential associations between time used to explore the intervention and if participants completed the data collections in the respective studies. Actual P values are reported. All analyses were based on complete data, that is, no imputations were performed.

Data were analyzed using IBM SPSS Statistics V25.0 and STATA v 15.1.

**Results**

**Patient Characteristics**

Participants in the AdultCan and Heart trials who completed baseline questionnaires had a mean age of 61 years (SD 10.6) and 62 years (SD 8.1), respectively, and at least 90.29% (1665/1844) were born in Sweden, and more than 44.74% (825/1844) had some university education. In the AdultCan trial, the proportion of female participants was more than double that in the Heart trial (for more details, Table 3).
Table 3. Characteristics and commencement data of participants.

<table>
<thead>
<tr>
<th>Characteristics and commencement data</th>
<th>AdultCan trial</th>
<th>Heart trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Completed BL questionnaire (n=909)</td>
<td>Did not complete BL questionnaire (n=374)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>61.3 (11)</td>
<td>62.5 (11)</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>N/A</td>
<td>846 (90.5)</td>
</tr>
<tr>
<td>Born in Sweden, n (%)</td>
<td>819 (90.1)</td>
<td>N/A</td>
</tr>
<tr>
<td>Highest level of education, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary school</td>
<td>184 (20.2)</td>
<td>N/A</td>
</tr>
<tr>
<td>High school</td>
<td>296 (32.6)</td>
<td>N/A</td>
</tr>
<tr>
<td>University ≤3 years</td>
<td>193 (21.2)</td>
<td>N/A</td>
</tr>
<tr>
<td>University &gt;3 years</td>
<td>236 (26.0)</td>
<td>N/A</td>
</tr>
<tr>
<td>Study group, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference group</td>
<td>664 (72.9)</td>
<td>N/A</td>
</tr>
<tr>
<td>Control group</td>
<td>121 (13.3)</td>
<td>N/A</td>
</tr>
<tr>
<td>Treatment group</td>
<td>124 (13.6)</td>
<td>N/A</td>
</tr>
<tr>
<td>Log-ins for noncompleters BL questionnaire, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1 log-ins</td>
<td>N/A</td>
<td>83 (22.2)</td>
</tr>
<tr>
<td>No log-ins</td>
<td>N/A</td>
<td>291 (77.8)</td>
</tr>
<tr>
<td>Time to first log-in (d:h:min), median (range)</td>
<td>6:11:59 (0:00:01-59:04:44)</td>
<td>N/A</td>
</tr>
<tr>
<td>First log-in duration (min:s), median (range)</td>
<td>44:08 (00:31-180:06)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

aBL: baseline.
bN/A: not applicable

Commencement

A total of 70.85% (909/1283) of participants in the AdultCan trial and 86.82% (935/1077) of participants in the Heart trial completed all questionnaires at baseline (Table 3). Moreover, 6.47% (83/1283) of the participants in the AdultCan trial did not complete all baseline questionnaires after being logged in at least once, and 22.68% (291/1283) of participants did not log in at all. In the Heart trial, these numbers were approximately half (Table 3). The median response time, from receiving the welcome email to the first log-in, was slightly more than 6 days in the AdultCan trial and almost 4 days in the Heart trial. Of those who completed all questionnaires at baseline, 73.0% (664/909) in the AdultCan trial and 74.4% (696/935) in the Heart trial were allocated to the reference group and not randomized. The median duration of the first log-in, from the first to the last click, was 44 minutes and 38 minutes for the AdultCan and Heart trials, respectively. At baseline, 54.3% (494/909) of the participants in the AdultCan trial and 35.8% (335/935) of the participants in the Heart trial logged out of the portal by a click. No differences in age or gender were found between participants who completed the baseline questionnaires and those who did not.

The times when the participants logged in for the first time are illustrated in Figure 1. In the AdultCan trial, 54.8% (498/909) of the first-time log-ins were on weekdays between 8 AM and 5 PM, representing normal office hours. The corresponding figure for the Heart trial was 52.2% (488/935).
Retention

A total of 73.7% (84/114) of those randomized to treatment in the AdultCan trial and 70.3% (78/111) of those in the Heart trial explored the intervention within the session when they completed baseline questionnaires and were randomized to the treatment group. Thereafter, within a 14 day-period after randomization, separate from the randomization session, 29.8% (34/114) of the participants in the AdultCan trial and 72.1% (80/111) of the participants in the Heart trial explored the intervention at least once. The median total time participants were exploring the intervention during the first 14 days after randomization was 7 minutes for the AdultCan trial and 47 minutes for the Heart trial (Table 4). Figure 2 provides a detailed description of the distribution of total time spent exploring the intervention.

Table 4. Number of participants in the treatment group exploring the intervention within 14 days after randomization and their time spent on exploring.

<table>
<thead>
<tr>
<th>Measures of exploration</th>
<th>AdultCan trial (n=144)</th>
<th>Heart trial (n=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exploring the intervention, n (%)</td>
<td>92 (80.7)</td>
<td>103 (92.8)</td>
</tr>
<tr>
<td>Total time spent exploring the intervention (min:s), median (range)</td>
<td>6:58 (00:01-461:40)</td>
<td>47:14 (00:22-486:06)</td>
</tr>
</tbody>
</table>

Figure 2. Total time spent in exploring the intervention within 14 days after randomization by number of participants in the treatment group in AdultCan and Heart trials.
Overall, the questionnaires were completed using the web-based platform by 44%-85% of the participants in the different study groups (treatment, control, and reference group) at the 2 follow-ups (Table 5). In the Heart trial, more participants in the control group compared with the treatment group completed the questionnaires using the web-based platform both at follow-up 1 and follow-up 2. No differences between the groups were found in the AdultCan trial at follow-up 1, but at follow-up 2, the reference group completed the questionnaires the most and the treatment group the least (Table 5).

Table 5. Web-based completion rates for the follow-ups for the AdultCan and Heart trials.

<table>
<thead>
<tr>
<th>Follow-up completion</th>
<th>AdultCan trial</th>
<th>Heart trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference, n (n=112), n (%)</td>
<td>Control (n=111), n (%)</td>
</tr>
<tr>
<td>Completing FU1</td>
<td>N/A c</td>
<td>82 (67.7)</td>
</tr>
<tr>
<td>Completing FU2</td>
<td>558 (84)</td>
<td>94 (77.7)</td>
</tr>
</tbody>
</table>

aP values from chi-square tests.
bFU: follow-up.
cN/A: not applicable.

When combining total exploration time, the first 14 days with retention, completing follow-up 1 and follow-up 2 were positively associated with the exploration time for the first 14 days after randomization in the Heart trial but not with any of the follow-ups in the AdultCan trial (Table 6). When dividing participants in the Heart trial into an active and a passive treatment group, based on a median split in exploration time (median 47 minutes and 14 seconds), 55% (30/55) in the passive treatment group compared with 80% (45/56) in the active group and 85.2% (104/122) in the control group completed follow-up 1. At follow-up 2, the corresponding figures were 31% (17/55), 55% (31/56), and 62.3% (96/122).

Table 6. Total time exploring the intervention during the first 14 days cross-tabled with completion of follow-up measures.

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>AdultCan trial</th>
<th>Heart trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Completed web-based follow-up</td>
<td>Did not complete web-based follow-up</td>
</tr>
<tr>
<td>Follow-up 1</td>
<td>75 (66)</td>
<td>39 (34)</td>
</tr>
<tr>
<td>n (%)</td>
<td>Total time spent exploring the intervention (min:s), median (range)</td>
<td>6:35 (00:01-461:40)</td>
</tr>
<tr>
<td>Follow-up 2</td>
<td>83 (73)</td>
<td>31 (27)</td>
</tr>
<tr>
<td>n (%)</td>
<td>Total time spent exploring the intervention (min:s), median (range)</td>
<td>7:34 (00:01-461:40)</td>
</tr>
</tbody>
</table>

aDiff.: difference in median times between those who completed web-based follow-ups and those who did not.
bP values from Mann-Whitney U-tests.

Response to Prompts and Reminders

Across the 3 data collection time points explored in this study, the proportion of participants responding within 7 days from the prompt without a reminder was between 36% and 66%. Within 5 days of the first reminder, sent out via SMS and email, an additional 40%-86% of the remaining participants responded.

In the AdultCan trial, the second reminder, sent via SMS and email, generated between 36% and 50% additional responses from the remaining participants. In the Heart trial, the second reminder, via telephone, generated 34%-69% additional responses among those who had not responded so far (Table 7).
Discussion

Principal Findings

The results show that at commencement, most recruited and consenting participants logged in and completed the baseline questionnaires. Most nonresponders did not log in at all. In contrast to previous studies [29] that have indicated that age and gender are related to attrition, no difference in gender or age was found between the participants who finished baseline and those who did not. This may be partly because of age heterogeneity. Fewer participants in the AdultCan trial than those in the Heart trial completed the baseline questionnaires. This could have many reasons, such as recruitment procedure, intervention type, disease severity, and so on. Most participants in the AdultCan trial were undergoing active cancer treatment at the time of inclusion, whereas the focus of participants in the Heart trial was on secondary prevention. Most participants who completed the baseline questionnaires completed the questionnaire within 1 week of receiving the welcome email with log-in credentials from the portal.

One argument for using web-based interventions is that they can be accessed at any time. Although most participants had their first log-in on weekdays and during the day, 45%-48% of the participants chose to commence the studies outside common office hours when face-to-face psychological support is usually not offered. The log-in times were similar in the 2 studies regarding time of day and day of the week and also similar to what has been reported in other studies [30]. It is known that the time of day and the day of week people prefer to answer surveys are related to sociodemographic and health characteristics [31]. As internet interventions are flexible in time, they may be able to reach patients in need at convenient times.

Most participants opened at least one item of the intervention directly after being randomized to treatment. Furthermore, in the Heart trial, 72% of the participants explored the intervention in separate sessions during the following 14 days. This was more than that in the AdultCan trial. Median time logged in during the first 14 days was also longer in the Heart trial than in the AdultCan trial. This was expected owing to the intervention formats, as the Heart trial was a therapist-supported iCBT intervention, whereas the AdultCan trial offered self-help psychoeducation without individual support during the first 2 weeks examined in this study. In addition, therapist-supported iCBT was restricted to 10 weeks, whereas self-help psychoeducation in the AdultCan trial was available for 24 months. However, the overall intervention use over the first 2 weeks was relatively low. Persuasive features such as feedback have been suggested to increase use [32] and were available in the Heart intervention. However, the participants had to log in without any specific prompts to notice the feedback.

Most participants (66%-85%) were retained in the studies and answered the follow-up questionnaires. When comparing completion rates between the study groups, the control group in the Heart trial had a higher rate than that in the treatment group at both follow-ups. A similar pattern was evident in the AdultCan trial at follow-up 2, where the reference group had the highest completion rate and the treatment group the lowest. Although the more active treatment participants in the Heart study also had a higher completion rate than those who were less active, the active participants were still less likely to complete the follow-ups than the control group. This was an unexpected finding. It may be that participants felt obliged to contribute to a certain amount and that those participating in the intervention thought they had filled their quota even before the follow-up questionnaires. To the best of our knowledge, there are no previous systematically summarized studies reflecting on such patterns.

Prompts and reminders for completing questionnaires were sent via SMS and email. Most participants answered the questionnaires after the prompt without any reminders. However, the following 2 consecutive reminders were useful in increasing the response rates, not only when executed via telephone calls but also via SMS and email. The results are in line with previous research showing that reminders contribute to the overall response rate [33] and that participants find reminders acceptable and useful [25]. In the Heart trial, participants were offered paper forms as a secondary response alternative at the second reminder, which should be considered when interpreting the sometimes very low retention rates.

Table 7. Responses to reminders at baseline and the 2 follow-ups.

<table>
<thead>
<tr>
<th>Time of response</th>
<th>AdultCan</th>
<th>FU1*1</th>
<th>FU2</th>
<th>Heart</th>
<th>FU1</th>
<th>FU2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n (%)</td>
<td>N</td>
<td>n (%)</td>
<td>N</td>
<td>n (%)</td>
</tr>
<tr>
<td>Response after prompt, n (% of all)</td>
<td>1165</td>
<td>413 (35.5)</td>
<td>169</td>
<td>112 (66.2)</td>
<td>797</td>
<td>442 (55.5)</td>
</tr>
<tr>
<td>Response to the first reminder, n (% of remaining)</td>
<td>752</td>
<td>299 (39.8)</td>
<td>57</td>
<td>49 (86.0)</td>
<td>355</td>
<td>151 (42.5)</td>
</tr>
<tr>
<td>Response to the second reminder, n (% of remaining)</td>
<td>453</td>
<td>162 (35.8)</td>
<td>8</td>
<td>4 (50.0)</td>
<td>204</td>
<td>99 (48.5)</td>
</tr>
<tr>
<td>No response, n (% of all)</td>
<td>1165</td>
<td>291 (25.0)</td>
<td>169</td>
<td>4 (2.4)</td>
<td>797</td>
<td>105 (13.2)</td>
</tr>
</tbody>
</table>

*FU: follow-up.
Strengths and Limitations

The log data collected for this study allowed for a unique possibility of exploring these aspects that are important for the success of web-based interventions. Using participants in 2 web-based intervention studies gave us a large sample size of 2360 participants. There are several differences between the studies, making them difficult to compare; hence, they are described as separate cases with few comparisons. However, the results were similar, and the 2 cases provided cumulative information for the exploration of use patterns. Another strength is that both studies recruited clinically and consecutively, resulting in a sample from all patients, not only self-selected highly motivated participants in web-based interventions. We believe that a more detailed log data on participants’ use patterns could improve the development of future web-based interventions.

The second reminder at follow-up 1 and 2 in the Heart trial was made by telephone. To maximize responses, participants were offered to answer the questionnaire by pen and paper if they were reluctant to log in and answer via the portal. However, as this study focuses on use patterns, the questionnaires filled in by pen and paper answers were not considered. However, they have been reported in the Heart main study outcomes [8].

All data were logged using the portal. Researchers decided what to log beforehand but did not influence the data during data collection. There are some missing data, especially regarding reminders, and the data were not logged properly when the study commenced. However, the quality of the data extracted and analyzed in this study was high and reliable.

Conclusions

Although use patterns differed slightly between the 2 studies, some general conclusions can be drawn. Most people who consented to participate in the study commenced by completing the baseline questionnaires within 1 week. Although many participants answered the questionnaires on the portal during office hours, approximately half of them did so during the weekend or in the evenings, suggesting that flexibility contributes to commencement and use. Participants in the study treatment groups tended to have lower completion rates for the follow-up questionnaires than those in the control or reference groups. This unexpected finding would be interesting for further investigations. Reminders were important to improve the completion rate of questionnaires at baseline and at follow-up. A second reminder was effective in increasing the completion rate. To summarize, our results show that log data provide a rich source of information for a better understanding of use patterns in web-based intervention and retention in eHealth trials. We found that commencement and retention are related to, among other things, flexibility, study design features, and reminders. Our results not only largely support previous findings but also indicate some unexpected user patterns to be investigated further. Refined logging and complementary interviews could potentially provide an even better understanding of these behavioral patterns. As we learn more about users’ detailed behaviors, we need improved intervention design and data collection that use the strengths and weaknesses of the internet format.

Acknowledgments

This study was funded by the Swedish Research Council for the strategic research program U-CARE. The funder was not involved in the review or approval of the manuscript.

Conflicts of Interest

None declared.

References


Abbreviations

HADS: Hospital Anxiety and Depression Scale
iCBT: internet-based cognitive behavioral therapy
MADRS-S: Montgomery-Åsberg Depression Rating Scale-Self-Report
RCT: randomized controlled trial

©Athanasios Andriopoulos, Erik M G Olsson, Ylva Hägg Sylvén, Jonas Sjöström, Birgitta Johansson, Louise von Essen, Helena Grönqvist. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 12.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Classification of the Use of Online Health Information Channels and Variation in Motivations for Channel Selection: Cross-sectional Survey

Di Zhang¹, PhD; Zhen Shi¹, MSc; Hongchao Hu¹, MA; Gang (Kevin) Han², PhD

¹The Research Center of Journalism and Social Development, Renmin University of China, Beijing, China
²Greenlee School Journalism and Communication, Iowa State University, Ames, IA, United States

Corresponding Author:
Gang (Kevin) Han, PhD
Greenlee School Journalism and Communication
Iowa State University
119 Hamilton
613 Wallace Rd
Ames, IA, 50011-4010
United States
Phone: 1 515 294 0482
Email: ghan@iastate.edu

Abstract

Background: Existing health education and communication research routinely measures online channel use as a whole by, for example, evaluating how frequently people use the internet to search for health information. This approach fails to capture the complexity and diversity of online channel use in health information seeking. The measurement of generic online channel use may cause too much error, and it lends no support to media planning in public health promotion campaigns or scholarly research involving online channel use.

Objective: This study intends to present a thorough picture of patterns of online health information channel use and classify the use of various types of online health information channels, including WeChat, microblogs, web portals, search engines, mobile apps, and online forums. Under the framework of the risk information seeking and processing model, this study also analyzes the differences in individuals’ motivations for channel selection to offer further evidence to validate the classification scheme.

Methods: This study sampled 542 Chinese internet users in Beijing. The average age of the respondents was 33 years, female respondents accounted for 52.0% (282/542) of the sample, and the average monthly income ranged from US $900 to $1200. The study surveyed the use of 13 commonly used online health information channels and various sociopsychological factors associated with online health information seeking.

Results: This study derived 3 categories of online health information channels: searching, browsing, and scanning channels. It was found that the use of online searching channels was affect driven ($B=0.11; \beta=0.10; P=.02$) and characterized by a stronger need for health knowledge ($B=0.09; \beta=0.01; P<.001$). The use of browsing channels was directly influenced by informational subjective norms ($B=0.33; \beta=0.15; P=.004$) and perceived current knowledge ($B=0.007; \beta=0.09; P=.003$). The use of scanning channels was mainly influenced by informational subjective norms ($B=0.29; \beta=0.15; P=.007$).

Conclusions: The results of this study suggest that health communication practitioners and scholars may consider measuring the use of internet, new media, or online media more precisely instead of simply asking the public about the frequency of online channel use or internet use in the acquisition of health information. Scholars and practitioners may consider measuring the use of online health information channels by using the 3-category scheme described in this study. Future research is encouraged to further explore how people process health information when using different online channels.

(J Med Internet Res 2021;23(3):e24945) doi:10.2196/24945

KEYWORDS
search; browse; scan; health information seeking; channel selection; health information; health education; health communication; online media

https://www.jmir.org/2021/3/e24945 J Med Internet Res 2021 | vol. 23 | iss. 3 | e24945 | p.384 (page number not for citation purposes)
Introduction

Background

People across the globe increasingly name online channels as one of their top choices when acquiring health information and knowledge [1], which accordingly attracts scholarly attention. Most existing studies treat online channels as a whole by, for example, evaluating how frequently people use the internet to search for health information [2,3]. In this study, online health information channels refer to online communication media and applications that collect health information and knowledge from sources, repackage them, and then distribute them to people [4]. However, terms such as “new media,” “online media,” and “internet” are very generic. Treating the internet as a whole does not reflect the complexity and diversity in the use of online health information channels [5]. Therefore, the first goal of this study is to survey the use of various types of online health information channels, thus presenting a more nuanced picture of the use of online health information channels.

In addition to describing the channel use frequencies, the second goal is to classify the use of various online health information channels into different categories from the perspective of information-seeking behaviors, which differs from the existing division method. When there is a need to analyze online channels separately, health communication researchers routinely divide online health information channels into news portals (such as news websites and health websites) and social media, as in the case of the Health Information National Trends Survey. This classification scheme is based on the differences in the diversity of content creators, platform structure, and connections between users [6], which is inherently the perspective of the platform designers and operators rather than the users. However, this perspective is increasingly incompatible with consumer-centered health communication campaign design, which assumes that satisfying individual needs is the key to effective campaigns [7]. In the era of the internet, it is more noticeable that individuals select communication channels to meet their felt needs [8]. Given that individual needs drive different styles of information-seeking behaviors, such as searching, browsing, and scanning [9,10], the development of an information-seeking, behavior-based channel classification scheme can be potentially more helpful for contemporary health communication researchers and practitioners, who would be able to use fewer measurement items while increasing the validity of the measurement in both academic and formative research of health information acquisition behavior. For instance, web portals can apply to both browsing and scanning, so web portals fall into both categories in this study. From what has been discussed above, the following research question was proposed: What are the patterns of online health information channel use?

Third, this study examines the factors associated with online health information channel selection under the framework of the risk information seeking and processing (RISP) model, which depicts the various sociopsychological factors behind information seeking and processing [12]. The results of the study can contribute to the literature on RISP by explaining the variance in channel selection, which is a crucial part of information seeking that is underexplored [13].

Literature Review

Classification of Online Channel Use and Health Information–Seeking Behaviors

With the rise of the internet and mobile phones, people in countries like the United States and China frequently search for health information on the internet [14,15]. Additionally, evidence collected in multiple countries revealed that people who search for health information use various types of online channels, such as search engines, health web portals, social networking sites, and online support groups [14,16,17]. This study intended to pinpoint the underlying patterns by classifying the use of online health information channels into clusters based on health information acquisition behaviors, which differs from the existing division method from the perspective of platform designers and operators. Current research on health information seeking suggests 3 types of behaviors: searching, browsing, and scanning [9,10]. People acquire health information mainly through 2 routes, active seeking and scanning [9]. Active seeking refers to an intentional process of acquiring health information, which implies more active efforts in health information seeking [9,18]. Research in library and information science and health informatics implies that active seeking can be further divided into searching and browsing, which vary in the degree of specificity of information seeking [19]. In health information, searching, which is directed, refers to users searching the internet for answers related to specific diseases or symptoms [10,20]. Browsing, which is undirected and motivated by curiosity, refers to users browsing health information without the intent to acquire knowledge about specific diseases or symptoms, consuming health information regularly and habitually, and following the structure and layout of information prepared by the publisher of the website or account [10,20]. In contrast, scanning is defined as a process in which people both encounter health information or knowledge while engaged in tasks unrelated to health and make a decision to process it [9], which is an effort less active than active seeking [21].

Different channel types can fulfill different information-seeking strategies because of the interface designs and functionalities of these channels [11]. According to interviews before data collection, people generally use a specific online channel to engage in the primary information acquisition activity. However, one particular channel can be suitable for more than one type of health information acquisition behavior. For instance, web portals can apply to both browsing and scanning, so web portals fall into both categories in this study. From what has been discussed above, the following research question was proposed: What are the patterns of online health information channel use?

Health Information Channel Selection and RISP

As opposed to many existing channel choice studies that emphasize the influences of channel characteristics (eg, ease of use, interactivity, privacy, and media scale) [22,23], this study explains the channel choice using an audience-centered approach because channel use depends on audience needs, particularly their psychological needs [4,24,25]. Specifically, the study used RISP as the theoretical model, which combines theories such
as the heuristic-systematic model and the theory of planned behavior [12,26-29]. RISP was chosen for two other reasons. First, RISP has often been applied in the context of health risks, such as environmental health [30], vaccines [31], and clinical trial enrollment [32]. Second, channel choice can reflect different combinations of information-seeking and processing strategies, two major dependent variables in RISP. Different types of online health information channel use vary in information-seeking strategies (route [nonactive] vs nonroutine [active]) [11,33] and may result in differences in information processing (heuristic vs systematic) [12]. In RISP, a combination of the 4 attributes in information seeking and processing results in a fourfold typology: (1) routine (ie, habitual, ritual) seeking with heuristic processing, (2) routine seeking with systematic processing, (3) nonroutine seeking with heuristic processing, and (4) nonroutine seeking with systematic processing [12]. In reference to the abovementioned conceptual definitions of browsing, searching, and scanning, channel choice based on information-seeking strategies may represent different combinations of information-seeking and processing strategies, thus making RISP an ideal theoretical framework. For instance, searching (active but directed) is similar to nonroutine seeking with systematic processing.

RISP studies primarily focus on the following key predictor variables: information insufficiency, informational subjective norms, perceived hazard characteristics, affective responses, relevant channel beliefs, and perceived information-gathering capacities. Figure 1 shows the conceptual model consisting of predictor and outcome variables.

**Figure 1.** Conceptual model. The lines between current knowledge and negative affect and information sufficiency threshold were added for the purpose of statistical control. Thus, these lines are unmarked. H: hypothesis.

Information insufficiency refers to the perceived cognitive need for additional information, which is the perception of a gap between one’s existing knowledge and a level of knowledge sufficient to handle risks confidently (information sufficiency threshold) [12,33]. Previous studies confirm that information insufficiency leads to active information seeking and systematic processing [34,35]. Additionally, perceived knowledge is essentially the complement to the sufficiency threshold link for purposes of assessing regressed change and difference scores; RISP meta-analyses and marketing research suggest that current knowledge accounts for a substantial amount of variance in information seeking [36] and systematic processing [37-39]. Since previous RISP studies did not directly examine channel choice, 2 sets of hypotheses without directions were proposed for the 2 variables:

- **H1:** Controlling for current knowledge, the information sufficiency threshold is related to the use of searching sites (H1a), browsing sites (H1b), and scanning sites (H1c).
- **H2:** Current knowledge is related to the use of searching sites (H2a), browsing sites (H2b), and scanning sites (H2c).

Perceived information-gathering capacity refers to one’s perceived abilities to acquire and process risk-related information [26,29,33], which is positively associated with current knowledge and information seeking [30,40]. Motivated by information insufficiency or pressure from social norms to seek information, people may need confidence that they are able to perform information-seeking tasks [41]. Thus, the following were proposed:

- **H3:** Current knowledge is positively associated with perceived information-gathering capacity.
H4: Perceived information-gathering capacity is related to the use of searching sites (H4a), browsing sites (H4b), and scanning sites (H4c).

Perceived hazard characteristics are one’s cognitive evaluation of the nature of hazards [33]. Perceived hazard characteristics include personal control, trust in risk management, perceived threats to personal values, and risk judgment [12,33]. However, this study focused on the perceived probability of contracting a disease (short for perceived risk afterwards) because most people are unlikely to have serious diseases. Previous RISP studies have found that risk judgment can potentially increase the level of negative affect [12,41,42], which further contributes to more information seeking and processing via one’s information insufficiency level or directly [40]. Thus, the following were proposed:

H5: Perceived risks are positively associated with negative affect.

Affective responses are induced by risk perception and can lead to a higher level of information insufficiency [12]. Negative affect was found to influence information-seeking behaviors directly [40]. Thus, the following were proposed:

H6: Negative affect is positively associated with the information insufficiency threshold.

H7: Negative affect is related to the use of searching sites (H7a), browsing sites (H7b), and scanning sites (H7c).

Informational subjective norms are the perceived socioenvironmental influence on an individual’s subjective assessment of information held to handle a given risk and motivation to seek and process information [33]. Informational subjective norms consist of two dimensions, injunctive and descriptive [35], which have been found to influence information seeking [36,43]. Thus, the following were proposed:

H8: Informational subjective norms are positively associated with the information sufficiency threshold (H8a) and current knowledge (H8b).

H9: Informational subjective norms are related to the use of searching sites (H9a), browsing sites (H9b), and scanning sites (H9c).

Relevant channel beliefs refer to people’s beliefs about channels that carry risk-related information, including their trustworthiness and usefulness, that could influence information seeking and processing either as a main effect or as a moderator [12,33]. Thus, the following was proposed:

H10: Relevant channel beliefs are related to the use of searching sites (H10a), browsing sites (H10b), and scanning sites (H10c).

Sample
This study used survey data collected in 2015 because, according to the surveys by the China Internet Network Information Center in 2015 and 2020, penetration rates of major new media applications related to this study (search engines, news applications, and mobile communication apps, including WeChat and microblogs) did not change much between 2015 and 2020. The survey targeted residents in Beijing because Beijing had China’s highest internet penetration rate in 2015, at 76.5% [44], which partially excludes the problem of the physical digital divide. Given its vibrant internet activities and high economic level (including gross domestic product per capita), which is comparable to developed countries, the choice of Beijing residents as the sample renders the results useful for scholars in Western countries such as the United States, where most health communication studies take place.

The researchers hired Sojump, a Chinese online panel company, to collect the data because this study only focused on internet users, which allowed the researchers to remove those without internet access and thus the problem of the digital divide. This study used quota sampling to draw participants, which is common for online panel surveys [45]. The quota sampling scheme used age group and gender as the criteria in designing subgroups (an equal number of respondents in the 8 subgroups). Age in this study was divided into the categories of 18 to 25 years, 26 to 30 years, 31 to 40 years, and 41 years and older. The researchers oversampled people older than 30 years because that age is positively related to perception of health risks, which may elicit health information seeking. In the panel, 170,000 participants were from Beijing. For this study, Sojump randomly sent survey invitations in September 2015 to 9500 people within the panel who were registered and confirmed as from Beijing. The researchers oversampled people older than 30 years because that age is positively related to perception of health risks, which may elicit health information seeking. In the panel, 170,000 participants were from Beijing. For this study, Sojump randomly sent survey invitations in September 2015 to 9500 people within the panel who were registered and confirmed as from Beijing. The data collection process lasted for 10 days and resulted in a sample size of 542. The average age of the respondents was 33 years old, female respondents accounted for 52.0% (282/542) of the sample, and the average monthly income ranged from US $900 to $1200.

Dependent Variables
The outcome variable was the extent to which an individual uses a particular online channel to obtain health information, and this was measured on a 7-point scale. According to preliminary in-depth interviews with Chinese health communication practitioners and users, the researchers pinpointed 9 types of commonly used online health information channels. Given that one channel can be suitable for more than one type of information acquisition behavior, the researchers measured the frequencies of 13 types of online health information channel use (Table 1).
Table 1. Descriptive statistics of online channel use in Beijing, China (N=542).

<table>
<thead>
<tr>
<th>Category and online health information channels</th>
<th>Mean^a (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Browsing channels^b</strong></td>
<td></td>
</tr>
<tr>
<td>WeChat© official accounts (ie, health-related official accounts, similar to Facebook pages)</td>
<td>4.58 (1.92)</td>
</tr>
<tr>
<td>Microblogs (ie, health microblogs, similar to Twitter)</td>
<td>4.22 (2.05)</td>
</tr>
<tr>
<td>Web portals (ie, health section, similar to Yahoo)</td>
<td>3.85 (1.91)</td>
</tr>
<tr>
<td>Online professional health sites (similar to WebMD)</td>
<td>3.72 (1.98)</td>
</tr>
<tr>
<td>Mobile phone health apps</td>
<td>3.67 (2.05)</td>
</tr>
<tr>
<td>Online forums (ie, forums related to a particular disease or health problem)</td>
<td>3.61 (2.02)</td>
</tr>
<tr>
<td><strong>Searching channels^b</strong></td>
<td></td>
</tr>
<tr>
<td>Search engines</td>
<td>5.29 (1.64)</td>
</tr>
<tr>
<td>Online encyclopedia sites</td>
<td>4.61 (1.84)</td>
</tr>
<tr>
<td>Question-and-answer sites</td>
<td>4.51 (1.85)</td>
</tr>
<tr>
<td><strong>Scanning channels^d</strong></td>
<td></td>
</tr>
<tr>
<td>WeChat Moments (similar to Facebook News Feed)</td>
<td>5.12 (1.66)</td>
</tr>
<tr>
<td>Web portals (ie, nonhealth sections)</td>
<td>4.52 (1.67)</td>
</tr>
<tr>
<td>Microblogs (ie, nonhealth microblogs)</td>
<td>4.38 (1.81)</td>
</tr>
<tr>
<td>Online forums (ie, nonhealth forums)</td>
<td>4.06 (1.82)</td>
</tr>
</tbody>
</table>

^aScale of 1 to 7: 1=never, 7=very often.

^bBrowsing channels and searching channels are the channels for active seeking.

^cWeChat is China’s largest mobile messenger service and its functionality is similar to Facebook.

^dScanning channels are the channels for incidental exposure, passive exposure, and routine seeking.

When wording the question items, the researchers took into account whether a channel was for active seeking or incidental exposure (scanning). For active-seeking channels, the survey participant was asked, “Over the past year, to what extent have you used the following channel to acquire information or knowledge related to generic health, disease prevention/treatment and healthy living?” [9]. For scanning channels, the survey participant was asked “Over the past year, to what extent did you accidently pay attention to information or knowledge related to generic health, disease prevention/treatment and healthy living while engaged in media tasks other than health information search?” [9]. As shown in Table 1, search engines (active) and WeChat Moments (incidental exposure, similar to Facebook News Feed) were the 2 most frequently used channels (search engines: mean 5.29, SD 1.64; WeChat Moments: mean 5.12, SD 1.66). Online health forums and mobile health apps were the 2 least used channels (health forums: mean 3.61, SD 2.02; health apps: mean 3.67, SD 2.05).

**Predictor Latent Variables**

This study measured 7 RISP predictors. Table 2 lists specific survey question items and their descriptive statistics.
Table 2. Descriptive statistics of RISP predictor variables (N=542).

<table>
<thead>
<tr>
<th>Variables and questions</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information insufficiency</strong>a (1-100 scale)</td>
<td></td>
</tr>
<tr>
<td>Perceived current health knowledge:</td>
<td>59.88 (17.13)</td>
</tr>
<tr>
<td>Estimate your knowledge of health, with 1=knowing nothing and 100=knowing everything you could possibly know about health maintenance.</td>
<td></td>
</tr>
<tr>
<td>Sufficiency threshold:</td>
<td>73.27 (20.56)</td>
</tr>
<tr>
<td>This time, using that same scale, estimate how much knowledge you think you need on health maintenance.</td>
<td></td>
</tr>
<tr>
<td>**Information subjective norms (1-5 scale)**b</td>
<td></td>
</tr>
<tr>
<td><strong>Injunctive:</strong></td>
<td></td>
</tr>
<tr>
<td>My family expects me to seek health knowledge.</td>
<td>3.78 (0.88)</td>
</tr>
<tr>
<td>My friends expect me to seek health knowledge.</td>
<td>3.62 (0.94)</td>
</tr>
<tr>
<td><strong>Descriptive:</strong></td>
<td></td>
</tr>
<tr>
<td>People in my life whose opinions I value seek health knowledge.</td>
<td>3.53 (0.86)</td>
</tr>
<tr>
<td><strong>Perceived risk</strong>c (1-5 scale)</td>
<td></td>
</tr>
<tr>
<td>My health may face problems in the next year.</td>
<td>2.51 (1.09)</td>
</tr>
<tr>
<td>In the next year, I may possibly suffer from diseases that may impact my job or life.</td>
<td>2.44 (1.18)</td>
</tr>
<tr>
<td>In the next year, I am confident about my health (reverse coding).</td>
<td>2.20 (0.97)</td>
</tr>
<tr>
<td><strong>Negative affect</strong>d (1-5 scale)</td>
<td></td>
</tr>
<tr>
<td>How much of the following do you feel about your health?</td>
<td>3.11 (1.05)</td>
</tr>
<tr>
<td>Not worried…Very worried</td>
<td></td>
</tr>
<tr>
<td>How much of the following do you feel about your health?</td>
<td>2.71 (1.14)</td>
</tr>
<tr>
<td>Not anxious…Very anxious</td>
<td></td>
</tr>
<tr>
<td><strong>Relevant channel beliefs</strong>e (1-5 scale)</td>
<td></td>
</tr>
<tr>
<td>To what extent do you trust health information on web portals?</td>
<td>3.53 (0.74)</td>
</tr>
<tr>
<td>To what extent do you trust health information on social media?</td>
<td>3.46 (0.82)</td>
</tr>
<tr>
<td>To what extent do you trust health information on mobile phone apps?</td>
<td>3.45 (0.92)</td>
</tr>
<tr>
<td><strong>Perceived information-gathering capacities</strong>f (1-5 scale)</td>
<td></td>
</tr>
<tr>
<td>It is difficult to find health knowledge (reverse coding).</td>
<td>3.39 (1.06)</td>
</tr>
<tr>
<td>I don’t know where to find health knowledge (reverse coding).</td>
<td>3.37 (1.07)</td>
</tr>
<tr>
<td>I have a hard time understanding health knowledge (reverse coding).</td>
<td>3.38 (1.23)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>33.01 (9.19)</td>
</tr>
<tr>
<td><strong>Gender (female), %</strong></td>
<td>52.0 (——)</td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td>3.76 (1.51)</td>
</tr>
</tbody>
</table>

aIn the questionnaire, the item “current knowledge” was presented first, followed by the item “sufficiency threshold.”
bα=.70.
cα=.81.
dα=.79.
eα=.61.
fα=.82.

Information insufficiency was assessed using 2 items: perceived current health knowledge and information sufficiency threshold [12]. In the analysis, information insufficiency’s influence on health information seeking was evaluated by modeling the information sufficiency threshold when controlling for the self-assessment of current health knowledge.

Informational subjective norms included injunctive and descriptive norms [35]. The former refers to important others’
attitudes toward one’s behaviors, while the latter refers to important others’ behaviors. A total of 3 items were used.

Perceived risks evaluated one’s self-assessed probability of suffering from diseases or encountering health problems, which is consistent with previous RISP research [36]. This construct consisted of 3 items with a 5-point scale.

Negative affect assessed one’s negative feeling related to their health status [36]. It consisted of 2 items.

Relevant channel beliefs evaluated one’s belief that online channels are capable of supplying trustworthy information [35]. In this study, the 3 items specifically tapped into the dimension of trust, since Chinese online media are often criticized for containing misinformation related to health.

Perceived information-gathering capacities assessed one’s belief that they are capable of accessing and understanding health information [35]. Three 5-point items were used to measure this concept.

### Results

#### Overview

The researchers analyzed the data using structural equation modeling techniques. Initially, the researchers reduced the use of 13 online channels into 3 groups of variables, which were used as endogenous variables [32]. Then, the structural model was built. The lavaan package in R was used to test hypotheses.

#### Measurement Model

Three measurement models were constructed and compared (Multimedia Appendix 1 illustrates the specific measurement model–building procedures). The third measurement model had the best model fit (Table 3). The third measurement model classified the 13 channel use variables into 3 groups: browsing, searching, and scanning channels. Additionally, the third measurement model correlated the error terms of 6 pairs of variables of channel use that have moderate to high levels of correlation due to shared technical platforms (Multimedia Appendix 2). For instance, people who prefer health sections of web portals are likely to have the habit of using web portals, which raises their chances of encountering health messages when using web portals for tasks unrelated to health.

<table>
<thead>
<tr>
<th>Model</th>
<th>Chi-square (df)</th>
<th>$\chi^2/df$</th>
<th>RMSEA(^b)</th>
<th>CFI(^c)</th>
<th>SRMR(^d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measurement model</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model 1: Baseline (2-factor)(^e)</td>
<td>1149.1 (303)</td>
<td>3.79</td>
<td>0.072</td>
<td>0.86</td>
<td>0.059</td>
</tr>
<tr>
<td>Model 2. Revised (3-factor)(^f)</td>
<td>904.8 (296)</td>
<td>3.06</td>
<td>0.062</td>
<td>0.90</td>
<td>0.052</td>
</tr>
<tr>
<td>Model 3: Revised + correlated error</td>
<td>638.0 (290)</td>
<td>2.20</td>
<td>0.047</td>
<td>0.94</td>
<td>0.049</td>
</tr>
<tr>
<td><strong>Structural model</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model 1: Baseline conceptual</td>
<td>923.0 (343)</td>
<td>2.69</td>
<td>0.056</td>
<td>0.91</td>
<td>0.081</td>
</tr>
<tr>
<td>Model 2: Revised</td>
<td>931.7 (351)</td>
<td>2.65</td>
<td>0.055</td>
<td>0.91</td>
<td>0.083</td>
</tr>
</tbody>
</table>

\(^a\) Recommended cutoff points for model fit indices [46-48]: SRMR of <0.08; RMSEA of <0.08; CFI of >0.90 (ideally CFI of ≥0.95); $\chi^2/df$ of <3. Hu and Bentler [47] suggest a 2-index presentation strategy, recommending a RMSEA of 0.06 or lower and a SRMR of 0.09 or lower.

\(^b\) RMSEA: root mean square error of approximation.

\(^c\) CFI: comparative fit index.

\(^d\) SRMR: standardized root mean residual.

\(^e\) 2-factor: active seeking and scanning channels.

\(^f\) 3-factor: browsing, searching, and scanning channels.

The results from the measurement model suggested that the use of online health information channels can be divided into 3 categories: browsing, searching, and scanning channels (Table 1). Browsing channels consist of health sections of web portals ($B=1.00; \beta=0.72; P<.001$), professional health sites ($B=1.01; \beta=0.70; P<.001$), microblogs ($B=1.01; \beta=0.67; P<.001$), WeChat official accounts ($B=0.91; \beta=0.64; P<.001$), mobile health apps ($B=1.08; \beta=0.73; P<.001$), and online forums ($B=1.09; \beta=0.75; P<.001$).

Searching channels include search engines ($B=1.00; \beta=0.65; P<.001$), search engines ($B=1.35; \beta=0.79; P<.001$), and question-and-answer sites ($B=1.35; \beta=0.78; P<.001$).

Scanning channels encompass incidental exposure to health information on web portals ($B=1.00; \beta=0.73; P<.001$), microblogs ($B=1.02; \beta=0.69; P<.001$), WeChat Moments ($B=0.68; \beta=0.50; P<.001$), WeChat Moments ($B=1.14; \beta=0.76; P<.001$), and online forums ($B=1.14; \beta=0.76; P<.001$).

#### Structural Model

The bottom of Table 3 presents the model fit indices for the structural model. Two structural models, conceptual and revised (removing the nonsignificant paths), were compared. The popular model fit indices were roughly the same. The revised model (Figure 2) was retained, since the likelihood test suggested that the 2 competing models were not significantly

https://www.jmir.org/2021/3/e24945
different ($\Delta \chi^2 = 8.7, \ P = .37$). Figure 2 presents test results of H1 to H10.

H1 examined the extent to which the information sufficiency threshold was associated with online channel choice. According to the results, the information sufficiency threshold was positively associated only with the use of the online searching channel ($B = 0.09; \ \beta = 0.01; \ P < .001$) and was negatively related to the use of online browsing channels ($B = -0.004; \ \beta = -0.064; \ P = .03$). H1a and H1b were supported. However, the information sufficiency threshold was not related to the use of scanning channels, and H1c was not supported. H2 analyzed in what way current knowledge was related to online channel selection. It was found that current knowledge was only positively associated with the use of online browsing channels ($B = 0.007; \ \beta = 0.09; \ P = .003$), not searching (H2a) and scanning (H2c) channels. Thus, only H2b was supported.

H3 examined the positive association between current knowledge level and perceived information-gathering capacities and was supported ($B = 0.01; \ \beta = 0.19; \ P < .001$). H4 examined the relationship between perceived information-gathering capacities and online channel selection. It was found that perceived information-gathering capacities had negative associations with online scanning channel use ($B = -0.39; \ \beta = -0.26; \ P < .001$). Thus, H4b was supported. Conversely, perceived information was not related to the use of online searching and browsing channels, and H4a and H4b were not supported.

H5 predicted the positive association of perceived risks with negative affect, and it was supported ($B = 0.44; \ \beta = 0.43; \ P < .001$).

H6 predicted that negative affect would be positively associated with the information sufficiency threshold. However, this was not supported. H7 examined the extent to which negative affect was associated with channel choice. The results suggested that negative affect was positively associated only with online searching channel use ($B = 0.11; \ \beta = 0.10; \ P = .02$) and not the use of the other 2 types of online channels. Thus, only H7a was supported.

H8a and H8b tested the positive relationship between informational subjective norms and the information sufficiency threshold and current knowledge, both of which were supported. The results suggested that informational subjective norms were positively associated with the information sufficiency threshold ($B = 7.58; \ \beta = 0.23; \ P < .001$) (H8a) and current knowledge ($B = 4.95; \ \beta = 0.18; \ P < .001$) (H8b). H9 examined the relationship between informational subjective norms and online channel selection. The results revealed that informational subjective norms were directly related to online browsing ($B = 0.33; \ \beta = 0.15; \ P = .004$) (H9b) and scanning channels ($B = 0.29; \ \beta = 0.15; \ P = .007$) (H9c). However, informational subjective norms did not have a direct association with the use of searching channels (H9a).

H10 tested whether relevant channel beliefs were related to online channel use, which was supported. Additionally, the sizes of the coefficients were roughly the same (for searching channels [H10a]: $B = 1.28; \ \beta = 0.58; \ P < .001$; for browsing channels [H10b]: $B = 1.79; \ \beta = 0.63; \ P < .001$; for scanning channels [H10c]: $B = 1.66; \ \beta = 0.66; \ P < .001$).

**Figure 2.** Revised model. The numbers in parentheses are standardized coefficients and the numbers preceding the parentheses are unstandardized coefficients.
Discussion

Overview
This study described how people in Beijing, China, use online channels to acquire health information. The results suggested that the 13 commonly used online health information channels can be divided into 3 categories: browsing, searching, and scanning channels (Table 1). These were also corroborated by the underlying motivational mechanism.

Diverse Use of Online Health Information Channels
This study found that Chinese people use online health information channels to different extents. Along with search engines, China’s largest messenger service, WeChat (WeChat Moments, a type of scanning channel), was reported as one of the 2 most frequently used channels. Other frequently used channels included WeChat official accounts (similar to Facebook pages), online encyclopedia sites, question-and-answer sites, microblogs (browsing and scanning), and web portals (scanning). The descriptive statistics clearly show that although search engines were the most frequently used, the importance of social media in online health information acquisition in China outweighs that of the channels run by institutions, which is in line with previous studies that found that people in East Asia prefer social media when seeking health information [17].

Patterns of Online Health Information Channel Use
The confirmatory factor analysis further revealed that the use of online health information channels can be classified into 3 categories. From the perspective of the theory of channel complementarity [8], the variable clustering pattern may hint that people use different online channels with similar functions complementarily to obtain health information. Search engines, online encyclopedias, and question-and-answer sites are grouped together. When people use search engines, they use specific keywords to actively search for information related to specific health concerns. Online encyclopedia sites are user-generated reference “books” in which people also commonly use specific keywords to query information. Additionally, question-and-answer site users with specific questions in mind actively solicit answers from fellow users, which is similar in nature to user behaviors on search engines and online encyclopedias. Therefore, search engines, online encyclopedias, and question-and-answer sites are online searching channels that users mainly use to search for answers related to health concerns. An alternative explanation might be that, from researchers’ anecdotal observations, search engines in China often return top results linking users to online encyclopedia sites and question-and-answer sites, which suggests that these two types of sites successfully apply search engine optimization strategies.

Web portals (eg, health sections), official accounts on WeChat, microblogs (eg, health microblog accounts), professional health sites, mobile health apps, and online health forums are combined into a separate group: online browsing channels. The content and layout of the content on the first 5 online channels are commonly prepared by professional editors; users normally follow the structure of information prepared by the publisher [10]. It is also noted that online health forums join the other 5 channels mentioned earlier. While online health forums allow users to solicit answers about specific questions, many users are usually spectators scrolling through the posts and threads of others. Thus, the use of online health forums is more similar to the use of health sections of web portals than the use of search engines and question-and-answer sites.

Updates on WeChat Moments and microblogs, web portals (eg, general news section), and online forums not related to health are grouped together as online scanning channels. Users encounter health information on these channels when engaged in tasks other than active health information seeking.

Differences in Sociopsychological Mechanisms for Channel Choice
This study further pinpointed the variation in motivation to use different types of health information channels from the perspective of RISP [12,33] and showed the validity of RISP in explaining information channel selection. The differences in sociopsychological mechanisms for channel selection corroborated the validity of the results generated by confirmatory factor analysis.

The use of searching channels, including search engines, question-and-answer sites, and online encyclopedia sites, is motivated by the intention to acquire more health knowledge (information sufficiency threshold) and by negative affect. Additionally, online searching channel use is indirectly caused by perceived risks via negative affect and indirectly influenced by informational subjective norms via the information sufficiency threshold. An individual who chooses search engines to search for specific disease-related keywords to reduce uncertainties is likely to feel threatened by health problems and have a stronger need for health knowledge.

The use of online scanning channels, including WeChat Moments, microblogs, online forums, and web portals, is driven primarily by informational subjective norms. An individual who pays attention to health information or knowledge on online scanning channels is unlikely to be concerned about their health status or increasing their knowledge. The use of online scanning channels to obtain health knowledge is attributed more to pressure from the individual’s interpersonal social network.

Similar to the use of online scanning channels, the use of online browsing channels is also directly driven by influence from one’s social network. Additionally, informational subjective norms predict the use of browsing channels via current knowledge. Browsing content on online professional health sites, for instance, does not necessarily mean that an individual can immediately benefit from the content read. Only if the individual understands the potential long-term benefits of that information or knowledge can they take the time to process the information. A higher level of current knowledge may help individuals be aware of the long-term benefits of health knowledge accrualment. In other words, the use of browsing channels is comparable to reading lengthy books, while the use of searching channels is similar to looking up the definition of a term in a dictionary.
Interestingly, information-gathering capacity was negatively associated with the extent to which respondents used scanning channels. Being able to locate health knowledge might prevent users from using scanning channels because they might believe in other, more efficient routes of obtaining health information, such as those under the category of searching or browsing channels.

**Practical Implications**

The results of the study suggest that health communication practitioners and scholars should measure “internet,” “new media,” and “online media” more precisely instead of simply asking the public about the frequency of internet use in health information acquisition. The measurement of generic internet use may cause too much error, and it lends no support to media planning in a public health promotion campaign.

More importantly, as contemporary health care consumers reside in a multichannel environment [49], health communication practitioners and scholars may consider developing more appropriate methods of classifying these channels to better manage them. As mentioned above, this study devises a new classification scheme based on health information–seeking behaviors. Practitioners may consider categorizing online channels using the new scheme generated by this study, which may better cater to the needs of individuals planning consumer-centered health communication campaigns.

The channel choice pattern and underlying sociopsychological mechanisms generate useful insights to improve health information strategies as well. We found that the use of online searching channels was uniquely driven by the need for more health knowledge and by stronger negative affect. In other words, people who use search engines, online encyclopedias, and question-and-answer sites may readily accept the answers found through these channels and use the knowledge to guide their health behaviors if they find the answers plausible. However, these 3 types of channels are often dominated by nonmedical professionals and possibly contain misinformation [50], so professional health agencies may consider establishing closer partnerships with these channels.

It was found that the use of online browsing channels was uniquely driven by self-reported current knowledge level, which implies that people with higher health literacy are more likely to choose browsing channels. Since most browsing channels are run by institutions, these channels and websites should focus on the provision of more advanced health knowledge. The basics should be left to sites such as online encyclopedias.

This study also found that the likelihood of using online scanning channels was primarily influenced by informational subjective norms. Additionally, health culture, which makes health a shared value, is beneficial to people’s health behaviors [51]. This means that if we could build a culture of health conducive to the habitual acquisition of health knowledge, users would be likely to process at least some health information encountered on online scanning channels. However, it should be noted that scanning channels may also contain a considerable amount of health content generated by nonprofessionals. Accuracy of online health information is always a concern [50], so practitioners should involve themselves as much as possible in such channels.

**Limitations and Future Studies**

This study is not without limitations. Constrained by budgets, this study used an online panel to collect data. Although the sample covered a range of age groups, this study did not sample enough older adults, which to some extent limited the generalization of the results to the entire population. Additionally, online panels consist of respondents who are paid to respond to the survey questions. These respondents may differ from the general population, which may bias the results of the study.

Since this study revealed that motivations behind using different types of channels differ, future studies may further explore the differences in the impacts of online channel use on health knowledge gains and behavioral changes. Moreover, future research is advised to further explore how people process information when using different types of online health information channels. The fourfold typology of information seeking and processing suggests that different information-seeking strategies may possibly entail different styles of information processing. Researchers do not examine online health information channel use and selection for the sake of merely understanding channel selection; instead, the ultimate goal of such research is to have a better understanding of how different channel choices influence changes in people’s cognition, attitudes, and behaviors.

**Acknowledgments**

This research was supported by National Social Science Foundation of China (No. 20&ZD319).

**Conflicts of Interest**

None declared.

Multimedia Appendix 1

Model building.

[DOCX File, 18 KB - jmir_v23i3e24945_app1.docx ]

Multimedia Appendix 2
References


49. Krivich M. The healthcare consumer lives in a multichannel environment; the response is? LinkedIn. URL: https://www.linkedin.com/pulse/healthcare-consumer-lives-multichannel-environment-michael-j/ [accessed 2021-03-03]

Abbreviations

RISP: risk information seeking and processing
Contribution of Free-Text Comments to the Burden of Documentation: Assessment and Analysis of Vital Sign Comments in Flowsheets

Zhijun Yin1,2, MSc, PhD; Yongtai Liu2, MSc; Allison B McCoy1, PhD; Bradley A Malin1,2,3, PhD; Patricia R Sengstack4, DNP, RN

1Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, United States
2Department of Electrical Engineering and Computer Science, Vanderbilt University, Nashville, TN, United States
3Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN, United States
4School of Nursing, Vanderbilt University, Nashville, TN, United States

Corresponding Author:
Zhijun Yin, MSc, PhD
Department of Biomedical Informatics
Vanderbilt University Medical Center
2525 West End Ave., Suite 1475
Nashville, TN, 37203
United States
Phone: 1 615 936 3690
Email: zhijun.yin@vanderbilt.edu

Abstract

Background: Documentation burden is a common problem with modern electronic health record (EHR) systems. To reduce this burden, various recording methods (eg, voice recorders or motion sensors) have been proposed. However, these solutions are in an early prototype phase and are unlikely to transition into practice in the near future. A more pragmatic alternative is to directly modify the implementation of the existing functionalities of an EHR system.

Objective: This study aims to assess the nature of free-text comments entered into EHR flowsheets that supplement quantitative vital sign values and examine opportunities to simplify functionality and reduce documentation burden.

Methods: We evaluated 209,055 vital sign comments in flowsheets that were generated in the Epic EHR system at the Vanderbilt University Medical Center in 2018. We applied topic modeling, as well as the natural language processing Clinical Language Annotation, Modeling, and Processing software system, to extract generally discussed topics and detailed medical terms (expressed as probability distribution) to investigate the stories communicated in these comments.

Results: Our analysis showed that 63.33% (6053/9557) of the users who entered vital signs made at least one free-text comment in vital sign flowsheet entries. The user roles that were most likely to compose comments were registered nurse, technician, and licensed nurse. The most frequently identified topics were the notification of a result to health care providers (0.347), the context of a measurement (0.307), and an inability to obtain a vital sign (0.224). There were 4187 unique medical terms that were extracted from 46,029 (0.220) comments, including many symptom-related terms such as “pain,” “upset,” “dizziness,” “coughing,” “anxiety,” “distress,” and “fever” and drug-related terms such as “tylenol,” “anesthesia,” “cannula,” “oxygen,” “motrin,” “rituxan,” and “labetalol.”

Conclusions: Considering that flowsheet comments are generally not displayed or automatically pulled into any clinical notes, our findings suggest that the flowsheet comment functionality can be simplified (eg, via structured response fields instead of a text input dialog) to reduce health care provider effort. Moreover, rich and clinically important medical terms such as medications and symptoms should be explicitly recorded in clinical notes for better visibility.

(J Med Internet Res 2021;23(3):e22806) doi:10.2196/22806

KEYWORDS

electronic health system; documentation burden; flowsheets; content analysis; vital sign comments; free text
**Introduction**

**Background and Motivations**

Electronic health record (EHR) systems have been widely adopted in clinical settings over the past decade [1]. These systems have provided many benefits that include, but are not limited to, improving quality of care [2], reducing prescription errors [3], and facilitating biomedical research [4]. Despite such benefits, documentation burden has been recognized as a negative artifact of adopting EHR systems. For instance, it was shown that primary care clinicians spent more than 50% of their time in front of an EHR system, thus reducing their time in interactions with patients [5]. In another study, it was reported that ophthalmologists spent approximately 3.7 hours per day using EHRs [6]. It has also been shown that nurses, one of the largest EHR system users, enter approximately 640 flowsheet data entries during a 12-hour shift, nearly one data point every minute in acute care [7]. In addition, in a web-based survey conducted in the Nursing Quality and Care Forum, 78% of the participants confirmed that documentation in EHRs is time-consuming and difficult to complete, and 68% suggested that such documentation contributed little value to patient care [8].

Documentation burden originates from various factors, such as the complex functionalities of EHR systems (which itself is partially due to increasingly sophisticated health care routines), increase in the amount of data being collected, and the challenge of prioritizing the information scattered in different locations in an EHR system [9]. The US Department of Health and Human Services has released strategies to reduce the burden of using health information technology (and EHRs in particular) [10], noting that the causes of documentation burden are many and complex and must be addressed on several levels by EHR vendors, regulatory agencies, insurers, and health care organizations themselves. In particular, one of the proposed strategies is to simplify documentation requirements for evaluation and management by streamlining Medicare Physician Fee Schedule final rules.

In addition to policy changes, it has been suggested that alternative recording strategies could reduce documentation burden. In one study, a smartwatch app with voice recognition was designed to help nurses record discussions during patient care, which could subsequently be uploaded to the EHR system [11,12]. A more recent study suggested that clinical documentation based on a collaborative wiki could provide opportunities to reduce documentation burden [13]. Other proposals include using artificial intelligence apps for auto-generation (eg, for treatment planning or summarization for radiation oncology [14]) or motion sensors and cameras to automatically populate EHR data (eg, in emergency care [15]). However, these approaches are limited in that most are in a prototype phase and are unlikely to be ready for implementation in the near future. Although it has been shown that using medical scribes (individuals who specialize in transcribing information during encounters into EHRs in real time) can reduce the documentation burden for physicians [16,17], scribes require a significant amount of training and clear coordination with physicians. In addition, the presence of a scribe might cause uncomfortable conversations during physician-patient encounters.

An alternative solution, with the potential for an immediate effect, is to customize the functionalities of an existing EHR system. For instance, it was shown that turning off certain interruptive notifications could help reduce EHR alert fatigue [18,19]. However, before doing this, it is necessary to investigate the functionality that is going to be customized to minimize negative consequences. In addition, organizations are beginning to examine free-text comments in EHRs, particularly those found in nursing flowsheets where the intent is to provide a place for succinct and standard responses.

**Free-Text Comments in Flowsheets**

Flowsheets are standardized tools in EHR systems that are helpful in documenting longitudinal patient information (eg, assessments, observations, and routine care) in a grid-type format [20]. In each flowsheet entry, a health care provider can enter values into a cell from provided lists or types in numerical values such as blood pressure (BP) or temperature. Additional free-text comments can be entered into a flowsheet cell, but this is not mandatory. By default, the comments (if any) are hidden behind an icon within the flowsheet entry. Health care providers can review a comment by clicking or hovering over the icon to open the comment display dialog. Figure 1 depicts a screenshot of a vital sign flowsheet with comments entered for BP. Although the flowsheet comments are optional, some health care providers find them useful and make an extra effort to provide them [21]. However, comments may introduce a negative consequence. In addition, organizations are beginning to examine free-text comments in EHRs, particularly those found in nursing flowsheets where the intent is to provide a place for succinct and standard responses.
Figure 1. Example of a vital sign comment that is entered in the Epic system. © 2020 Epic Systems Corporation.

Research Objectives

In this study, we seek to investigate the nature of flowsheet comments and their contribution to the documentation burden. In particular, we focused on the vital signs in flowsheets and extracted all their related comments written in 2018 in Epic, the EHR system that is in use at the Vanderbilt University Medical Center (VUMC). Specifically, we investigated the following research questions (RQs):

• RQ1: How often are the free-text comments in vital sign flowsheet entries made and by whom?
• RQ2: What are the general topics communicated in these comments?
• RQ3: Are there any specific medical terms mentioned in these comments?

Investigating the first question provides insight into how often health care providers use the flowsheet comment functionality. Answering the latter 2 questions provides insight into potential improvements to this functionality in an EHR system. Without an understanding of how often this feature is used and the purpose it serves, it is difficult to identify potential improvements to reduce the need to add documentation beyond the expected and standard responses in a flowsheet. If medical terms or concerns are being added to essentially hidden flowsheet comments, organizations can identify system usability enhancements to better capture patient issues that need to be addressed.

Methods

Data Preparation

In this study, we collected all vital signs and their comments (if present) that were recorded in flowsheets between January 1, 2018, and December 31, 2018, at VUMC. We focused on 5 specific vital signs that are commonly collected for routine clinical use in both the inpatient and outpatient settings: body temperature (Temp), BP, oxygen saturation (SpO₂), pulse rate (Pulse), and respiration rate (Resp). For each vital sign flowsheet entry, we collected the user ID, user role, documented time, and the free-text comment entered. Our study did not involve any patients and was designated as exempt from human subject research under a VUMC Internal Review Board protocol. Multimedia Appendix 1 presents the number and percentage of other types of vital signs.

Commenting Statistics and Temporal Trend

To investigate RQ1, for each vital sign, we captured the total number of unique users who entered at least one value in the flowsheet (total users), the number of unique users who made at least one comment (users commenting), the total number of flowsheet entries (total entries), the number of entries with comments (entries with comments), and the median number of words in the comments (comment length). We also showed the temporal trend by illustrating the number of comments of each vital sign that were generated weekly in 2018. In addition, we counted the number of comments per user role and ranked them based on their comment volume in descending order. We report the top-ranked roles that together generate at least 90% of all the comments.
Topic Modeling

To gain insights into what was communicated in these comments, we had to rely on an efficient method to summarize such a large volume of free texts. Topic modeling is a computational method for discovering the latent topics that occur in a collection of documents. To apply this technique, we first manually cleaned the comments by replacing commonly misspelled words with canonical representations. For example, we replaced `rnotified` with `rn notified`. After data cleaning, we applied latent Dirichlet allocation (LDA), specifically its implementation in the Gensim Python package (version 3.8.0), to identify topics. LDA is a common topic modeling technique in natural language processing to infer 2 distributions from a large number of documents. The first distribution describes the probability that a topic is sampled to form a document. The second distribution describes the probability that a term is sampled from a topic. We used the first distribution to determine the popular topics mentioned in vital sign comments and the second distribution to explain what a specific topic is talking about.

As LDA is an unsupervised learning method, we applied the coherence score (specifically, C^2) with a default sliding window of 110) to optimize the number of topics. The coherence score measures the extent to which the most relevant terms (with the highest probabilities) in a topic coexist with each other in either an external data set or the documents that are applied to train topic modeling. The higher the coherence score, the more interpretable the topics. In this study, we treated each vital sign as a single document and trained LDA models for 2 to 30 topics (with a step size of 1) using all the vital sign comments. Each candidate model was trained 10 times based on a different random seed. Although the best practice is to select the model that achieves the largest coherence score [22], there may be multiple LDA models that achieve coherence scores that are not significantly different from each other. As such, we empirically chose a model from these candidates that has (1) a large average coherence score, which leads to high interpretability; (2) a small SD, which tends to generate a stable model; and (3) a small number of topics, which reduces the chance of overlaps between topics.

Medical Terms Extraction

LDA is often effective at characterizing what is generally discussed in documents because it estimates the probabilities from term frequency (where a higher frequency indicates a larger probability). However, this technique is limited in that it is not oriented to represent detailed information, which is particularly a concern when relevant terms are rare. On the basis of this fact, we further applied Clinical Language Annotation, Modeling, and Processing (CLAMP, version 1.6.0), a toolkit that incorporates named-entity recognition algorithms, to identify medical terms with respect to 3 categories, that is, problems, treatments, and laboratory tests, as defined in CLAMP [23]. Examples of such terms are presented in the Results section. We use these medical terms to supplement the topics to gain a better understanding of the content of comments.

Results

Summary Statistics

During the 1-year study period (2018), there were a total of 209,055 free-text comments entered into flowsheets to further explain the data values entered for vital signs. Table 1 shows the basic statistics of the collected data. It can be seen that 63.33% (6053/9557) of the users who entered any vital signs made at least one comment in the vital sign flowsheet entries. Although BP received the second smallest number of flowsheet entries, it had the largest proportion of users who made comments and the largest number (proportion) of entries with comments. Similarly, Temp had the smallest number of total flowsheet entries but the second largest proportion of entries with comments. In contrast, Pulse and Resp had the smallest number (proportion) of entries with comments. Among these 5 vital signs, SpO\textsubscript{2} had the largest number of vital sign entries. In total, 0.69% (209,055/29,995,045) of the vital sign entries received additional comments.

Table 1. Data summary statistics\textsuperscript{a}.

<table>
<thead>
<tr>
<th>Type</th>
<th>Users commenting, n (%)</th>
<th>Total users, n</th>
<th>Entries with comment, n (%)</th>
<th>Total entries, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP\textsuperscript{b}</td>
<td>4733 (52.25)</td>
<td>9058</td>
<td>107,413 (2.04)</td>
<td>5,268,477</td>
</tr>
<tr>
<td>Pulse</td>
<td>3066 (33.76)</td>
<td>9081</td>
<td>16,814 (0.21)</td>
<td>7,898,699</td>
</tr>
<tr>
<td>Resp\textsuperscript{c}</td>
<td>2346 (28.85)</td>
<td>8132</td>
<td>10,883 (0.18)</td>
<td>5,994,777</td>
</tr>
<tr>
<td>SpO\textsubscript{2}\textsuperscript{d}</td>
<td>3614 (44.52)</td>
<td>8118</td>
<td>38,819 (0.55)</td>
<td>7,058,507</td>
</tr>
<tr>
<td>Temp\textsuperscript{e}</td>
<td>3631 (44.08)</td>
<td>8238</td>
<td>35,124 (0.93)</td>
<td>3,774,585</td>
</tr>
<tr>
<td>Total</td>
<td>6053 (63.33)</td>
<td>9557</td>
<td>209,055 (0.69)</td>
<td>29,995,045</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Note that the users can document multiple types of vital signs. As a result, the total number of unique users is the union, as opposed to the sum, of the set users associated with a vital sign.

\textsuperscript{b}BP: blood pressure.

\textsuperscript{c}Resp: respiration rate.

\textsuperscript{d}SpO\textsubscript{2}: oxygen saturation.

\textsuperscript{e}Temp: body temperature.
Figure 2 shows the histogram of the comment length (the number of words) for each vital sign. From the figure, it can be seen that for almost all the comments, the number of words was less than 15. Although most comments were short (with a median number of words of 2), the number of all the words used in these comments was still 697,340, owing to the large data volume.

**Figure 2.** Histogram of comment length for each type of vital sign. BP: blood pressure; Pulse: pulse rate; Resp: respiration rate; SpO₂: oxygen saturation; Temp: body temperature.

**Comments Stratified by User Role**

Figure 3 depicts the user roles that generated at least 90% of the comments for each vital sign. It can be seen that the user roles that were most likely to compose comments were registered nurse, technician, and licensed nurse. Although medical assistant and nursing student were among the top-ranked user roles, they generated a substantially smaller number of comments. It can also be seen that the user role registered nurse generated the largest number of comments for Temp, SpO₂, Resp, and Pulse, whereas the user role technician generated the largest number of BP comments. The user role licensed nurse generated the second largest number of SpO₂ comments.

**Figure 3.** User roles with the largest number of comments per vital sign. Only the user roles that together generated at least 90% of the comments for each vital sign are shown. Registered Nurse and Technician are two user roles that generated the largest number of vital sign comments. BP: blood pressure; Pulse: pulse rate; Resp: respiration rate; SpO₂: oxygen saturation; Temp: body temperature.
Figure 4 shows the number of comments for each vital sign in each week in 2018. Although the number of BP comments had a slightly increasing trend, the other 4 vital signs had a relatively constant number of comments for each of the 52 weeks. This suggested that the commenting phenomenon was quite stable in this clinical setting.

Figure 4. The temporal patterns of the number of comments for each type of vital sign. BP: blood pressure; Pulse: pulse rate; Resp: respiration rate; SpO₂: oxygen saturation; Temp: body temperature.

Topic Analysis

On the basis of our criteria, we empirically generated 13 topics from the flowsheet comment (see Multimedia Appendix 1 for details on how 13 topics were selected). Table 2 shows the topics, their most relevant terms, and the probability distribution. The relevant terms were selected based on their probability rank (in descending order) within a topic. For example, “notify,” “uto” (unable to obtain), “fussy,” and “move” were the most relevant terms in topic T8, indicating that a related measurement might not be obtained. Owing to the overlap between topics (eg, though a manual review), we further categorized these topics into 5 groups by examining the topic words and the associated comments (eg, examining the comments with the largest distribution of a particular topic). The percentage of each group was calculated by summing the percentage of each topic within the group. From the table, it can be seen that most comments communicated the notification of a result to health care providers (0.347), the context of a measurement (0.307), and an inability to obtain a vital sign (0.224). The other 2 topics corresponded to the measurement method (0.071) and simultaneous filling (0.051).
Table 2. Topics generated from vital sign comments.

<table>
<thead>
<tr>
<th>Label for group and topic</th>
<th>Most relevant words</th>
<th>Topic distribution (probability)</th>
<th>Group distribution (probability)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification T1</td>
<td>notify, rn, nurse, lie, standing, manually, informed, &lt;NAME&gt;, trach, &lt;NAME&gt;</td>
<td>0.106</td>
<td>0.347</td>
</tr>
<tr>
<td>T3</td>
<td>nurse, notify, call, high, pressure, heat, primary, hfov, report, warmer</td>
<td>0.090</td>
<td></td>
</tr>
<tr>
<td>T9</td>
<td>notify, rn, nurse, elevated, &lt;NAME&gt;, abnormal, supine, &lt;NAME&gt;, &lt;NAME&gt;</td>
<td>0.076</td>
<td></td>
</tr>
<tr>
<td>T6</td>
<td>notif, team, md, bedside, notifed, order, cct, page, monitor, np</td>
<td>0.075</td>
<td></td>
</tr>
<tr>
<td>Context</td>
<td></td>
<td>0.092</td>
<td>0.307</td>
</tr>
<tr>
<td>T13</td>
<td>room, air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T4</td>
<td>arm, pt, nc, blanket, place, warm, apply, hugger, bair, baby</td>
<td>0.080</td>
<td></td>
</tr>
<tr>
<td>T12</td>
<td>post, bath, temp, stand, sit, min, provider, eoi, inform, care</td>
<td>0.075</td>
<td></td>
</tr>
<tr>
<td>T7</td>
<td>patient, give, sleeping, tylenol, pain, med, state, liter, due, floor</td>
<td>0.060</td>
<td></td>
</tr>
<tr>
<td>Unable to obtain T8</td>
<td>patient, uto, fussy, move, crying, kicking, agitate, screaming, unit, moving</td>
<td>0.084</td>
<td>0.224</td>
</tr>
<tr>
<td>T2</td>
<td>patient, refuse, vital, sleep, asleep, time, mom, awake, defer, request</td>
<td>0.072</td>
<td></td>
</tr>
<tr>
<td>T11</td>
<td>patient, move, cry, upset, good, attempt, uto, obtain, kick, uta</td>
<td>0.068</td>
<td></td>
</tr>
<tr>
<td>Measure method T10</td>
<td>manual, cuff, bp, unable, nurse, check, arm, temp, read, recheck</td>
<td>0.071</td>
<td>0.071</td>
</tr>
<tr>
<td>Simultaneous filing T5</td>
<td>datum, user, filing, simultaneous, previous, doppler, predose, cchd, unnotifed, present</td>
<td>0.051</td>
<td></td>
</tr>
</tbody>
</table>

a Topic T13 only has 2 words with positive probabilities, whereas the probability of all the other words was zero and are thus not displayed. The names in T1 and T9 are replaced with <NAME> for anonymity.
b rn: registered nurse.
c hfov: high-frequency oscillatory ventilation.
d md: doctor of medicine.
e cct: critical care team.
f np: nurse practitioner.
g pt: patient.
h nc: nasal cannula.
i temp: body temperature.
j min: minute.
k eoi: evidence of insurability.
l bp: blood pressure.
m cchd: critical congenital heart disease.

To better understand each topic, we showed the comment samples, their dominant topics (the topic with the largest probability), and topic percentages in Table 3. It should be noted that the names of health care providers mentioned in some notification-related samples were replaced with <NAME> for anonymity. Although the meanings of the samples were straightforward and clearly linked to the associated topic groups, there are still several observations that we want to highlight here. First, despite the short length, the content of comment samples contained rich information, some of which was beyond
the vital signs themselves. For example, some samples in the context and notification topic groups included information regarding medications (e.g., nitro paste and BP meds). This confirmed the necessity of conducting a further medical term analysis to obtain more insights into this type of information. Second, the unable to obtain topic group mainly documented why a measurement was not obtained. Finally, after a close examination of the comments with T10 (simultaneous filing topic group) as the dominant topic, we found that this topic might refer to a conflicting input of a vital sign between an automatic interface and a health care provider.

Table 3. Examples of comments for each topica.

<table>
<thead>
<tr>
<th>Topic group</th>
<th>Topic</th>
<th>Topic distribution (probability)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Notification</strong></td>
<td>“Notified &lt;NAME&gt;, RN and &lt;NAME&gt;, MSN”</td>
<td>T1 0.182</td>
</tr>
<tr>
<td></td>
<td>“Nurse notified that pressure is high”</td>
<td>T3 0.139</td>
</tr>
<tr>
<td></td>
<td>“&lt;NAME&gt;, RN and Professor &lt;NAME&gt; notified”</td>
<td>T9 0.147</td>
</tr>
<tr>
<td></td>
<td>“Paged neuro stroke team about BP, team ordered nitro paste”</td>
<td>T6 0.204</td>
</tr>
<tr>
<td><strong>Context</strong></td>
<td>“Room air, baseline oxygen sat 87% on room air preop”</td>
<td>T13 0.135</td>
</tr>
<tr>
<td></td>
<td>“Eating cold food and has heating pad under back/arm area”</td>
<td>T4 0.183</td>
</tr>
<tr>
<td></td>
<td>“Transfusion ended. No s/sx of blood transfusion reaction”</td>
<td>T12 0.170</td>
</tr>
<tr>
<td></td>
<td>“Patient has not taken her BPb meds today”</td>
<td>T7 0.135</td>
</tr>
<tr>
<td><strong>Unable to obtain</strong></td>
<td>“uto, patient fussy, moving”</td>
<td>T8 0.143</td>
</tr>
<tr>
<td></td>
<td>“Mom refused vitals, requests patient not be disturbed until wakes”</td>
<td>T2 0.184</td>
</tr>
<tr>
<td></td>
<td>“Patient upset, no BP obtained, multiple attempts”</td>
<td>T11 0.151</td>
</tr>
<tr>
<td><strong>Measure method</strong></td>
<td>“Manual BP (arm measured 31 cm, used adult size cuff)”</td>
<td>T10 0.181</td>
</tr>
<tr>
<td><strong>Simultaneous filing</strong></td>
<td>“Paced simultaneous filing. User may not have seen previous data”</td>
<td>T11 0.161</td>
</tr>
</tbody>
</table>

aThe dominant topic (e.g., the topic with the largest probability) in each topic group is shown in the Topic column, and the corresponding probability is shown in the Topic Distribution column.
bBP: blood pressure.

Figure 5 shows how each topic group is represented in each vital sign. Specifically, we used the dominant topic to determine which topic group a comment is assigned to and then counted the number of comments in each topic group for each vital sign. For example, all the 4 comment samples under Notification in Table 3 were assigned to this topic group because their dominant topics (T1, T3, T6, and T9) belonged to Notification (Table 2). It can be seen that some topic groups are specific to certain vital signs. For example, notification was the dominant topic group in BP and Resp, whereas context was the dominant topic group in SpO2. In addition, Pulse had notification and unable to obtain as dominant topic groups, whereas temp had context and notification as dominant topic groups.
Figure 5. Distribution of topic groups in each vital sign. Each comment is assigned to the topic group that its dominant topic belongs to. BP: blood pressure; Pulse: pulse rate; Resp: respiration rate; SpO$_2$: oxygen saturation; Temp: body temperature.

Medical Term Extraction

We applied CLAMP to generate 4187 unique medical terms or phrases that were found in 22.02% (46,029/209,055) of all vital sign comments. Of these comments, 7.66% (16,023/209,055) contained treatment-related keywords, 8.66% (18,095/209,055) contained test-related keywords, and 7.16% (14,978/209,055) contained problem-related keywords. Multimedia Appendices 2-4 depict the word clouds of the medical terms in each category. The terms bp and fussy covered 30.47% (5814/19,080) and 24.68% (3941/15,966) of all the test- and problem-related medical terms, respectively. Given their dominance, they are not reported in Multimedia Appendices 2 and 3. From the figure, we can see that test-related medical terms were mainly related to vitals, which intuitively makes sense because this study focused on vital sign comments. However, there were other tests, such as magnetic resonance imaging, which were mentioned in these comments. The problem-related terms included many symptom-related terms such as “pain,” “upset,” “dizziness,” “coughing,” “anxiety,” “distress,” and “fever.” Treatment-related terms included “tylenol,” “anesthesia,” “cannula,” “oxygen,” “motrin,” “rituxan,” “bair hugger blanket,” and “labetalol.”

Discussion

Principal Findings

This study has several notable findings. First, we found that 63.33% (6053/9557) of the EHR users who recorded vital signs in flowsheets also entered at least one comment, and most of these users were either (registered) nurses or technicians. Although only 0.69% (209,055/29,995,045) of the 5 types of vital sign entries received comments, there were approximately 210,000 comments. Furthermore, our topic analysis showed that these comments mainly corresponded to how the vital signs were measured, any issues encountered while taking the vital signs, or notifications to health care providers. Further inspection of the medical terms indicated that there were still many test-, problem-, and treatment-related data that were recorded in these comments. These nurses and technicians clearly felt the need to capture more information than the simple numeric value that the flowsheet required, as documented in a study that examined the flowsheet comments for 201 patients who experienced cardiac arrest [21]. However, despite its potential usefulness, our findings suggest that there are better alternative solutions for effective information recording.

Documentation Burden of Flowsheet Comments

First, although only a small proportion of flowsheet vital sign entries had comments, when considering a median typing speed of 30 words per minute [24], the composition of 700,000 words in 210,000 comments still implies approximately 23,333 minutes (389 hours) of comment documentation. Although, on average, each user spent about 1 minute to document, the time used for writing such comments was substantial for some Epic users because the 5 vital signs were only a small fraction of all the different types of flowsheet entries. This raises the question: Is it necessary to retain such functionality in the EHR system? Some studies have shown that patients who died tended to receive more vital sign comments than other patients [25,26]. However, it is unclear if such an association is useful in practice because it might be the severity of the condition that led to a higher volume of vital sign comments. Alternatively, it is still helpful to simplify the commenting functionality to save the
users’ effort in this circumstance. According to our topic analysis, most comments were related to either notification (0.347), the context of performing a measurement (0.307), or notification (0.224). Although context might provide additional information about a measurement, it is unclear whether recording that a health care provider was notified about a measurement contributes to the understanding of a patient’s health condition. A deeper review of the identified topics could help determine the need for configuration improvements to the system. For instance, are comments related to notification entered to address potential litigation or is there a true concern for the patient’s condition? Are there other signs of patient deterioration? Are comments related to the context of the vital signs already documented elsewhere in a more appropriate location? Are comments related to the inability to take a patient’s vital signs fulfilling the nursing mantra of if it’s not documented, it’s not done and a potential legal consequence? Unfortunately, there has been little investigation into the motivation for recording notifications.

Visibility of Medical Information in Comments

In addition, the medical term analysis raises another question: Should such medical information be recorded in flowsheet entry comments? In EHRs, this information should at least be recorded in clinical notes, which ensures that such information could be referred to in the future. However, flowsheet comments are not displayed or automatically pulled into any clinical notes. Rather, the only way to review an existing comment is to locate the flowsheet on the correct date and open the comment display dialog. As such, we suspect that flowsheet comments are seldom reviewed by other health care providers, except the user who made them. Although this needs to be verified (eg, which might be possible through a review of the EHR access logs), it was reported that 5.6% of the alert comments regarding potentially very important clinical safety issues were overlooked [27]. Furthermore, a study showed that only 16% of nursing notes were read by physicians and 38% were read by other nurses [28]. As such, it appears that the flowsheet entry comments might not be in a proper place to store medical-related information. Although only a fraction of notes are examined by others, recording such information in clinical notes seems a better approach to record the information and access it in the future.

Potential Changes to EHR Design

Finally, based on this analysis, we believe there are at least two ways by which this functionality could be better oriented toward a user-centered design. First, the ability to enter free-text comments in a flowsheet row can be removed from the EHR system. Although this may save health care providers’ time and effort, it should only be considered after a careful examination of the utility of this functionality, an endeavor that is beyond the scope of this investigation. Second, we suspect that one possible explanation for recording notification is related to the potential for future lawsuits. This notion was highlighted in an interview with 5 acute care nurses, all of whom agreed that notification comments in a flowsheet help to cover them legally [21]. If this information must be stored, then it can be designed using structured response fields (eg, in the form of a simple checkbox) such that users do not have to click the comment entry icon, open a dialog box, and then enter comments. This design should be suitable for capturing when a measurement is reliable or unable to obtain as well. Moreover, any medical-related information should be recorded in clinical notes for future reference. We believe that such a design will be much more efficient and ensure that important information can be easily reviewed in the future. However, we acknowledge that a user-centered design approach would help understand the need for, as well as how to improve, the functionality.

Limitation and Future Work

Despite the merits of this work, there are several limitations that we wish to highlight, which could guide future research. First, we only examined the data from a single clinical environment, which may limit the generalizability of our findings. However, this functionality exists across all Epic implementations and is therefore likely to be a widespread phenomenon. Second, we only examined vital sign comments; thus, it is unclear if these findings would hold with other types of flowsheet entries. Third, we only focused on the dominant topic when analyzing the distribution of topic groups within each vital sign. Owing to the brevity of flowsheet comments, topic modeling strategies that are explicitly oriented to handle texts of shorter length should be considered in future investigations. Fourth, we replaced only the misspellings for certain frequent terms. Correcting the spelling errors and resolving aliasing issues (ie, when 2 terms correspond to the same underlying concept) for the entire vocabulary may improve the quality of topic modeling, but determining the best approach to use is beyond the scope of this investigation. Future work may also consider extracting concepts based on specific nursing terminologies in addition to the general medical terms to interpret the comments from a nursing perspective. In addition, it might be beneficial to investigate how the use of comments varies across patient characteristics and settings (eg, comments made during a hospital encounter vs those made outside of a hospital encounter). Moreover, we only examined the comments based on their content. To fully understand this functionality and information, potential future work includes examining the motivation of recording notification in comments, the extent to which such comments would be accessed by other health care providers, and the association between the content of flowsheet comments and patients’ health-related behaviors or outcomes.

Conclusions

Documentation burden is a recognizable issue when modern EHR systems are increasingly adopted in health care. One potential solution to reduce such burden is to simplify the existing functionalities of an EHR system. In this study, we examined the nature of vital sign comments in flowsheets using the data generated in the Epic system at VUMC. We found that most of the comments were related to the notification of a result to health care providers, the context of a measurement, and an inability to obtain a vital sign. We also extracted many medical terms (eg, symptoms or medications) from these comments. Considering that flowsheet comments are not displayed or automatically pulled into any clinical notes, we believe that such functionality can be simplified via structured response
fields instead of a text input dialog to reduce health care provider effort.

Acknowledgments
This work was partially sponsored by the National Institutes of Health under grant UL1TR002243.

Authors' Contributions
ZY and PS proposed the research question. AM collected the data. ZY and YL designed and conducted the experiments. ZY drafted the manuscript. ZY, PS, BM, AM, and YL edited and reviewed the final manuscript.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Supplemental material.

Multimedia Appendix 2
Word cloud of medical terms regarding tests. The font size of each word is proportional to its frequency in flowsheet comments.

Multimedia Appendix 3
Word cloud of medical terms regarding problems. The font size of each word is proportional to its frequency in flowsheet comments.

Multimedia Appendix 4
Word cloud of medical terms regarding treatments. The font size of each word is proportional to its frequency in flowsheet comments.

References


Abbreviations

BP: blood pressure
CLAMP: Clinical Language Annotation, Modeling, and Processing
EHR: electronic health record
LDA: latent Dirichlet allocation
Pulse: pulse rate
Resp: respiration rate
RQ: research question
SpO₂: oxygen saturation
Temp: body temperature
VUMC: Vanderbilt University Medical Center
©Zhijun Yin, Yongtai Liu, Allison B McCoy, Bradley A Malin, Patricia R Sengstack. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 04.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Review

eHealth Applications to Support Independent Living of Older Persons: Scoping Review of Costs and Benefits Identified in Economic Evaluations

Sandra Sülz1, PhD; Hilco J van Elten1, PhD; Marjan Askari1, PhD; Anne Marie Weggelaar-Jansen1,2, PhD; Robbert Huijsman1,3, PhD

1Erasmus School of Health Policy & Management, Rotterdam, Netherlands
2Clinical Informatics, Eindhoven University of Technology, Eindhoven, Netherlands
3Geriant, Heerhugowaard, Netherlands

Corresponding Author:
Sandra Sülz, PhD
Erasmus School of Health Policy & Management
PO Box 1738
Rotterdam, 3000 DR
Netherlands
Phone: 31 104088531
Email: sulz@eshpm.eur.nl

Abstract

Background: eHealth applications are constantly increasing and are frequently considered to constitute a promising strategy for cost containment in health care, particularly if the applications aim to support older persons. Older persons are, however, not the only major eHealth stakeholder. eHealth suppliers, caregivers, funding bodies, and health authorities are also likely to attribute value to eHealth applications, but they can differ in their value attribution because they are affected differently by eHealth costs and benefits. Therefore, any assessment of the value of eHealth applications requires the consideration of multiple stakeholders in a holistic and integrated manner. Such a holistic and reliable value assessment requires a profound understanding of the application’s costs and benefits. The first step in measuring costs and benefits is identifying the relevant costs and benefit categories that the eHealth application affects.

Objective: The aim of this study is to support the conceptual phase of an economic evaluation by providing an overview of the relevant direct and indirect costs and benefits incorporated in economic evaluations so far.

Methods: We conducted a systematic literature search covering papers published until December 2019 by using the Embase, Medline Ovid, Web of Science, and CINAHL EBSCOhost databases. We included papers on eHealth applications with web-based contact possibilities between clients and health care providers (mobile health apps) and applications for self-management, telehomecare, telemedicine, telemonitoring, telerehabilitation, and active healthy aging technologies for older persons. We included studies that focused on any type of economic evaluation, including costs and benefit measures.

Results: We identified 55 papers with economic evaluations. These studies considered a range of different types of costs and benefits. Costs pertain to implementation activities and operational activities related to eHealth applications. Benefits (or consequences) could be categorized according to stakeholder groups, that is, older persons, caregivers, and health care providers. These benefits can further be divided into stakeholder-specific outcomes and resource usage. Some cost and benefit types have received more attention than others. For instance, patient outcomes have been predominantly captured via quality-of-life considerations and various types of physical health status indicators. From the perspective of resource usage, a strong emphasis has been placed on home care visits and hospital usage.

Conclusions: Economic evaluations of eHealth applications are gaining momentum, and studies have shown considerable variation regarding the costs and benefits that they include. We contribute to the body of literature by providing a detailed and up-to-date framework of cost and benefit categories that any interested stakeholder can use as a starting point to conduct an economic evaluation in the context of independent living of older persons.

(J Med Internet Res 2021;23(3):e24363) doi:10.2196/24363
Introduction

Background and Motivation
The use of information and communication technologies in health care is regarded as an important piece of the puzzle of increasing health care costs and demand [1], particularly if it targets older persons with substantial health care costs [2]. Induced by an aging population that stays home longer, an increase in self-management, and a changing role of informal caregivers, the demand for health care delivery, and the role of technology are changing rapidly. To contain health care costs and maintain the quality of care and living, governments direct policies to stimulate eHealth to increase and support self-management [3]. In this study, eHealth is defined in line with the description by Eysenbach [4] and the different taxonomies described by Oh et al [5]: eHealth is at the intersection of medical informatics, public health, and business and offers health services to support care delivery, manage care, promote prevention, and educate; it is delivered or enhanced through the internet and related technologies (eg, domotics, wearables, and sensors). In the domain of older persons living at home, we define eHealth as web-based contact possibilities between the clients and health care providers and applications for self-management, telehomecare, telemedicine, telemonitoring, and telerehabilitation.

eHealth has shown to be valuable in promoting medication adherence and improving self-management in the population of older persons [6]. In addition, eHealth can be used to monitor clinical signs, collect health information, support users in activities related to their health, and promote a healthy lifestyle or arrange remote consultations [7-10]. Growing internet access, increasing use of mobile apps, and current technology trends create opportunities for novel services and new forms of health care through eHealth [11,12]. Governments are also increasingly funding initiatives that replace traditional care with alternatives that use information and communication technologies to remotely monitor and deliver health care services. Primary funding motivation is economic in nature—promoting preventive measures to avoid costly consequences and stimulate efforts to increase access to care [13].

Although eHealth is frequently considered a promising development, these applications are not without considerable costs. eHealth equipment must be purchased, and systems must be operated and maintained. Data recorded by eHealth should be monitored. However, frequently, the stakeholder who benefits from the application is not the same stakeholder who is paying for it. Costs and benefits affect different stakeholders and potentially also at different points in time; therefore, the economic interests of stakeholders are often not aligned. From the health provider perspective, such an investment does not make an economic sense, whereas it might be highly valuable from a societal perspective, considering the total benefits and costs regardless of where they occur. Any assessment of the value of an eHealth application, therefore, requires considering multiple stakeholders in a holistic and integrated assessment of all costs (ie, the direct and indirect and short- and long-term costs) and all benefits (ie, the direct and indirect and short- and long-term gains) of an eHealth application. This rationale represents the core of economic evaluations in health care [14]. Economic evaluations in health care come in different forms such as cost-effectiveness analyses (CEAs), cost utility analyses (CUAs), and cost-benefit analyses (CBAs). Regardless of the type, they have in common considering both costs and benefits, that is, what we have to give up and what we will gain. The main difference is the way in which gain is incorporated: CEAs consider a one-dimensional measure of the gain, which only allows for a comparison of programs with the same effect measures. CUAs assess gain through utility, frequently in quality-adjusted life years, which is comparable between health programs. CBAs assess the gain monetarily, that is, costs and outcomes are directly on the same scale [14,15].

Research Objective
If an interested stakeholder wants to conduct an economic evaluation, that is, apply such an evaluation to a specific case, he or she must first identify the relevant cost and benefit elements. For this identification step, the body of literature can serve as a valuable source of information. Currently, it is unclear what types of information are available in the literature about the relevant cost and benefit elements of eHealth. Therefore, we conducted a scoping review to systematically map the literature in this area and to develop an up-to-date framework for conducting all-inclusive economic evaluations of eHealth applications that support independent living of older persons.

Methods
Scoping Review
Our research methodology was drafted using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) protocols, specifically for scoping reviews. Among other things, scoping reviews are appropriate for identifying key characteristics and factors related to a concept [16]. Consequently, they lend themselves naturally to our research objectives.

Search Query and Inclusion and Exclusion Criteria
For this study, we identified papers published until December 2019 using the Embase, Medline Ovid, Web of Science, and CINAHL EBSCOhost databases. Additional papers were identified by scanning the references of the identified papers (indicated as other sources in the PRISMA flowchart in Figure 1). An experienced librarian developed search strings with some unique features to combine search terms effectively [17,18] and conducted the search. Our search terms are derived from the inclusion and exclusion criteria specified later, and the complete search query is provided in Multimedia Appendix 1.
The inclusion and exclusion criteria were specified to guide the identification process. We included original papers that were peer reviewed, had an empirical or prescriptive nature, and were written in English. Research protocols, commentaries, and editorial papers were excluded from the study. We also excluded reviews to avoid duplicate findings and avoid relying on the review’s interpretation of the cost and benefit labels. Concerning the patient population, we included papers that focused on patients with an average age of at least 65 years and who were living independently at their usual place of residence. Studies were excluded if they considered nonOLDER persons (ie, infants, adolescents, and a sample mean age younger than 65 years) or if the patient population received care in any institutionalized form (ie, hospitals, nursing homes, rehabilitation clinics, and hospice). In terms of the eHealth application, we focused on eHealth applications with web-based contact possibilities between clients and health care providers, including mobile health (mHealth) apps, and applications for self-management, telehomecare, telemedicine, telemonitoring, telerhabilitation, and active healthy aging technologies for older persons. Papers with the following technologies were excluded: papers describing technology not connected to the internet (eg, implantable cardioverter defibrillator) and papers on health information systems, electronic health records, robotics, and telephone consults only. To obtain a comprehensive overview, we did not use a strict definition of economic evaluation and did not constrain our search to particular types of economic evaluations. The only constraint on which we relied was that economic evaluations required both costs and benefits. Therefore, we included papers that measured at least one monetary aspect and one benefit of eHealth applications in any shape or form (eg, medical expenditures and analyzing clinical effects). Papers that only described or analyzed costs at an aggregated level or (clinical) effects were excluded.

**Screening and Eligibility**

Initially, 2 of the authors (SS and HE) screened a small sample simultaneously to align the assessment. Subsequently, SS and HE conducted abstract and title screening, with each screening half of the identified references. The studies were labeled not relevant or potentially relevant based on the inclusion criteria. A random sample of the references was blindly double-checked by AW and RH. The random set has been created by selecting every 10th article from the set of annually ordered articles. Interrater reliability was evaluated using the Cohen kappa (κ) index, which is a robust statistic useful for interrater reliability testing [19]. This double screening yielded a fair overlap between the assessments by SS or HE and AW or RB (Cohen κ index=0.28). After realigning the inclusion and exclusion criteria and rescreening all of the references with previous disagreements (conducted by AW), substantial improvements in the alignment were achieved (Cohen κ index=0.75).

In the next screening round, SS and HE conducted the screening based on full texts, and both authors went independently through all of the references initially labeled as potentially relevant. This double-blind screening yielded a substantial overlap (Cohen κ index=0.64). SS and HE discussed all of the references for which their assessments diverged and thus resolved disagreements.

**Data Extraction and Categorization**

Two authors (SS and HE) extracted the following information from the studies: patient population, country, type of eHealth intervention, type of analysis that the papers report performing, the specific cost types that the studies considered, and the
specific benefits, gains, and consequences that the studies included. Subsequently, we categorized the costs and benefits. We started with 4 categories pertaining to (1) implementation activities for the eHealth application, (2) operating and maintenance activities for the eHealth application, (3) processes of health care delivery, and (4) outcomes. While extracting the information, we further refined these categories depending on activities, stakeholders, and institutions such that the subcategories were mutually exclusive but sufficiently broad to capture related items.

Results

Study Selection

The search and screening processes are shown in Figure 1. The database and manual searches resulted in 1799 papers. After the first round of removal of duplicate papers and title and abstract screening, the remaining 201 papers were subjected to full-text reading. After the second step, 55 papers met our inclusion criteria and were included in the final set for analysis. The included references were published in the 2000-2019 time frame, with 5 included papers from the first 5-year period (2000-2004), 12 between 2005 and 2009, 17 between 2010 and 2014, and 21 between 2015 and 2019.

Patient Characteristics

The patient characteristics were rather broad; however, most studies focused on chronic or cardiovascular diseases. Of the 55 references, 13 had a patient population with various chronic health problems [13,20-31]. Cardiovascular problems received specific attention in 17 studies [32-48]. In 10 studies, the focus was on chronic obstructive pulmonary disease [49-58], and in 2 studies, the focus was on chronic skin problems [59,60]. Other studies considered diabetes [61], age-related macular degeneration [62], post-knee arthroplasty patients [63], Parkinson disease [64], and terminal patients [65]. Five studies did not specify any health conditions or diseases [66-70]. Of the 55 studies, 3 focused on mental and behavioral disorders such as anxiety [71], dementia [72], and depression [73].

Country

The studies in English were geographically clustered, with 26 studies conducted in North America, among which 20 occurred in the United States [20-23,25-28,30,31,33,34,37,38,42,61,62,64,67,68] and 6 in Canada [29,40,49,51,63,66]. Among the 22 studies conducted in Europe, they were spread across countries, with 5 studies conducted in England and the United Kingdom [24,41,43,44,53]; 3 each in Denmark [50,52,58], Italy [32,45,55], the Netherlands [35,39,72]; 2 each in Austria [46,60] and Germany [47,54]; and 1 each in France [59], Spain [although not explicitly stated in the paper] [57], Norway [70], and Sweden [69]. Finally, 4 studies took place in Australia [36,56,71,73] and 3 in Asia, among which 2 were in Japan [13,65] and 1 in Taiwan [48]. With the study in Taiwan being the only one conducted in a country that is not a part of the Organization for Economic Cooperation and Development, there was a strong emphasis on economically strong countries with aging populations.

Type of eHealth Interventions

The majority of included studies focused on telemonitoring or remote monitoring involving the measurement of vital statistics and the transmission of patient data followed by an assessment—either automatically or manually—and triggering action by health care professionals if required [22-25,27-30,32-35,38-43,45-51,53,54,56,57,62,65,68,70]. In addition, other eHealth forms included in our review related to video consultations and virtual visits [20,21,23,30,37,42,48,55,59,61,63,64,69]; deployment of sensor technology to analyze behavioral patterns and wireless transmitters [13,26,48,61,66,67,70,72]; email messaging services and web portal access [44,69,71,73]; online disease management courses or resources [44,71,73]; internet-delivered cognitive behavioral therapy [71,73]; remotely supervised rehabilitation activities, such as assistant mHealth [36,52,58]; and digital data transmission [60]. Note that some studies blended various eHealth forms and applications and that there was some ambiguity in the terminology, with telehealth often being used interchangeably with telemedicine, telemonitoring, or remote monitoring. The specific eHealth interventions analyzed in the studies are described in Multimedia Appendix 2 [13,20-73].

Specific Cost and Benefit Types

When we consider eHealth applications, what direct and indirect costs and benefits (or consequences) might be relevant to consider? Tables 1-3 provide an answer by outlining the different cost and benefit types that the studies included in our review considered. Table 1 shows the eHealth intervention costs categorized into implementation and operating activities. Table
2 provides an overview of the consequences of eHealth and focuses on resource usage. Finally, Table 3 depicts eHealth consequences in terms of outcomes categorized by stakeholder group.

Table 1. Intervention costs of eHealth applications.

<table>
<thead>
<tr>
<th>Intervention costs</th>
<th>Considered by number of studies</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implementation activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>License or software or initial fee purchase</td>
<td>7</td>
<td>[13,24,29,50,51,59,72]</td>
</tr>
<tr>
<td>Equipment installation</td>
<td>18</td>
<td>[13,24,29,34,35,38,50-53,55,61,63,65,66,69,70,72]</td>
</tr>
<tr>
<td>Training or education of operators</td>
<td>10</td>
<td>[24,25,29,35,44,50,52,53,61,70]</td>
</tr>
<tr>
<td>Technician travel time to install equipment</td>
<td>5</td>
<td>[30,36,40,52,63]</td>
</tr>
<tr>
<td><strong>Operating activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance (server, host, call center, or station)</td>
<td>18</td>
<td>[13,24,26,28,29,35,37,39,40,43,50,51,53,55,59,65,66,68,69]</td>
</tr>
<tr>
<td>Periodic fees (for licenses, insurance, etc)</td>
<td>15</td>
<td>[24,29,31,35,37,38,43,50,55,59,61,68,71-73]</td>
</tr>
<tr>
<td>Medical staffing: reviewing or assessing or intervening</td>
<td>26</td>
<td>[13,24,29,32,34-36,38,40,41,44,45,53,55-57,61-63,65,66,69-73]</td>
</tr>
<tr>
<td>Nonmedical staffing: technical support</td>
<td>14</td>
<td>[13,24,29,39,40,50,51,53,61,63,66,68,69,72]</td>
</tr>
<tr>
<td>Technician travel time to maintain equipment</td>
<td>1</td>
<td>[24]</td>
</tr>
</tbody>
</table>
Table 2. Intervention consequences—resource usage.

<table>
<thead>
<tr>
<th>Intervention consequences</th>
<th>Considered by the included studies, n</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>eHealth usage by patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Televists: number or duration of visits</td>
<td>17</td>
<td>[20,22,23,25,30-32,35,37,39,44,45,51,56,61,64,70]</td>
</tr>
<tr>
<td><strong>Health resource usage by patient—community health services or primary care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Travel time or transportation costs (eg, for ambulance)</td>
<td>9</td>
<td>[39,44,46,53,55,59,60,64,67]</td>
</tr>
<tr>
<td>General practitioner: number or duration of visits</td>
<td>16</td>
<td>[24,28,31,35,39,40,44,45,52,55-57,59,68,71,73]</td>
</tr>
<tr>
<td>Walk-in center: number or duration of visits</td>
<td>2</td>
<td>[24,44]</td>
</tr>
<tr>
<td>Physiotherapist: number of sessions</td>
<td>5</td>
<td>[24,39,52,59,63]</td>
</tr>
<tr>
<td>Psychologist: number of sessions</td>
<td>2</td>
<td>[24,39]</td>
</tr>
<tr>
<td>Community nurse: number or duration of visits</td>
<td>4</td>
<td>[24,39,44,50]</td>
</tr>
<tr>
<td>Home care: number or duration of visits</td>
<td>27</td>
<td>[21-25,28-32,34,37-39,49-51,55-57,61,64-67,69,72]</td>
</tr>
<tr>
<td>Meals on wheels</td>
<td>1</td>
<td>[24]</td>
</tr>
<tr>
<td><strong>Day services</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day care</td>
<td>2</td>
<td>[24,69]</td>
</tr>
<tr>
<td>Same-day surgeries</td>
<td>1</td>
<td>[67]</td>
</tr>
<tr>
<td><strong>Institutionalized care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rehabilitation clinics: number or duration of admissions</td>
<td>2</td>
<td>[50,54]</td>
</tr>
<tr>
<td>Skilled nursing facilities: number or duration of admissions</td>
<td>6</td>
<td>[27,62,67,69,70,72]</td>
</tr>
<tr>
<td>Long-term care: number or duration of admission</td>
<td>2</td>
<td>[24,67]</td>
</tr>
<tr>
<td>Hospice: number or duration of admissions</td>
<td>2</td>
<td>[21,35]</td>
</tr>
<tr>
<td><strong>Hospital use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient clinic: number or duration of visits to specialists</td>
<td>21</td>
<td>[21,24,27,28,34,35,40,43,45,46,48,50,52-54,56,59,60,62,67,68]</td>
</tr>
<tr>
<td>Hospital: number or duration of admissions</td>
<td>40</td>
<td>[21,24,25,27-31,33,34,36-59,65-68,70,71,73]</td>
</tr>
<tr>
<td>Intensive care unit: Admissions</td>
<td>2</td>
<td>[55,57]</td>
</tr>
<tr>
<td><strong>Drug treatment and laboratory diagnostics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication, prescriptions, or medical supplies</td>
<td>16</td>
<td>[21,24,31,38,39,43,44,50,52,54,55,59,62,67,71,73]</td>
</tr>
<tr>
<td>Laboratory</td>
<td>3</td>
<td>[66,67]</td>
</tr>
</tbody>
</table>
### Table 3. Intervention consequences—stakeholder outcomes.

<table>
<thead>
<tr>
<th>Intervention consequences</th>
<th>Considered by the included studies, n</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient or client outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical health status (mortality, morbidity, cardiovascular events, exacerbations, etc)</td>
<td>14</td>
<td>[30,32,34,33,44,46,47,54,55,59-61,68]</td>
</tr>
<tr>
<td>Psychological health status (anxiety, depression, or empowerment)</td>
<td>4</td>
<td>[22-24,66]</td>
</tr>
<tr>
<td>QALYs&lt;sup&gt;a&lt;/sup&gt;</td>
<td>12</td>
<td>[24,35,36,39-41,44,50,52,62,71,73]</td>
</tr>
<tr>
<td>Quality of life (if not measured in QALYs but differently)</td>
<td>11</td>
<td>[24,28,33,37,38,42,47,56,61,64,66]</td>
</tr>
<tr>
<td>Setting-specific quality of care indicators</td>
<td>1</td>
<td>[31]</td>
</tr>
<tr>
<td>Satisfaction (with the device or eHealth service)</td>
<td>8</td>
<td>[20,23,25,29,31,40,51,66]</td>
</tr>
<tr>
<td>Satisfaction (in general)</td>
<td>5</td>
<td>[22,28,30,37,61]</td>
</tr>
<tr>
<td>Patient experience or perceived benefits</td>
<td>3</td>
<td>[57,65,69]</td>
</tr>
<tr>
<td>Well-being</td>
<td>1</td>
<td>[72]</td>
</tr>
<tr>
<td>Time spent in the usual place of residence</td>
<td>1</td>
<td>[26]</td>
</tr>
<tr>
<td>Transfer to a different level of care</td>
<td>1</td>
<td>[30]</td>
</tr>
<tr>
<td>Time absent from work (productivity loss or loss of income)</td>
<td>2</td>
<td>[44,62]</td>
</tr>
<tr>
<td>Device-related technical events</td>
<td>2</td>
<td>[43,47]</td>
</tr>
<tr>
<td><strong>Professional caregivers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction with the device</td>
<td>2</td>
<td>[20,25]</td>
</tr>
<tr>
<td>Satisfaction in general</td>
<td>1</td>
<td>[30]</td>
</tr>
<tr>
<td>Travel time to patient’s home</td>
<td>11</td>
<td>[20,25,28,30-32,49,51,56,63,65,70]</td>
</tr>
<tr>
<td><strong>Informal caregivers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time absent from work (productivity loss)</td>
<td>2</td>
<td>[62,70]</td>
</tr>
<tr>
<td>Burden</td>
<td>1</td>
<td>[66]</td>
</tr>
<tr>
<td>Well-being</td>
<td>1</td>
<td>[72]</td>
</tr>
<tr>
<td><strong>Transfer payments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attendance allowance (recipients receive payments to manage their own health)</td>
<td>1</td>
<td>[69]</td>
</tr>
<tr>
<td>Respite care (payments made to relieve informal caregivers from providing care)</td>
<td>1</td>
<td>[69]</td>
</tr>
</tbody>
</table>

<sup>a</sup>QALYs: quality-adjusted life years.

### Level of Integration

Although Tables 1-3 provide an extensive overview of cost and consequence aspects already considered in previous studies, they indicate that there is diversity in how many different aspects the studies have considered. For all the studies, we determined whether they included at least one element of implementation costs, operating costs, and consequences such as eHealth and resource usage, patient outcomes, professional caregiver outcomes, and informal caregiver outcomes. The studies had different foci and different levels of integration, as outlined by the diversity in Figure 2. Each study is represented by 1 bar decomposed into the cost and consequence subcategories considered in the study. The group of 28 studies on the left considered at least one implementation and one operating activity, in addition to the consequences of the eHealth intervention [13,24,29,31,34-41,44,50,51,53,55,56,59,61,63,65,66,69-73]. The middle group of 13 studies contains either implementation or operating activities, in addition to consequences [22,23,25,26,28,30,32,43,47,52,57,62,68]. Finally, the 14 studies on the right do not consider implementation and operating activities but only focus on the consequences [20,21,27,33,45,46,48,49,54,58,60,64,67].
Prominent and Lacking Features

Tables 1-3 also show that some components have received more attention than others. Concentrating on the different consequences, we observed the following: If patient outcomes are considered, the focus lies on physical outcomes [30,32-34,43,44,46,47,54,55,59-61,68] and quality of life or quality-adjusted life years [24,35,36,39-41,44,50,52,62,71,73]. Productivity loss because of time absent from work received less attention, with only 4% (2/55) of the studies incorporating it [44,62]; however, this outcome is understandable given that our review focused on the population of older persons, which predominantly no longer participates in the labor market. In terms of resource utilization, there is a strong emphasis on home care visits, indicated by 49% (27/55) of the included studies [21-25,28-32,34,37-39,49-51,55-57,61,64-67,69,72], and hospital usage covered, indicated by 73% (40/55) of the included studies [21,24,25,27-31,33,34,36-59,65-68,70,71,73]. This outcome can be explained by many of the included studies relying on remote monitoring or virtual visits to substitute for home care visits or to prevent exacerbations that lead to hospital admissions.

Comparing the consequences for professional caregivers and informal caregivers, it becomes obvious that certain elements are missing across all included studies. For instance, 4% (2/55) of the included studies considered the satisfaction of professional caregivers (in general or with the device) [20,25]; however, the satisfaction of informal caregivers was not captured in any of the included studies. Similarly, for professional caregivers, 20% (11/55) of the included studies captured the travel time to patients’ homes [20,25,28,30-32,49,51,56,63,65,70]; however, this aspect was neglected for informal caregivers. Conversely, for informal caregivers, emotional burden and well-being were captured by 4% (2/55) of the included studies [66,72], whereas none of the included studies focused on these 2 aspects for professional caregivers.

Our final observation relates to the research and development (R&D) costs of eHealth applications. In fact, none of the included studies considered R&D costs, which is understandable from the perspective that these costs have already been spent by the time that the eHealth application is set up and running. However, it implicitly assumes that R&D costs only occur before the eHealth intervention is set up and that there is no ongoing refinement.

Discussion

Principal Findings

We conducted this review to establish a framework of costs and benefits considered in the economic evaluations of eHealth applications that support the independent living of older persons. Our search identified 55 papers that conducted economic evaluations. All of the identified papers focused on independent living of older persons in their role as patients with one or more chronic conditions. The identified papers considered a range of different types of costs and benefits. Costs pertain to implementation activities and operating activities related to eHealth applications. Benefits (or consequences) can be categorized according to stakeholder groups, that is, patients, caregivers, and health care provider organizations. These benefits can be further divided into stakeholder-specific outcomes and resource utilization. Some cost and benefit types have received more attention than others. For instance, patient outcomes are predominantly captured via quality-of-life considerations and various types of physical health status indicators. From a resource utilization perspective, a strong emphasis is placed on home care visits and hospital usage. One reason for this emphasis is the frequency in which studies focus on remote monitoring to prevent unnecessary hospital admissions or to substitute for home care visits.

Our data extraction also revealed a set of elements that have not been considered across all of the identified papers, including...
travel time and satisfaction of informal caregivers, emotional burden and well-being of professional caregivers, and last but not least, the R&D costs of the eHealth application. The reasons why these aspects have been neglected can be manifold: they might have been irrelevant from the perspective from which the economic evaluation was carried out, they might have been unobservable because of long time lags beyond the time frame of the evaluation, or it might have been infeasible to capture and quantify these aspects because of methodological obstacles or data unavailability. That the initial R&D costs of the eHealth applications have not been considered can be justified with the sunk cost argument—by the time that the evaluation takes place, the R&D costs have already been spent. In this sense, the eHealth application is considered a static technology. In the longer run, however, the eHealth application might require an upgrade to comply with new laws and regulations, for reasons pertaining to data privacy, data security, data storage, or improvements in usability. Whether these upgrade costs are indeed relevant for future economic evaluations depends on the perspective and time frame.

Like any other technology, eHealth applications are subject to change. Fueled by the increasing availability of data, changes in law and regulations and improved usability, new fields, and areas of applications might emerge. Our framework is based on eHealth applications currently in place. Future eHealth applications might generate costs and benefits that are different from the eHealth applications on which our framework is based.

**Implications for Research and Practice**

Economic evaluations of eHealth applications are gaining momentum, as indicated by the increasing number of publications and reviews [74,75]. Health economic frameworks and principles are described, and the steps to measure costs and benefits are emphasized [14,15]. Our review directly connects to the measurement aspect by focusing on its first step, that is, the identification of costs and benefits. We contribute to the body of literature by providing a detailed and up-to-date framework of cost and benefit categories.

If we consider eHealth, there are many stakeholders involved, such as patients, eHealth suppliers (formal and informal) caregivers, funding bodies, health authorities, and so on. Notably, these stakeholders are likely to attribute different values to eHealth applications because they are affected differently by their costs and benefits. This fact has consequences for investment and funding decisions, and it has long been argued that decision making remains hampered by the lack of reliable cost and benefit estimations [14,15]. To obtain reliable cost and benefit estimates, our framework could be of help by providing a starting point for the identification process. Our framework can support this goal: however, the measuring and valuing process must be context-specific and tailored to the case at hand. How to value components that, for instance, do not lend themselves naturally to being quantified in countable units, such as the feeling of safety [76], is worthy of study in itself and beyond the scope of our review. The variety that we observe in terms of costs and consequences considered in the economic evaluations and the type of analysis performed and the extent to which the costs and consequences are integrated indicates that the field has not yet reached consensus on a standard procedure for determining eHealth value. Whether and to what extent the observed variety is actually linked to the quality of the economic evaluation is an interesting avenue for future research.

Financial costs directed to patients or informal caregivers might be an obstacle to using the eHealth service or application or continuation of usage of these services, especially in countries where mandatory health insurance coverage is lacking. Although a recent study in the Netherlands identified finance as a factor not significantly related to intention to use medical apps among older persons [77], future studies should focus on how the costs are covered and who should pay for the direct or indirect costs of eHealth.

**Conclusions**

A holistic and reliable value assessment of eHealth applications requires a profound understanding of the applications’ costs and benefits. The first step in measuring costs and benefits is identifying the relevant costs and benefit categories that the eHealth application affects. We conduct a scoping review to support this identification process by providing an overview of the direct and indirect costs and benefits that economic evaluations have incorporated so far. Our cost-and-benefit framework is particularly useful in the context of eHealth applications that support the independent living of older persons. As this patient group is expected to be increasingly targeted to applications that support the independent living of older persons [77], future studies should focus on how the costs are covered and who should pay for the direct or indirect costs of eHealth.

**Acknowledgments**

This work was supported by Dutch ZonMw grant number 639003401. The authors would like to thank Wichor Bramer from the Erasmus MC Medical Library for developing and updating the search strategies. The authors further benefited from discussions with the project team Value-Driven eHealth, that is, Rachita Auragh, Karlijn Cranen, Tyrell Creton, Marleen de Mul, and Mildred Visser and their collaboration with Henk Herman Nap (Vilans) and Eveline Wouters (Tilburg University and Tranzo).

**Authors’ Contributions**

All authors have contributed to the conception and design of the review, that is, specifying the inclusion and exclusion criteria (SS, HE, MA, AW, and RH), abstract and title screening (SS, HE, AW, and RH), full-text screening, and data extraction (SS and
HE). SS and HE drafted the manuscript. MA, AW, and RH worked on the revisions of the paper. All authors provided feedback on the multiple draft versions. SS finalized the revisions.

**Conflicts of Interest**

None declared.

Multimedia Appendix 1

Search strategy.

[PDF File (Adobe PDF File), 114 KB - jmir_v23i3e24363_app1.pdf ]

Multimedia Appendix 2

Type of eHealth intervention, patient population, country, and analysis type.

[PDF File (Adobe PDF File), 175 KB - jmir_v23i3e24363_app2.pdf ]

**References**


Abbreviations

CBA: cost-benefit analysis
CEA: cost-effectiveness analysis
CUA: cost utility analysis
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analysis
R&D: research and development

© Sandra Sülz, Hilico J van Elten, Marjan Askari, Anne Marie Weggeelaar-Jansen, Robbert Huijsman. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 09.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research.
Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Effort-Optimized Intervention Model: Framework for Building and Analyzing Digital Interventions That Require Minimal Effort for Health-Related Gains

Abstract

The majority of digital health interventions lean on the promise of bringing health and self-care into people’s homes and hands. However, these interventions are delivered while people are in their triggering environments, which places competing demands on their attention. Individuals struggling to change or learn a new behavior have to work hard to achieve even a minor change because of the automatic forces propelling them back to their habitual behaviors. We posit that effort and burden should be explored at the outset and throughout the digital intervention development process as a core therapeutic mechanism, beyond the context of design or user experience testing. In effort-focused conceptualization, it is assumed that, even though goals are rational and people want to achieve them, they are overtaken by competing cognitive, emotional, and environmental processes. We offer the term effort-optimized intervention to describe interventions that focus on user engagement in the face of competing demands. We describe design components based on a 3-step process for planning an effort-optimized intervention: (1) nurturing effortless cognitive and environmental salience to help people keep effort-related goals prominent despite competition; (2) making it as effortless as possible to complete therapeutic activities to avoid ego depletion and self-efficacy reduction; and (3) turning the necessary effortful activities into sustainable assets. We conclude by presenting an example of designing a digital health intervention based on the effort-optimized intervention model.

Introduction

Effort is physical, mental, or emotional exertion in an attempt to meet a goal. The effort exerted by an individual depends on the interplay between internal (eg, cognitive ability, motivation) and external (eg, social and environmental) facilitators and the barriers between an individual and their desired objective [1,2]. Substantial research has highlighted that reducing the effort needed to achieve an objective will increase the likelihood of achieving that objective in contexts ranging from consumer behavior to friendship [3]. The modern consumer technology industry has essentially been built on the premise of reducing the complexity and number of steps needed to reach desired objectives. Subsequently, the majority of digital health interventions have leaned on the promise of bringing health and self-care into people’s homes and hands, overcoming the barriers to traditional services such as distance to a clinic, transportation, childcare, and more [4-8].

Despite the fact that digital interventions have significantly expanded their reach, with tens of millions of app downloads, the retention rates across the range of digital interventions remain very poor, with only 4% of behavioral health app users continuing use after 15 days [9]. Subsequently, findings suggest that user engagement with a digital intervention is 4 times higher.
under trial in comparison with the use of the same intervention in the real world [10]. A recent report [11] on the use of MindSpot, an Australian digital mental health service may shed light on this phenomenon—the researchers reported an increase in the proportion of users looking for confidential assessment and a substantial decrease in the proportion of users looking for a traditional course-based internet intervention [11]. This suggests that many users are expecting far shorter therapeutic encounters such as microinterventions [12] compared with what would have been traditionally expected from users engaging digital health interventions.

We propose that a primary challenge with user engagement in digital interventions is that individuals who are struggling to change must work hard to achieve even a minor change because of the automatic forces propelling them back to their habitual behaviors [13-15]. Substantial literature has emphasized the continuum of automatic processes driving psychological distress and effortful processing fostering psychological health [16,17]. Not surprisingly, those with severe addiction and mental health disorders typically require a higher level of care (eg, inpatient care) to reduce the severity of symptoms in a controlled environment where recovery is the most salient cue. In effect, individuals have the headspace to work on their goals without being bombarded by environmental cues [18].

An effort-focused intervention model changes our conceptualization in the sense that we assume that goals are rational and that people want to achieve them. However, competing events in people’s lives either require less effort or are more salient. As the next generation of digital health interventions is developed, we argue that an exploration of effort and burden should form the baseline for intervention development.

Existing Literature on Effort Reduction

The fields of user experience, heuristic evaluation, and persuasive design focus on principles such as user control, simplicity, predictability, and satisfaction specifically designed to increase engagement [19-21]. The outputs of these efforts range from autofill opportunities to 1-click shopping and frictionless feeds. In behavioral economics, effort reduction is often achieved with a default option [22]. For example, in their seminal paper on organ donation, Johnson and Goldstein [23] posited that one of the mechanisms of increased donations is that “making a decision often involves effort, whereas accepting the default is effortless.” Environmental engineering theory, popularized by books [24], and seminal studies [25] on manipulating availability and access to different foods have revealed that reducing cognitive effort by making healthier choices available and unhealthy choices more burdensome to obtain improves healthy behaviors significantly and unconsciously. Underlying gamification presents perceived effort reduction by enhancing reward and reinforcement while pursuing a goal in a fun and engaging way [26]. Subsequently, a recent review [27] has shown that clinical applications that reduce the effort required from participants to engage in a desired response decrease self-injurious behavior, decrease pica, and increase appropriate eating.

These approaches are used often in the digital behavior change, supplemented by targeted persuasive intervention design for behavior change. For example, the Fogg model introduced the concept of the trigger into social-cognitive theory [28,29], that is, triggers presented at the right time in the right context reduce cognitive effort and increase motivation. More comprehensive taxonomies and persuasive models have been developed to identify core elements of behavior change interventions that drive engagement. For example, Oinas-Kukkonen and Harjumaa [30] developed a set of principles to build sustainable interventions that include concepts such as tunneling and choice reduction to foster engagement. Michie and colleagues [31] have developed a set of core behavior change principles, in which effort-reduction is implied, to guide intervention development heavily focused on learning theory and shaping behavior.

One of the reasons text-messaging interventions are acceptable may not be because they are just-in-time interventions, but rather, because individuals do not have to do anything except passively receive a text message once they sign-up. Text-messaging interventions have higher engagement over time than app-based interventions for perhaps no other reason than their effortlessness. For example, after 10 months of being signed up for the Text4Baby SMS intervention, 74.4% of mothers were still receiving messages [32]. To further increase sustained engagement the study [32] reported that “the extra step required to update the service with the birth date is being removed in case this has been a barrier to maintaining participation.”

We are not positing that the focus on effort reduction is a new phenomenon. We are suggesting that effort reduction is often overlooked by our field as we develop interventions from the outset and at every stage of intervention engagement. The theories described above such as tunneling, persuasive design, and gamification are methods that reduce effort as a passive result of the optimal state rather than by the design goal of fostering such a state. If we focus on gamification alone, for example, we may miss opportunities for effort reduction at every stage of the behavior change process; however, if we focus on effort reduction, gamification will likely be included as one task within a larger effort-optimized intervention model.

Effort Optimized Intervention Model: Fostering Effortful Behavior by Making it as Effortless as Possible

We offer the term effort-optimized intervention to describe interventions that focus on generating engagement with processes of therapeutic change in the face of competing demands. Here engagement refers to the time window of the intervention itself which may vary—mostly stretching from days to months [12]—and refers to the notion that the user has to engage with the intervention for the targeted time window for it to reach a desired impact. Understanding effort optimization starts with the question “what is the lowest burden method to trigger behavior change?” For example, if one is
trying to reduce arousal before bedtime, interventions may require a range of engagement levels (Figure 1).

Exploring the continuum of required effort enables the selection of interventions that meet individuals where they are in terms of motivation, ability, and barriers [28]. A person with almost no self-efficacy in changing a behavior may easily change the display options on their mobile phone to reduce blue light after 8 PM but may be unlikely to engage in guided paced breathing. At the same time, there may be no barriers to creating additive models of effortful engagement for those who are motivated and engaged. Unfortunately, the majority of effort targets for behavioral and mental health have fallen on the higher end of the spectrum. As a result, we are required to optimize effortful behaviors in times when we cannot make them fully effortless or passive.

We describe a 3-step process in the design of an effort-optimized intervention sequence, involving (1) nurturing salience to increase the chance of desired behaviors occurring in the face of competition; (2) making it as effortless as possible to complete therapeutic activities in order to avoid ego depletion and self-efficacy reductions; and (3) turning the necessary effortful activities into sustainable assets.

Figure 1. Effortless to effortful intervention examples.
Availability is the ease with which one is able to think about the target object at a given time point. A simple way to manipulate an object’s availability is to trigger it using just-in-time mobile reminders or environmental triggers [33]. Critically, availability can be manipulated cognitively by priming people to think in a certain manner at a given time point, thus creating automaticity [34]. Presenting a certain object can prime a goal-directed behavior in the direction of the desired target, whether it be by using words associated with homophobia to increase implicit antigay bias [35], holding a warm object to increase altruism [36], or using the words “substance abuser” or “person with a substance-use disorder” to manipulate individuals’ assumptions about whether someone should go to jail or to treatment [37]. These examples are congruent with the notion that creating cognitive prominence can trigger goal-directed behaviors without having to overtly instruct someone to be more mindful of a goal. Availability can also be triggered overtly through motivational reminders and environmental cues embedded in just-in-time digital interventions [38]. The end goal is to increase goal availability during an effortful decision by reducing the amount of effort needed to retrieve the information.

An object is actionable when the person knows exactly what to do to achieve the desired outcome and how to do it at a given time point. The steps must become salient so that some action can be taken when goal-striving is triggered. Implementation intentions are priming methods that create if–then statements to trigger attention for a future desired outcome by making the association between a trigger and the resulting step-by-step behavior more immediate and less effortful [39,40]. Implementation intentions consist of a basic 2-step process to increase actionable behavior toward a goal, for example, (1) “when I sit down for dinner” (trigger); (2) “I will ask everyone to talk about one thing they are grateful for before I put the first bite in my mouth” (script). Other examples include online graphic illustrations and scenario-based scripts [41] to accompany text guidance. Using graphics targets different memory mechanisms and can help make a script more accessible from multiple pathways.

### Table 1. Summary of the effort-optimized intervention 3-step design process and related components.

<table>
<thead>
<tr>
<th>Component</th>
<th>Explanation</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nurturing salience</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increasing task or goal availability</td>
<td>How easy is it to think about the goal compared to competing demands at a desired time point?</td>
<td>Just-in-time text messaging or push notifications about the targeted task; using implementation intentions to mark dinner as an environmental cue for a parent to conduct a family gratitude exercise</td>
</tr>
<tr>
<td>Creating an actionable script</td>
<td>Triggering a step-by-step script to convey exactly what to do to foster the automaticity of the script during the task</td>
<td>Embedding a simple step-by-step app guidance for parents learning what to do in the face of their child’s panic attack</td>
</tr>
<tr>
<td>Incentive salience for a task or goal</td>
<td>A cognitive process that includes an automatic motivational component that links a person’s desires to a rewarding stimulus to create a feedback loop toward behavior change</td>
<td>Offering a meaningful immediate reward through the app such as celebration of a successful running exercise</td>
</tr>
<tr>
<td>Optimizing novelty</td>
<td>Avoiding habituation by not presenting similar stimuli over and over again and varying the affective impact on the individual</td>
<td>Changing the delivery medium of inspirational motivational messages from text, video, and audio across a program</td>
</tr>
<tr>
<td><strong>Making the completion of therapeutic activities as effortless as possible</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting graded tasks</td>
<td>Determining small and achievable goals, and moving forward in small steps</td>
<td>A mobile app beginning running distance at 0.5 km and gradually stepping the user up to 5 km</td>
</tr>
<tr>
<td>Setting dynamically tailored tasks</td>
<td>Adapting to the user’s state based on passive data tasks they care about and past failures and successes</td>
<td>When it takes more time for the user to acquire a skill, they receive additional features from the program prior to moving forward.</td>
</tr>
<tr>
<td>Reducing the effort required to engage in therapeutic activities</td>
<td>Keeping all relevant tools available in-house; making it as easy as possible to perform the activity</td>
<td>Taking a photo of a meal through the app which analyzes it to document calorie intake; automatically triggering changes to screen color temperature based on time of day</td>
</tr>
<tr>
<td><strong>Turning effort into assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documenting and reflecting on past effort-related activities in a meaningful way</td>
<td>Turning effort into assets by documenting and reflecting on aspects users care about during the therapeutic process; once assets are made, users are inclined to keep investing so that their assets will not go to waste</td>
<td>Presenting effortful activities the user conducted (eg, user reports on socializing with a friend) and how these activities are helpful (eg increase life satisfaction other time)</td>
</tr>
<tr>
<td>Turning effort into a meaningful narrative</td>
<td>Helping people acknowledge the link between the effort they just exerted and their commitment to the therapeutic process</td>
<td>Upon reporting a positive interaction with their child, parents are asked to celebrate investing effort in becoming better parents</td>
</tr>
<tr>
<td>Reframing effort as positive</td>
<td>Embedding a narrative in which the reward is the respect for asserting effort beyond skills acquisition</td>
<td>Encouraging users who finished an online learning on coping with depression by stressing out how this activity shows their commitment to feeling better</td>
</tr>
</tbody>
</table>
The rewarding aspect, defined as **incentive salience**, is a cognitive process that includes an automatic motivational component that links a person’s desires or actions to a rewarding stimulus [42]. Incentive salience creates a feedback loop by which promise of the reward drives a person’s attention. When it comes to behavior change in a person’s natural environment, we assume that the reward for maladaptive behaviors such as parents yelling at their kid to “shut up” will be immediate (silence). Changing a person’s behavior to adopt better practices requires significant effort and the promise of long-term rewards (eg, reducing behavior problems). Technological advances such as immersive virtual reality experiences, neurostimulation, and even actively targeting incentive salience by manipulating immediate rewards can create a reward-based feedback loop for behavior change. Immediate rewards can be produced by rewarding the attempt at the behavior and not the outcome (eg, making sure the parents understand that they are being evaluated based on their responses and not based on their child’s behaviors and immediately celebrating their successes in improving their daily practices).

When we teach or ask the user to conduct a new internal (eg, cognitive reframing) or external (eg, exposure) therapeutic process or activity, the quality of our digital message delivery also affects how salient the targeted process will be in the user’s mind. The more immersive, tangible, relatable, and personally tailored the message is, the more salient the targeted process will be. For example, when teaching a user to conduct an exposure paradigm, using automated scenario-based learning with video tutorials and relatable figures will be more immersive cognitively than explanations with texts; a text correspondence through an automated system that asks several questions and then provides personalized feedback and personalized motivational messaging that are meaningful in one’s life will be emotionally more salient than general statements. Furthermore, because stimulus quality plays a significant role in drawing the user’s attention, we must think about how to avoid habituation by not repeatedly presenting similar stimuli [43]. In effect, using novelty, such as changing the delivery medium, message type, and content, is key to maintaining user attention over time.

Finally, because the developers’ goal is to design an effort-related intervention sequence that is sustainable in people’s lives, they have to think about embedding these activities in an environmental context that will then serve as a natural environmental cue [44]. This enables the desired activity to be automatically triggered without having to draw attention to it—a requirement in the first steps of process acquisition. For example, when a desired positive interaction is to share a funny story with their child, parents could be prompted to do this during dinner. In this case, the developer views dinner time as an environmental cue.

From a public health perspective, when an individual is required to engage with a digital health intervention, it also means that unhealthy cognitions become more salient in the individual’s mind—they are available, rewarding, and actionable—otherwise, this person would not need an intervention. Therefore, examining the interaction between salience, effortful behavior, and motivation can help us to understand the type of salience manipulation needed in a particular intervention sequence.

**Promoting Desired Activities**

Figure 2 presents a model that describes the probability of an activity occurring in the face of competing activities as a function of effort, motivation, and salience. This conceptualization follows Fogg’s [28] work on determining the probability of a behavior occurring following a trigger based on the relationship between ability and motivation. We use effort instead of ability to stress the importance of subjective experience, which can fluctuate mainly due to levels of effort expenditure prior to a task and the available ego strength available to complete a task.

As shown in Figure 2, the probability of a behavior occurring is based on the relationship between effort and motivation. Activities located on the same curve have the same probability of occurring either because they are less effortful or because they are more motivating. Furthermore, if 2 prompted events compete over resources (eg, whether parents either yell at their kids or take deep breaths and try to calmly educate them), the activities located on a higher curve have a higher probability of occurring (that is, B will have a higher chance of occurring than A). Salience plays a crucial role in this process. Manipulating the salience of the desired activity (ie, making it more available, rewarding, and actionable) has the potential to increase the chances of the activity occurring in the face of competition by making the activity either more motivating or less effortful.

Availability increases the effortlessness of the targeted behavior because, in one’s subjective experience, there are fewer competing or available activities. For example, having a playlist on the way home from work that includes a 1-minute audioclip that discusses the desired pre-evening activity makes it more available in the person’s mind when they arrive home than other activities.

Actionability increases both effortlessness and motivation. For example, parents are presented with a tangible video that teaches them step-by-step what to do when their child misbehaves (scenario-based learning), then they must confirm their understanding using a worksheet in which they write their own step-by-step process for the exact targeted behavior and print it out, and later that week, when their child acts in a certain way, they can easily identify the event and know exactly what to do. Consequently, they need to exert less effort to identify the trigger and decide on the action.

Incentive salience involves making the reward clear, tangible, and relatable. For example, a parent drives home from work and is prompted to listen to a 1-minute motivational audioclip on the significance of playing together with their child—an audioclip that also directs them to reflect on their time playing with their parent and how meaningful it was. The novelty and emotional activation of this exercise increases the prominence of the reward and the availability of the desired behavior (which, as suggested, also reduces the effort exerted when performing this activity).
Making the Completion of Therapeutic Activities as Effortless as Possible

Overview
Developing models that are available, actionable, and rewarding require some effort at the outset of the behavior change process in order to reduce the effort exerted during daily goal-directed behaviors. This approach must also be accompanied by making the tasks themselves as effortless as possible.

Setting Graded and Dynamically Tailored Therapeutic Activities as Targets
The literature points to the importance of setting graded tasks, determining small and achievable goals, and moving forward in small steps as the user succeeds in prior steps [45]. Breaking a distal goal into achievable subgoals increases self-efficacy [46], which has been shown to be an important factor in determining whether a task will be initiated and successfully performed. From a behavior change standpoint, when using graded tasks, less effort is required for each activity. This increases the user’s ability to engage in the task, thereby increasing the chances that the triggered activity will occur [28,40,44]. Critically, the use of graded tasks also involves improvement of the user’s skills or condition in such a way that the next task becomes less effortful to achieve, as highlighted in shaping paradigms [47]. For example, when an untrained user is triggered by an app to run 5 km for the first time, the amount of effort required to complete this activity may be very high. However, if the user is triggered to run 1 km several times and then 3 km in a graded manner, the amount of effort related to running 5 km might be as little as it was to run 1 km for the first time.

One psychological technique that is not very common in digital interventions (though it could be easily incorporated) is the presentation of an artificial step prior to a subsequent step that otherwise might demand too much effort to complete. For example, when parents are taught to present an appropriate nonharsh consequence in the event of their child’s disobedience [48,49], this step may feel like a giant leap, thus demanding plenty of effort in the parents’ mind. We may, therefore, create another step of setting expectations for which parents are directed to sit with their child prior to changing the way they react to them and to simply present the fact that they are going to do whatever they can to help them, meaning the rules of the house are going to change. This strategy enables parents to acquire self-efficacy in a small manner prior to anything else and could be easily incorporated in an adaptive digital program.

As implied, the adaptive nature of the tasks involves taking the user’s state into account. User level of motivation is a moderating factor in determining the amount of effort the person is able to exert. Motivation is expected to fluctuate during the intervention based on prior successes and failures [50]. Users who encounter difficulties may require a different task or path than those who found the task easy to complete based on the interplay between self-efficacy, motivation, and goal achievement. Monitoring activities and user condition will enable the task to be dynamically tailored such that the effort required at any given moment is adequate. For example, adaptive goal interventions change the goal based on the user’s successes or failures in achieving the goal, such as by increasing the...
number of weekly drinks allowed in a drinking moderation intervention when goals are not being met or, conversely, by changing to abstinence if moderation is being met with repeated failures. The real-time adaptation of the digital intervention is effort-optimized to meet the user’s goals, motivation, and commitment [51].

Reducing the Effort Required to Engage in Therapeutic Activities

Developers can help to make therapeutic activities less effortful by reducing the cognitive and environmental effort required to successfully complete each activity [52-54]. Keeping all the relevant tools for completing a targeted activity within a digital component reduces the cognitive and environmental effort needed to search for those tools elsewhere [55]. It will be easier for users to follow a diet if the diet app makes all the information about the diet, the availability of support groups, and tools to document calorie intake available in-house [55].

Another aspect to consider is whether each tool makes it as easy as possible to conduct the desired activity [56,57]. For example, it would be easier for users to document their calorie intake if they could simply take a photograph of the meal and have the caloric results calculated automatically. Similarly, when training a behavior increases performance, a system can help to reduce the effort required for the training by providing the means to rehearse it [30]. Think, for example, of a person who is trying to overcome social phobia through graded tasks and who is now being asked to chat with a person they do not know in a nonjudgmental environment. In such an instance, providing an option of a click-button within the digital platform to connect them with a trained peer [58] would directly reduce the effort required.

Turning Effort Into Assets

An effort-optimized intervention does not mean that there is no effort on the part of the user. Indeed, effort contributes to sustainable change because the effort people are choosing or willing to make and the way they perceive it substantially impact the therapeutic process, intervention gains, and future effort capacity. Humans think in narratives with players, good and evil, conflicts, and dramatic changes in the plot [59]. Stories create structure because they have an inner rationale that corresponds with the past-present-future tenses, which enables people to predict the future based on the past. Therefore, people are built to create meaning based on their present experiences in a way that rationally fits with their past story and future direction, as captured in their identity, role in the world, and desires [59].

Effort is a very important ingredient in this process because the effort exerted for an activity will be used to create a meaning that mostly fits within the story we tell about ourselves. Experiments on cognitive dissonance theory and placebo effects strengthen this notion by showing that people who are asked to put more effort into an assignment later perceive it as being more meaningful to them [60]; meanwhile, people who pay more find a placebo to be more helpful [61]. Furthermore, several studies have suggested that people prefer to exert effort on a task when they are motivated to enhance their feelings of relatability, ownership, and control over the potential outcome. A notable example involves a US company that produced instant cakes (“just add water”) in the 1940s targeting women maintaining their households. The product did not sell very well until the company removed some ingredients from the mix, such as eggs and milk, which required the baker to do more work during the baking process. It seemed that, with the increased effort, the baker felt greater ownership over the result and more deserving of the compliments for their work [62]. This phenomenon is described by Ariely as the Ikea effect—a cognitive bias that leads us to place higher value on things that we help to create [62].

To summarize, effort is a crucial ingredient in the way we create meaning because the amount of effort we invest in an activity impacts the extent to which we build meaningful stories around that activity. Specifically, the more effort we invest in something, the more meaningful we find it and the more committed we are to it. To take a literary example, when the Little Prince tries to explain to the fox what makes his rose different from the thousands of roses that appear to be identical, “It is the time you have wasted for your rose that makes your rose so important,” he asserts [63].

Understanding this dynamic is key, as interventions that focus only on effort reduction and do not help people to feel that they have choice, acknowledge their work, and therefore, create meaning around the effort-based behaviors may fail in helping people to stay on the beneficial pathway when new challenges arise. In digital health interventions, people’s efforts can be translated into assets by helping them to acknowledge the meaning of their work. In this way, we reframe effort as something positive by stressing that the effort exerted shows the user’s commitment to and ownership of the therapeutic process. This shift toward a growth mindset and meaning-based acceptance can be embedded in all our work to increase effortlessness and decrease efficacy reductions based on an outcome mindset.

People’s efforts can be turned into investment by documenting the aspects they care about during the therapeutic process [55,64]. Because users have already invested in the activity and created some assets, they are more inclined to move forward and keep investing in this path so that their assets will not go to waste. We stress that the desired documentation should be connected to aspects that are highly meaningful in people’s lives, mostly within a social context, such as the time they got to spend with loved ones because they successfully executed an intervention’s task.

These three components of nurturing salience, reducing effort to engage in therapeutic activities, and shifting the meaning of effortful behavior to become an asset can be embedded in both new and existing digital interventions. Whether it be by creating a simple visual diagram of the goal of a lesson at the beginning of a module, playing music in the background randomly to keep users engaged while completing a task, or including a narrative of an effortful journey during periods of declining motivation, we can reduce the effort needed for users to achieve positive outcomes. In turn, this will enable users to achieve their goals.
without taking away from the core therapeutic skill components of many interventions.

**Designing a Digital Health Intervention Sequence Based on the Effort-Optimized Intervention Model**

To further clarify the effort-optimized intervention model and how to design a digital intervention sequence accordingly, we provide an example using common intervention content in parent training programs for young children with disruptive behavior disorders [65-67] aimed at increasing the positive interactions between parent and child. For brevity, we only discuss the aspects of effort optimization during skill acquisition time, not other important aspects such as persuasive design or the therapeutic alliance nurtured between the user and the program [52,68-70]. Our baseline is a standard digital parent training intervention in which parents complete a short interactive module about positive parenting practices. Parents are instructed to increase the positive interactions at home and then directed to the next module a week or two later, depending on success.

Planning an effort-optimized intervention begins with defining the task, considering how it might be perceived by the participant, and identifying competing activities or challenges. In our example, the task is to increase positive interactions when the parent and child are in the same surrounding (eg, at home). For parents, it can be difficult to foster positive interactions because it is not always highly enjoyable at first, especially for those who have not naturally exercised such practices before; parents might not have clear ideas about such interactions and how easily they can be incorporated on a daily basis. Furthermore, such interactions are not necessarily linked to a tangible clear reward. We offer a few common competing events which may require less effort than nurturing a positive interaction with the child (although they are not based on empirical studies, it is important to use clear examples here for didactic reasoning)—by letting a child play a mobile app or watch television which requires much less effort, parents may find that playing with their own mobile device requires less effort and is rewarding in the sense of passing the time, and while parents may have some house chores or work they can do later, finishing them early offers a clear reward. Based on these challenges, developers can use the effort-optimized intervention framework to increase the chances of the desired activity being completed in the face of competition. As shown in Table 2, each concept informs the design of the intervention in a way that is directly related to increasing the chances that users will reach their objective despite competition. First, realizing that parents may want to have positive interactions with their child but lack good ideas, we offer these ideas in a concrete way (eg, ideas for what to discuss in the evening). Second, as we believe that parents may find letting their child watch television to be more rewarding than interacting, we have to address this competing activity both directly by helping parents emotionally connect to the difference between the two activities and indirectly by making the desired activity more salient in their mind. Third, we must acknowledge the parents’ effort in order to create assets that help them feel good about the investment they have made. These considerations result in many new features that are not incorporated in a standard online module-based training environment.
Table 2. Features increasing parent–child positive interactions based on the effort-optimized intervention framework.

<table>
<thead>
<tr>
<th>Component</th>
<th>Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurturing salience</td>
<td>Triggers with relevant content (eg, ideas for what to discuss during dinner) sent in the hour before parents are home from work. Priming parents to ask themselves about opportunities for positive interactions in the face of competing events (eg, thinking that their child would prefer to watch television instead and so not trying) through consistent but variable triggers, such as text questions, motivational scripts, and other minimal cues.</td>
</tr>
<tr>
<td>Rewarding/incentive salience</td>
<td>Triggers connecting tangible rewards to the desired activities: “Think of your best memories with your parent. You putting some effort into playing with your child is something that will be far more memorable to you and him/her than times when you both watched separate screens.” Directing parents to celebrate their positive interactions with their kids and to report on it using a mobile app. Rewarding consistent attempts at behavior over outcomes through the platform (eg, the outcome is engaging in the behavior, not their child’s behavior).</td>
</tr>
<tr>
<td>Creating an actionable script</td>
<td>A tailored list of positive interactions with brief step-by-step instructions based on an online questionnaire parents were asked to complete.</td>
</tr>
<tr>
<td>Optimizing novelty</td>
<td>Sending all triggers above using different delivery mediums (text, audio, and video), timing (time of day, day, special events), and personas (instructor, peers, celebrity testimonial)</td>
</tr>
<tr>
<td>Embedding tasks based on natural environmental cues</td>
<td>Directing parents to find one positive activity to conduct during dinner, such as a gratitude exercise that can be triggered through the mobile device in the right time.</td>
</tr>
</tbody>
</table>

Making the completion of therapeutic activities as effortless as possible

| Setting graded tasks<sup>a</sup> | Asking parents to pick their preferred activities from an list of relevant activities, which automatically creates their own table that is then available on the website and as a printed version. |
| Setting dynamically tailored tasks<sup>a</sup> | Creating a task list based on efficacy and effort. For example, if the parents report very low efficacy or past failures, a first step may be directing parents to sit with their child when the child is watching television and initiating a conversation. |

Turning effort into assets

| Documenting and reflecting on past effort-related activities in a meaningful way | Documenting reports in an accumulated manner on the home page of the app or website that offers rewards based on the level of engagement (eg, the amount of quality time reported so far). If not engaged, simple motivational statements replace effortful behavior rewards. |
| Turning effort into a meaningful narrative; reframing effort as positive | Implementing automated feedback, which presents a narrative of them doing whatever they can to be good parents. For example: “the effort you invested today in trying to play with your kid shows how well you are committed to improve your relationship. You should be proud of yourself.” |

<sup>a</sup>Reducing the effort required to engage in therapeutic activities is embedded in this component as well.

Further Considerations, Future Directions, and Conclusions

Research and implementation of the effort-optimized intervention model demand that considerable attention be paid to some specific aspects. From a theoretical perspective, we need to learn more about what prevents people from performing desired behaviors at the individual level, even when they want to achieve them [2,71]. Studying such instances will enable developers to design user-centric products with relevant effort-optimized intervention sequences. Another line of research could focus on how people sustain beneficial behaviors over time, and more precisely, when and how competing events emerge and what people experience at these times. This knowledge will enable us to understand whether new triggers need to be incorporated into a future time window in order to avoid depletion. Finally, we need to learn how to develop effort-optimized intervention sequences so that they are not intrusive and thus eventually diminish people’s desire and tendency to self-manage their situation.

The mechanistic study of effort reduction has been explored more in the consumer social media and commerce sectors in the form of A/B testing paradigms. In such paradigms, small changes to the user experience are repeatedly tested to optimize engagement, as small changes often lead to massive shifts in engagement (eg, “like” button, frictionless feed, page load time). While there are significant differences among these activities that require little effort with little meaningful long-term reward—and potentially significant negative consequences over time—their success highlights that, to create positive change, our attention as interventionists needs to shift to increase the 3% to 6% engagement rate in health applications. This is especially true given that research has revealed very few differences in outcomes between interventions with differing content or behavior change targets [72]. Effort-optimized intervention paradigms are designed to ensure that equal weight is placed on the content of our interventions and on how we engage and sustain individuals using common processes that adapt to meet individual needs, both in terms of what people need and how they consume and integrate it into their lives.
Conflicts of Interest
AB has received payment for consulting from Pro-Change Behavior Systems. FM has several patents on using vibration, light and electrical stimulation to induce changes in one’s cardiovascular system.

References


58. Baunel A, Correll CU, Birnbaum M. Adaptation of a peer based online emotional support program as an adjunct to treatment for people with schizophrenia-spectrum disorders. Internet Interv 2016 May;4:35-42 [FREE Full text] [doi: 10.1016/j.interv.2016.03.003] [Medline: 30135788]


63. de Saint-Exupéry.


The Reliability of Remote Patient-Reported Outcome Measures via Mobile Apps to Replace Outpatient Visits After Rotator Cuff Repair Surgery: Repetitive Test-Retest Comparison Study for 1-Year Follow-up

Taek Ho Hong¹, MD; Myung Ku Kim¹, MD, PhD; Dong Jin Ryu¹, MD; Jun Sung Park¹, MD; Gi Cheol Bae¹, MD; Yoon Sang Jeon¹, MD, PhD

Department of Orthopedic Surgery, Inha University Hospital, Incheon, Republic of Korea

Corresponding Author:
Yoon Sang Jeon, MD, PhD
Department of Orthopedic Surgery
Inha University Hospital
27 Inhang-ro
Jung-gu
Incheon, 22332
Republic of Korea
Phone: 82 010 8353 3695
Email: ysjeon80@hanmail.net

Abstract

Background: With the development of health care–related mobile apps, attempts have been made to implement remote patient-reported outcome measures (PROMs). In order for remote PROMs to be widely used by mobile apps, the results should not be different depending on the location; that is, remote PROM results performed in locations other than hospitals should be able to obtain reliable results equivalent to those performed in hospitals, and this is very important. However, to our knowledge, there are no studies that have assessed the reliability of PROMs using mobile apps according to the location by comparing the results performed remotely from the hospital and performed at the outpatient visits.

Objective: The purpose of this study was to evaluate the reliability of remote PROMs using mobile apps compared to PROMs performed during outpatient follow-up visits after arthroscopic shoulder surgery.

Methods: A total of 174 patients who underwent arthroscopic rotator cuff repair completed questionnaires 2 days before visiting the clinic for the 1-, 2-, 3-, 6-, and 12-month follow-ups (test A). The patients completed the questionnaires at the clinic (test B) using the same mobile app and device for the 1-, 2-, 3-, 6-, and 12-month follow-ups. Test-retest comparisons were performed to analyze the differences and reliability of the PROMs according to the period.

Results: Comparisons of tests A and B showed statistically significant differences at 1, 2, and 3 months (all Ps<.05 except for the ASES function scale at 3-months) but not 6 or 12 months after surgery (all Ps>.05). The intraclass correlation values between the two groups were relatively low at the 1-, 2-, and 3-month follow-ups but were within the reliable range at 6 and 12 months after surgery. The rate of completion of tests A and B using the mobile app was significantly lower in the group older than 70 years than in the other groups for all postoperative periods (P<.001).

Conclusions: PROMs using mobile apps with different locations differed soon after surgery but were reliably similar after 6 months. The remote PROMs using mobile apps could be used reliably for the patient more than 6 months after surgery. However, it is to be expected that the use of mobile app–based questionnaires is not as useful in the group older than 70 years as in other age groups.

(J Med Internet Res 2021;23(3):e20989) doi:10.2196/20989

KEYWORDS
patient-reported outcome measures (PROMs); location; remote PROMs using mobile application; smartphone; mobile phone; follow-up loss
Introduction

Background
With the dramatically increased penetration rates worldwide [1], at 81% in the United States and 95% in South Korea [2], smartphones are becoming increasingly indispensable in everyday life [3]. A variety of mobile apps for information, communication, education, and entertainment purposes have been developed for smartphones [3], including mobile health care systems. Seto et al [4] developed a mobile phone–based telemonitoring program for patients with heart failure following acute decompensation. Denono et al [5] suggested that postoperative mobile apps after ambulatory lumbar discectomy were effective tools for spine surgeons.

With the development of health care–related mobile apps, attempts have been made to implement remote patient-reported outcome measures (PROMs). Skrepnik et al [6] assessed the impact of a novel smartphone app compared with standard follow-up on mobility following treatment with intra-articular injection in patients with knee osteoarthritis. Armstrong et al [7] evaluated the effect of home monitoring via a mobile app on the number of in-person visits following ambulatory surgery. Most studies reported that patients found mobile apps for remote follow-ups to be convenient, safe, and highly satisfactory [4-8]. Reliable remote follow-ups by mobile health care systems have several advantages over face-to-face follow-ups. In general, follow-up durations of at least 12 months to several years are required for reliable clinical study findings after surgery [9,10]. However, maintaining high rates of long-term follow-up is challenging due to poor patient compliance [10,11]. Remote follow-ups using mobile PROMs are also efficient in terms of health care costs compared to outpatient visits [12]. Considering the difficulty in long-term follow-up [10], the reduction in outpatient follow-ups, and the reduced health care costs [12], PROMs using mobile apps performed outside of clinics may be good alternatives. In order for remote PROMs to be widely used by the mobile app, the results should not be different depending on the location; that is, remote PROM results performed in locations other than hospitals should be able to obtain reliable results equivalent to those performed in hospitals, and this is very important. However, to our knowledge, there are no studies that have assessed the reliability of PROMs using mobile apps according to the location by comparing the results performed remotely from the hospital and performed at the outpatient visits.

Goal of This Study
Therefore, this study evaluated the reliability of remote PROMs using mobile apps compared to the PROMs performed by the same mobile apps during outpatient follow-up visits after arthroscopic shoulder surgery. We also analyzed the tendencies in differences with increasing time after surgery and observed the PROM participation rates of patients according to the follow-up periods with repetitive test-retest studies. We hypothesized that the results of the PROMs would be similar between those measured in outpatient clinic visits and those measured remotely using mobile apps.

Methods

Patients and Study Design
205 consecutive patients who underwent arthroscopic rotator cuff repair by a single surgeon were initially considered for this study between April 2018 and April 2019. Patients diagnosed with large or massive rotator cuff tears were excluded because of the difference in their rehabilitation schedules. Patients with dementia, mental retardation, illiteracy, or inability to use electronic devices were excluded because of the difficulty in completing questionnaires using electronic equipment. After exclusion, the remaining 174 patients (92 men and 82 women) prospectively conducted the test-retest comparisons, which were performed 5 times each to assess the results after surgery. The patients were instructed to complete questionnaires (visual analog scale [VAS], American Shoulder and Elbow Society [ASES] scale [13], and Disabilities of the Arm, Shoulder, and Hand [DASH] scale [14]) at other locations (test A) 2 days before visiting the clinic for the 1-, 2-, 3-, 6-, and 12-month postoperative follow-ups. Using the same app and electronic devices, namely, their mobile phones, each patient completed the same questionnaires at the clinic (test B) at 1, 2, 3, 6, and 12 months after surgery (Figure 1). The patients received mobile messages linked to an app for an electronic PROM system (Proscore, Incheon, South Korea). All patients who visited our clinic answered the same questionnaires with the mobile app before treatment. The timing of mobile messaging was determined to be 48 hours before the clinic visit based on a previous systematic review that reported test-retest reliability [15]. Of the 174 patients, test A (PROMs completed via the mobile app installed on the mobile phone of each patient 2 days before the clinic visit) was completed by 148 at 1 month, 135 at 2 months, 106 at 3 months, 77 at 6 months, and 59 at 12 months. All 174 patients visited our clinic at 1 month after surgery. However, the rates of outpatient visits with patients completing test B using the same app and electronic devices (the mobile phone of each patient) decreased over time, with 170 visiting at 2 months, 142 at 3 months, 112 at 6 months, and 95 at 12 months after surgery (Figure 1). All patients underwent the same course of rehabilitation. An abduction brace was applied for 4 weeks after surgery. Passive range of motion exercises were allowed from 4 to 8 weeks after surgery. Active range of motion exercises were conducted 8 weeks after surgery. This study, including the subject selection and data collection, was conducted under the approval of the Inha University Hospital Institutional Review Board (IRB INHA 2019-09-024) in accordance with the 1964 Declaration of Helsinki.
Scale Definitions and Measures
The VAS score is measured ranging from 0 to 10, with scores of 0 and 10 indicating “no pain” and “worst pain imaginable,” respectively. The ASES scale [13] consists of two subscales, namely, pain (1 item) and function (10 items). Each subscale is transformed to scores ranging from 0 to 50, based on patient responses. The sum of the two scales is the total score on the ASES scale, with a score of 100 points indicating perfect conditions of the shoulder. This study analyzed the total ASES scale score as well as the scores for the two subscales. The DASH scale comprises 30 items (21 on daily activities, 5 on symptoms, 3 on participation, and 1 on confidence in ability) [14]. Higher scores indicate worse upper limb function. We used an electronic PROM system (Proscore, Incheon, South Korea) available as an app for electronic devices that measures VAS, ASES scale, and DASH scale scores at locations other than the clinic. In this system, patients touched the answer on the screen instead of marking their responses on original paper questionnaires using a writing instrument. This change from paper-based to electronic-based measures is minor, according to the Food and Drug Administration guidelines [16].

Statistical Analyses
The data are expressed as means (standard deviations) or medians (ranges). Paired t tests (2-tailed) were used to evaluate differences between the answers for tests A and B; more specifically, the average score with standard deviations of the scale’s scores was calculated and analyzed using paired t tests. We also calculated the average absolute value of the differences between tests A and B. Intraclass correlation coefficients (ICCs) were calculated to estimate reproducibility and reliability between tests A and B. Statistical significance was indicated by P<.05. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp, Armonk, NY).

Results
The demographics of patients undergoing rotator cuff surgery are summarized in Table 1.

The average scores and absolute values of the differences between tests A and B are shown in Table 2 and Figure 2 for the 1-, 2-, 3-, 6-, and 12-month postoperative results. At 1, 2, and 3 months after surgery, test B showed significantly better outcomes compared to those of test A (Ps<.05), except for the ASES function subscale (P=.06 at 3 months). All parameters did not show statistically significant differences (all Ps>.05) between tests A and B at 6 and 12 months after surgery. The average absolute differences in VAS, ASES total, and DASH scores between tests A and B were 1.68, 14.72 and 11.28 points at 1 month after surgery, respectively. In most of the scales, the differences in the average and absolute differences gradually decreased with time after surgery. At 12 months after surgery, the average absolute value differences in VAS, ASES total, and DASH scores between tests A and B were greatly reduced (0.32, 5.48, and 4.46 points, respectively).
Table 1. Baseline demographic and clinical characteristics (N=174).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>59.38 (10.9)</td>
</tr>
<tr>
<td>Gender, female, n (%)</td>
<td>82 (47.1)</td>
</tr>
<tr>
<td>Side, n (%)</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>97 (55.7)</td>
</tr>
<tr>
<td>Left</td>
<td>77 (44.3)</td>
</tr>
<tr>
<td>Symptom duration (months), mean (SD)</td>
<td>11.18 (13.74)</td>
</tr>
<tr>
<td>Tear size, n (%)</td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>96 (55.2)</td>
</tr>
<tr>
<td>Medium</td>
<td>78 (44.8)</td>
</tr>
</tbody>
</table>
### Table 2. Mean (standard deviation) for each scale by 1-, 2-, 3-, 6-, and 12-month postoperative data analyzed by paired $t$ test or Wilcoxon signed rank test (N=174).

<table>
<thead>
<tr>
<th>POD and scale</th>
<th>Test A, mean (SD)</th>
<th>Test B, mean (SD)</th>
<th>Differences</th>
<th>$P$ value</th>
<th>Absolute differences$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POD 1 month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS$^c$ score</td>
<td>3.23 (1.69)</td>
<td>1.96 (1.16)</td>
<td>1.27</td>
<td>&lt;.001</td>
<td>1.68 (1.23)</td>
</tr>
<tr>
<td>ASES$^d$ total</td>
<td>50.02 (11.78)</td>
<td>60.56 (14.85)</td>
<td>−10.54</td>
<td>&lt;.001</td>
<td>14.72 (10.07)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>29.42 (8.85)</td>
<td>34.32 (11.73)</td>
<td>−4.90</td>
<td>&lt;.001</td>
<td>11.28 (7.53)</td>
</tr>
<tr>
<td>ASES function</td>
<td>20.60 (6.40)</td>
<td>26.24 (7.51)</td>
<td>−5.64</td>
<td>&lt;.001</td>
<td>7.53 (6.26)</td>
</tr>
<tr>
<td>DASH$^e$</td>
<td>64.01 (10.57)</td>
<td>53.82 (11.92)</td>
<td>10.19</td>
<td>&lt;.001</td>
<td>12.94 (9.35)</td>
</tr>
<tr>
<td><strong>POD 2 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>2.44 (1.62)</td>
<td>1.60 (1.17)</td>
<td>0.84</td>
<td>&lt;.001</td>
<td>1.25 (1.04)</td>
</tr>
<tr>
<td>ASES total</td>
<td>54.88 (15.93)</td>
<td>63.68 (12.89)</td>
<td>−8.80</td>
<td>&lt;.001</td>
<td>13.85 (9.41)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>32.55 (12.85)</td>
<td>35.96 (9.35)</td>
<td>−3.41</td>
<td>.003</td>
<td>10.88 (8.28)</td>
</tr>
<tr>
<td>ASES function</td>
<td>22.33 (7.62)</td>
<td>27.72 (8.52)</td>
<td>−5.39</td>
<td>&lt;.001</td>
<td>8.40 (6.46)</td>
</tr>
<tr>
<td>DASH</td>
<td>54.26 (9.82)</td>
<td>48.34 (11.81)</td>
<td>5.92</td>
<td>&lt;.001</td>
<td>9.49 (6.93)</td>
</tr>
<tr>
<td><strong>POD 3 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>2.24 (1.64)</td>
<td>1.54 (1.05)</td>
<td>0.70</td>
<td>.03</td>
<td>1.28 (0.95)</td>
</tr>
<tr>
<td>ASES total</td>
<td>62.73 (12.05)</td>
<td>67.15 (11.62)</td>
<td>−4.42</td>
<td>.01</td>
<td>11.43 (9.10)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>34.57 (9.93)</td>
<td>36.88 (8.00)</td>
<td>−2.31</td>
<td>.02</td>
<td>7.87 (6.36)</td>
</tr>
<tr>
<td>ASES function</td>
<td>28.16 (6.82)</td>
<td>30.27 (7.37)</td>
<td>−2.11</td>
<td>.06</td>
<td>6.60 (5.35)</td>
</tr>
<tr>
<td>DASH</td>
<td>48.10 (9.26)</td>
<td>43.36 (12.32)</td>
<td>4.74</td>
<td>&lt;.001</td>
<td>8.86 (7.06)</td>
</tr>
<tr>
<td><strong>POD 6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>1.06 (0.54)</td>
<td>0.88 (0.70)</td>
<td>0.18</td>
<td>.13</td>
<td>0.46 (0.59)</td>
</tr>
<tr>
<td>ASES total</td>
<td>74.28 (12.15)</td>
<td>77.19 (13.20)</td>
<td>−2.91</td>
<td>.09</td>
<td>8.78 (7.09)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>37.07 (8.86)</td>
<td>39.35 (7.83)</td>
<td>−2.28</td>
<td>.21</td>
<td>5.90 (5.94)</td>
</tr>
<tr>
<td>ASES function</td>
<td>37.20 (7.82)</td>
<td>37.84 (9.69)</td>
<td>−.64</td>
<td>.30</td>
<td>5.26 (4.82)</td>
</tr>
<tr>
<td>DASH</td>
<td>36.64 (10.95)</td>
<td>33.10 (9.54)</td>
<td>3.54</td>
<td>.48</td>
<td>7.73 (4.94)</td>
</tr>
<tr>
<td><strong>POD 12 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>0.83 (0.56)</td>
<td>0.77 (0.58)</td>
<td>0.06</td>
<td>.49</td>
<td>0.32 (0.47)</td>
</tr>
<tr>
<td>ASES total</td>
<td>78.78 (9.07)</td>
<td>79.96 (10.94)</td>
<td>−1.18</td>
<td>.17</td>
<td>5.48 (3.76)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>41.69 (6.53)</td>
<td>42.45 (5.67)</td>
<td>−0.76</td>
<td>.24</td>
<td>3.81 (3.75)</td>
</tr>
<tr>
<td>ASES function</td>
<td>37.08 (7.32)</td>
<td>37.51 (8.87)</td>
<td>−0.43</td>
<td>.32</td>
<td>3.47 (2.80)</td>
</tr>
<tr>
<td>DASH</td>
<td>31.34 (8.81)</td>
<td>30.29 (7.66)</td>
<td>1.05</td>
<td>.19</td>
<td>4.46 (3.74)</td>
</tr>
</tbody>
</table>

$^a$POD: postoperative duration.

$^b$Absolute differences are calculated by taking the greater value minus the smaller one between tests A and B.

$^c$VAS: visual analog scale.

$^d$ASES: American Shoulder and Elbow Society Shoulder Index.

$^e$DASH: Disabilities of the Arm, Shoulder, and Hand score.
To estimate the reproducibility and reliability between tests A and B, ICC values were calculated for each scale and subscale (Table 3). The VAS scale and ASES pain subscale showed relatively low ICC values compared to those of the other scales. The lowest ICC value for the VAS scale was observed at 1 month after surgery (0.51, moderate reliability). The low ICC values for the ASES pain subscale were observed at 1, 2, and 3 months after surgery (0.47, 0.46, and 0.47, respectively; poor reliability). Moderate ICC values were observed for the ASES function subscale at 1, 2, and 3 months after surgery (0.50, 0.53, and 0.67, respectively). At 6 months after surgery, all parameters showed good ICC values (0.77 for VAS, 0.83 for DASH scale, 0.80 for ASES function subscale, 0.78 for ASES pain subscale, and 0.78 for ASES total scale). Regarding the DASH scale, a good ICC value was observed at 6 months after surgery (0.83). The highest ICC values for all parameters were observed at 12...
months after surgery. VAS score, ASES pain subscale, and DASH scale showed good ICC values at 12 months after surgery (0.81, 0.76, and 0.87, respectively). The ASES function scale and the ASES total scale showed excellent ICC values at 12 months after surgery (0.91 and 0.90, respectively).

**Table 3.** Intraclass correlation coefficient values for each scale (N=174).

<table>
<thead>
<tr>
<th>Scale/subscale</th>
<th>Postoperative duration (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>VAS pain</td>
<td>0.51</td>
</tr>
<tr>
<td>ASES&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>0.47</td>
</tr>
<tr>
<td>Function</td>
<td>0.54</td>
</tr>
<tr>
<td>Total</td>
<td>0.5</td>
</tr>
<tr>
<td>DASH&lt;sup&gt;c&lt;/sup&gt; total</td>
<td>0.57</td>
</tr>
</tbody>
</table>

<sup>a</sup>VAS: visual analog scale.
<sup>b</sup>ASES: American Shoulder and Elbow Society Shoulder Index.
<sup>c</sup>DASH: Disabilities of the Arm, Shoulder and Hand score.

The rates of outpatient visits and completions of tests A and B according to the period for each age group are shown in Table 4. At 1 month, all 174 patients visited our clinic. However, with time after surgery, the number of outpatient visits gradually decreased. No significant differences in the numbers of outpatient visits were observed in terms of age ($P=.60, .54, .91$, and $.70$ for 2, 3, 6, and 12 months after surgery, respectively). The rate of completion of tests A and B using the mobile app was significantly lower in the group older than 70 years than in the other groups for all postoperative periods ($P<.001$).

**Table 4.** Visit rate and test-retest response rate by age at each postoperative period.

<table>
<thead>
<tr>
<th>Rates by postoperative period (months)</th>
<th>Age (years), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;50 (n=33)</td>
<td>50-59 (n=51)</td>
</tr>
<tr>
<td><strong>Outpatient visits (visit rate)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>33 (100)</td>
<td>51 (100)</td>
</tr>
<tr>
<td>2</td>
<td>32 (97.0)</td>
<td>51 (100)</td>
</tr>
<tr>
<td>3</td>
<td>28 (84.8)</td>
<td>42 (82.4)</td>
</tr>
<tr>
<td>6</td>
<td>20 (60.6)</td>
<td>32 (62.7)</td>
</tr>
<tr>
<td>12</td>
<td>15 (45.5)</td>
<td>29 (56.9)</td>
</tr>
<tr>
<td><strong>Test-retest responses (response/visit rate)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>32 (97.0)</td>
<td>48 (94.1)</td>
</tr>
<tr>
<td>2</td>
<td>30 (93.7)</td>
<td>45 (88.2)</td>
</tr>
<tr>
<td>3</td>
<td>25 (89.5)</td>
<td>37 (88.1)</td>
</tr>
<tr>
<td>6</td>
<td>19 (95.0)</td>
<td>26 (81.2)</td>
</tr>
<tr>
<td>12</td>
<td>13 (86.7)</td>
<td>22 (75.9)</td>
</tr>
</tbody>
</table>

In this study, 36 of 174 patients (20.7%) completed all follow-up visits (1, 2, 3, 6, and 12 months after surgery) and also completed tests A and B (completely implemented group). We also performed comparisons between tests A and B in this group to determine the average difference for each scale (Table 5). The ICC values between tests A and B in the completely implemented group (n=36) were similar to those for all 174 patients (Table 6). At 1, 2, and 3 months after surgery, test B showed significantly better outcomes than those of test A ($P<.05$), except for the ASES pain subscale and DASH scale. No parameter differed significantly between tests A and B at 6 and 12 months after surgery. The average absolute value of the differences for the VAS, ASES total, and DASH scores between tests A and B were 1.50, 15.97, and 10.28 points, respectively, at 1 month after surgery. In most of the scales, the average and the absolute differences gradually decreased with time after surgery. All parameters showed poor or moderate ICCs at 1, 2, and 3 months after surgery but showed moderate or good values at 6 months and peaked at 12 months after surgery for all parameters. The VAS score, ASES pain subscale, and ASES total scale showed good ICCs at 12 months after surgery (0.80, 0.82, and 0.88 respectively), while the ASES function scale and
the DASH scale showed excellent ICCs at 12 months after surgery (0.92 and 0.90, respectively).

Table 5. Mean (standard deviation) for each scale by 1-, 2-, 3-, 6-, and 12-month postoperative data analyzed by paired t test or Wilcoxon signed rank test in the completely implemented group (N=36).

<table>
<thead>
<tr>
<th>POD and scale</th>
<th>Test A, mean (SD)</th>
<th>Test B, mean (SD)</th>
<th>Differences</th>
<th>P value</th>
<th>Absolute differencesb</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POD 1 month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VASc score</td>
<td>3.05 (1.58)</td>
<td>1.88 (1.06)</td>
<td>1.17</td>
<td>.009</td>
<td>1.50 (1.02)</td>
</tr>
<tr>
<td>ASESd total</td>
<td>51.24 (10.84)</td>
<td>63.19 (13.11)</td>
<td>−11.95</td>
<td>&lt;.001</td>
<td>15.97 (9.92)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>30.27 (9.01)</td>
<td>35.97 (10.33)</td>
<td>−5.70</td>
<td>.02</td>
<td>10.28 (7.35)</td>
</tr>
<tr>
<td>ASES function</td>
<td>20.96 (7.18)</td>
<td>27.21 (7.23)</td>
<td>−6.25</td>
<td>&lt;.001</td>
<td>8.10 (5.97)</td>
</tr>
<tr>
<td>DASHe</td>
<td>64.75 (12.68)</td>
<td>55.48 (11.39)</td>
<td>9.27</td>
<td>&lt;.001</td>
<td>13.41 (8.86)</td>
</tr>
<tr>
<td><strong>POD 2 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>2.41 (1.61)</td>
<td>1.55 (1.22)</td>
<td>0.86</td>
<td>.004</td>
<td>1.47 (1.05)</td>
</tr>
<tr>
<td>ASES total</td>
<td>56.94 (12.20)</td>
<td>66.75 (9.08)</td>
<td>−9.81</td>
<td>&lt;.001</td>
<td>14.81 (9.99)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>33.33 (13.09)</td>
<td>37.78 (8.49)</td>
<td>−4.45</td>
<td>.03</td>
<td>10.01 (7.36)</td>
</tr>
<tr>
<td>ASES function</td>
<td>23.60 (6.75)</td>
<td>28.97 (7.42)</td>
<td>−5.37</td>
<td>&lt;.001</td>
<td>8.14 (5.26)</td>
</tr>
<tr>
<td>DASH</td>
<td>54.20 (9.82)</td>
<td>47.19 (10.20)</td>
<td>7.01</td>
<td>&lt;.001</td>
<td>9.54 (9.15)</td>
</tr>
<tr>
<td><strong>POD 3 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>2.24 (1.64)</td>
<td>1.54 (1.05)</td>
<td>0.70</td>
<td>.01</td>
<td>1.23 (1.09)</td>
</tr>
<tr>
<td>ASES total</td>
<td>62.51 (12.07)</td>
<td>67.15 (11.62)</td>
<td>−4.64</td>
<td>.02</td>
<td>12.73 (9.82)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>34.57 (9.93)</td>
<td>36.88 (8.00)</td>
<td>−2.31</td>
<td>.07</td>
<td>7.77 (6.80)</td>
</tr>
<tr>
<td>ASES function</td>
<td>27.93 (6.65)</td>
<td>30.26 (7.37)</td>
<td>−2.33</td>
<td>.03</td>
<td>7.54 (5.51)</td>
</tr>
<tr>
<td>DASH</td>
<td>48.10 (9.26)</td>
<td>43.36 (12.32)</td>
<td>4.74</td>
<td>.18</td>
<td>8.85 (6.81)</td>
</tr>
<tr>
<td><strong>POD 6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>1.06 (0.54)</td>
<td>0.88 (0.70)</td>
<td>0.18</td>
<td>.12</td>
<td>0.53 (0.60)</td>
</tr>
<tr>
<td>ASES total</td>
<td>74.28 (12.15)</td>
<td>77.19 (13.20)</td>
<td>−2.91</td>
<td>.18</td>
<td>9.16 (7.17)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>37.07 (8.86)</td>
<td>39.35 (7.83)</td>
<td>−2.28</td>
<td>.09</td>
<td>5.69 (6.67)</td>
</tr>
<tr>
<td>ASES function</td>
<td>37.20 (7.82)</td>
<td>37.84 (9.69)</td>
<td>−0.64</td>
<td>.73</td>
<td>5.51 (5.09)</td>
</tr>
<tr>
<td>DASH</td>
<td>36.64 (10.95)</td>
<td>33.10 (9.54)</td>
<td>3.54</td>
<td>.28</td>
<td>6.49 (4.36)</td>
</tr>
<tr>
<td><strong>POD 12 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS score</td>
<td>0.83 (0.56)</td>
<td>0.77 (0.58)</td>
<td>0.06</td>
<td>.17</td>
<td>0.36 (0.48)</td>
</tr>
<tr>
<td>ASES total</td>
<td>78.78 (9.07)</td>
<td>79.96 (10.94)</td>
<td>−1.18</td>
<td>.16</td>
<td>4.67 (3.39)</td>
</tr>
<tr>
<td>ASES pain</td>
<td>41.69 (6.53)</td>
<td>42.45 (5.67)</td>
<td>−0.76</td>
<td>.15</td>
<td>3.61 (3.50)</td>
</tr>
<tr>
<td>ASES function</td>
<td>37.08 (7.32)</td>
<td>37.51 (8.87)</td>
<td>−0.43</td>
<td>.56</td>
<td>3.38 (3.07)</td>
</tr>
<tr>
<td>DASH</td>
<td>31.34 (8.81)</td>
<td>30.29 (7.66)</td>
<td>1.05</td>
<td>.41</td>
<td>3.61 (2.52)</td>
</tr>
</tbody>
</table>

aPOD: postoperative duration.
bAbsolute differences are calculated by taking the greater value minus the smaller one, between tests A and B.
cVAS: visual analog scale.
dASES: American Shoulder and Elbow Society Shoulder Index.
eDASH: Disabilities of the Arm, Shoulder, and Hand score.
The results of this study revealed that the PROMs varied depending on the location for the initial 1-, 2-, and 3-month follow-ups after arthroscopic shoulder surgery. However, at 6 months or more after surgery, the PROMs using the mobile apps showed similar results regardless of location. The ICC analysis also showed a tendency toward relatively low values for 1, 2, and 3 months postoperatively according to the PROM location, while high values were recorded at the 6- and 12-month follow-ups. These findings indicated that PROMs performed using mobile apps at 6 months after surgery were adequately reliable and reproducible regardless of location. Therefore, the use of remote PROMs via mobile apps may be more valuable for follow-ups at 6 months or more after surgery, when the rate of follow-up loss is increased.

Most scales showed different outcomes for test B compared to those for test A at the initial 1, 2, and 3 months postsurgery. However, at 6 and 12 months after surgery, none of the scales differed significantly between tests A and B. The absolute values of the differences were also greatly reduced with time, and the reliability as assessed by ICC was adequately high after 6 months. These outcomes are consistent with those of previous studies on the test-retest reliability of PROMs. Chahal et al [17] reported good reliability of PROM for knee joint–specific questionnaires in a test-retest study conducted 6 months after multiligament knee injury. Bramming et al [18] reported that a PROM (forgotten joint score-12) showed high relative reliability in a test-retest study conducted at 6 months after hip arthroscopic surgery. The differences in follow-ups performed in the first 3 months postsurgery might be due to variability in patient conditions during the acute phase following surgery. Additionally, the differences may have decreased over time due to patients getting used to the test items by repeatedly performing PROMs. The absolute values of the differences between the two tests were also noteworthy, given that the purpose of this study was to measure the difference between outpatient and remote mobile apps. The absolute values of the differences for each scale were relatively high at the 1-, 2-, and 3-month follow-ups. However, at the 6- and 12-month follow-ups, all parameters showed reduced absolute differences.

These results also reinforce the reliability of the remote PROMs compared to outpatient PROMs for long-term follow-ups.

Clinical studies on patient outcomes after surgery generally require at least 12 months to several years of follow-up for recognition as reliable clinical studies [9,10]. To avoid biases in clinical studies using PROMs performed at the clinic, it is important to minimize loss to follow-up to the hospital [19,20]. However, maintaining high rates of long-term follow-up is challenging due to poor patient compliance [10]. Cronin et al [21] showed that 40% of patients with orthopedic trauma did not complete 90 days of follow-up. Zelle et al [19] also reported that patients with undifferentiated orthopedic trauma showed high rates (>70%) of noncompliance in the initial 6 months postsurgery. Considering that patients’ compliance with outpatient follow-up decreases over time after surgery [21], the reliability of PROMs via mobile apps regardless of the location for long-term follow-up after surgery is meaningful as these PROMs may be an option to assess patient condition without a need to travel to the hospital.

Even in terms of the cost benefits and efficient follow-ups for patients [12], the reliability of remote PROMs is also important. Higgins et al [22] compared a conventional in-person visit follow-up group (conventional group) to a non–face-to-face follow-up group using a mobile app (mobile app group) for 6 weeks after anterior cruciate ligament reconstruction. The mobile app group had 0.36 clinic visits during the study period, compared to 2.44 visits in the conventional group. The mobile app group spent Can $211 (US $166.16) less over 6 weeks than the other group. Thus, in terms of cost burden, remote PROMs may also have advantages over outpatient visits if the assessments are reliable.

Due to the recent infectious disease epidemics of COVID-19 [11], it is difficult to expect patients to comply with outpatient follow-ups in the absence of an emergency [23]. Remote PROMs are particularly valuable [11] as medical staff and national health care system resources are focused on a particular infectious disease [24-26]. Recent guidelines from the Journal of Bone and Joint Surgery [27] recommend the assessment of all planned elective or nonemergency surgical procedures and clinical visits to determine whether they can be postponed or canceled. If remote PROMs are reliable, they can be effective...
and highly utilized for reducing patient visits [11] and allow efficient distribution of the national health care system capacity when infectious disease outbreaks occur.

This study used an electronic PROM system (Proscore, Incheon, South Korea) available for mobile phones. The correlation between electronic measuring systems and conventional paper-and-pencil methods is reportedly reliable [28]. The compliance of patients for completing scoring tools using electronic systems is generally better than that for paper-and-pencil methods because it is more convenient and quicker [29]. However, older patients may not prefer performing PROMs with electronic devices because of less exposure to and familiarity with electronic devices compared to younger patients [29]. In this study, the rate of outpatient visits did not differ significantly by age; however, the rates of test-retest completion for both PROMs at outpatient visits and remote PROMs using mobile apps were statistically significantly lower in patients older than 70 years than those in other groups for all postoperative periods ($P<.001$). Instructions for the use of smartphone devices and apps must be provided to the elderly in order to use PROMs via mobile apps at locations other than hospitals.

In conclusion, PROMs performed using mobile apps in different locations showed varied results soon after surgery but were similar after 6 months, with reliable ICC values. The remote PROMs using mobile apps could be used reliably for the patient more than 6 months after surgery. However, it is to be expected that the use of mobile app–based questionnaires is not as useful in the group older than 70 years as in other age groups.

Acknowledgments
This paper was supported by Inha University.

Conflicts of Interest
None declared.

References
2. Wiggers K. Pew: Smartphone penetration ranges from 24% in India to 95% in South Korea. 2019. URL: https://venturebeat.com/2019/02/05/pew-south-korea-has-the-worlds-highest-smartphone-ownership-rate/ [accessed 2021-01-24]


Abbreviations

**ASES:** American Shoulder and Elbow Society

**DASH:** Disabilities of the Arm, Shoulder, and Hand

**ICC:** intraclass correlation coefficient

**PROMs:** patient-reported outcome measures

**VAS:** visual analog scale

---

©Taek Ho Hong, Myung Ku Kim, Dong Jin Ryu, Jun Sung Park, Gi Cheol Bae, Yoon Sang Jeon. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 01.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Preferences for Artificial Intelligence Clinicians Before and During the COVID-19 Pandemic: Discrete Choice Experiment and Propensity Score Matching Study

Taoran Liu¹*, BSc; Winghei Tsang²*, MBBS; Yifei Xie², MBBS; Kang Tian³, BSc; Fengqiu Huang¹, MPH; Yanhui Chen³, MBBS; Oiying Lau², MBBS; Guanrui Feng¹, MPH; Jianhao Du¹, MPH; Bojia Chu⁴, BA, MSc; Tingyu Shi³, BSc; Junjie Zhao⁹, MPH, PhD; Casper J P Zhang¹⁰, MPH, PhD; Wai-Kit Ming¹, MD, PhD, MPH, MMSc; Jian Huang⁹, MPH, PhD; Babatunde Akinwunmi⁷,⁸, MD, MPH, MMSc

¹Department of Public Health and Preventive Medicine, School of Medicine, Jinan University, Guangzhou, China
²International School, Jinan University, Guangzhou, China
³Faculty of Social Sciences, University of Southampton, Southampton, United Kingdom
⁴Department of Applied Mathematics, The Hong Kong Polytechnic University, Hong Kong, Hong Kong
⁵College of Computer Science and Technology, Henan Polytechnic University, Henan, China
⁶School of Applied Mathematics, Beijing Normal University (Zhuhai), Zhuhai, China
⁷Department of Obstetrics and Gynecology, Brigham and Women’s Hospital, Boston, MA, United States
⁸Center for Genomic Medicine, Massachusetts General Hospital, Harvard Medical School, Harvard University, Boston, MA, United States
⁹Department of Epidemiology and Biostatistics, School of Public Health, Imperial College London, London, United Kingdom
¹⁰School of Public Health, The University of Hong Kong, Hong Kong, Hong Kong

* these authors contributed equally

Corresponding Author:
Wai-Kit Ming, MD, PhD, MPH, MMSc
Department of Public Health and Preventive Medicine
School of Medicine
Jinan University
601 Huangpu W Ave
Tianhe District
Guangzhou, 510632
China
Phone: 86 85228852
Email: wkming@connect.hku.hk

Abstract

Background: Artificial intelligence (AI) methods can potentially be used to relieve the pressure that the COVID-19 pandemic has exerted on public health. In cases of medical resource shortages caused by the pandemic, changes in people’s preferences for AI clinicians and traditional clinicians are worth exploring.

Objective: We aimed to quantify and compare people’s preferences for AI clinicians and traditional clinicians before and during the COVID-19 pandemic, and to assess whether people’s preferences were affected by the pressure of pandemic.

Methods: We used the propensity score matching method to match two different groups of respondents with similar demographic characteristics. Respondents were recruited in 2017 and 2020. A total of 2048 respondents (2017: n=1520; 2020: n=528) completed the questionnaire and were included in the analysis. Multinomial logit models and latent class models were used to assess people’s preferences for different diagnosis methods.

Results: In total, 84.7% (1115/1317) of respondents in the 2017 group and 91.3% (482/528) of respondents in the 2020 group were confident that AI diagnosis methods would outperform human clinician diagnosis methods in the future. Both groups of matched respondents believed that the most important attribute of diagnosis was accuracy, and they preferred to receive combined diagnoses from both AI and human clinicians (2017: odds ratio [OR] 1.645, 95% CI 1.535-1.763; P<.001; 2020: OR 1.513, 95% CI 1.413-1.621; P<.001; reference: clinician diagnoses). The latent class model identified three classes with different attribute priorities. In class 1, preferences for combined diagnoses and accuracy remained constant in 2017 and 2020, and high accuracy
The combination of AI technology and human clinicians has greatly improved the efficiency and accuracy of diagnosis methods and substantially reduced diagnosis times and outpatient queuing times. In 2014, app developers from around the world made a total of US $663.8 million by selling AI health care apps, and their revenue is expected to reach US $666.2 million in 2021 [8]. However, there are various uncertainties with regard to preferences for different diagnostic methods among patients (ie, men and women) from high-income areas and low-income areas in China. Furthermore, there have been no studies that assess patients’ preferences for AI clinicians and human clinicians before and during the COVID-19 pandemic period, and analyze the aspects of patients’ decision-making behaviors during different periods of time.

This study aimed to compare people’s preferences for AI diagnoses and traditional diagnoses (ie, human clinicians’ diagnoses) before and during the COVID-19 pandemic. We assessed two groups of respondents with similar demographic characteristics. We recruited one group in 2017 and the other group in 2020 to learn whether people’s preferences for AI and traditional human clinicians were affected by the pressure of the COVID-19 pandemic. We performed propensity score matching (PSM) to match the two groups. We also conducted a discrete choice experiment (DCE) to quantify and measure peoples’ preferences for different diagnostic methods and identify factors that disrupted and impacted peoples’ decision-making behaviors.

**Methods**

**Overview**

We designed a web-based questionnaire to collect participants’ demographic information and investigate patients’ preferences for different diagnosis strategies (Multimedia Appendix 1). In brief, the questionnaire included 7 similar hypothetical scenarios. Respondents were asked to choose a preferred diagnosis strategy for each scenario.

We used the PSM method to match two different groups of respondents (ie, the 2017 group and the 2020 group) with similar demographic characteristics. In addition, we used multinomial logit (MNL) models [9,10] and latent class models (LCMs) [11] to quantify and measure people's preferences for different diagnosis methods and identify factors that disrupted and impacted people's decision-making behaviors.
to evaluate and investigate respondents’ preferences for different diagnosis strategies. We also compared the preferences of the matched respondents from the 2017 group to those of the 2020 group to identify heterogeneity or homogeneity in preferences for diagnosis attributes.

Selection of Attributes and Levels

Individuals could choose different levels of health care services for each diagnosis attribute. Patients from the outpatient queues of The First Affiliated Hospital of Jinan University (Guangzhou Overseas Chinese Hospital) and The First Affiliated Hospital of Sun Yat-sen University were randomly selected for this study. Each patient was prompted to hypothesize which diagnosis methods or attributes had a large impact on their decision (ie, the methods/attributes that were of prominent importance to each participant).

Textbox 1. Diagnosis attributes and their respective levels in this discrete choice experiment.

<table>
<thead>
<tr>
<th>Diagnosis attributes</th>
<th>Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic method</td>
<td>clinician diagnosis, artificial intelligence and clinician diagnosis, artificial intelligence diagnosis</td>
</tr>
<tr>
<td>Outpatient waiting time</td>
<td>0 minutes, 20 minutes, 40 minutes, 60 minutes, 80 minutes, and 100 minutes</td>
</tr>
<tr>
<td>Diagnosis time</td>
<td>0 minutes, 15 minutes, and 30 minutes</td>
</tr>
<tr>
<td>Diagnostic accuracy</td>
<td>60%, 70%, 80%, 90%, and 100%</td>
</tr>
<tr>
<td>Follow-up after diagnosis</td>
<td>yes and no</td>
</tr>
<tr>
<td>Diagnostic expenses</td>
<td>¥0, ¥50, ¥100, ¥150, ¥200, and ¥250 (a currency exchange rate of ¥1=US $0.16 is applicable)</td>
</tr>
</tbody>
</table>

DCE Instrument Design and Questionnaire

With regard to the design our DCE instrument, we used the fractional factorial design method [15,16] to identify the optimal number of treatment scenarios. This process was conducted with Lighthouse Studio version 9.8.1 (Sawtooth Software). In practice, it is not always feasible for respondents to choose among all of the possible combinations of attributes and levels (ie, full factorial design). The full factorial design of the DCE instrument had 3240 different combinations (ie, 3 × 6 × 3 × 5 × 2 × 6 = 3264), which is an unreasonable number of options to present to respondents. Thus, the fractional factorial method was essential in designing the DCE instrument. This method is based on the following two principles [15-17]: (1) orthogonality, which, in terms of the DCE, means that each attribute level should have little to no correlation with other attribute levels; and (2) balance, which means that each attribute should appear an equal number of times. After considering these principles, we provided 6 random questions and 1 fixed question to each respondent in the DCE.

The DCE questionnaire contained 2 parts. The first part required the respondents to fill in their demographic information, such as age (ie, 18-20, 21-25, 26-30, 31-35, 36-40, 41-45, 46-50, 51-55, 56-60, 61-65, 66-70, 71-75, 76-80, and 81-85 years), sex (ie, male or female), and educational level (ie, primary school student, primary school graduate, middle school student, middle...
school graduate, high school student, high school graduate, undergraduate, bachelor’s degree, graduate student, master’s degree, postgraduate student, and doctorate degree). The second part required the respondents to consider seven different scenarios. For each scenario, respondents were to imagine that they were in an outpatient queue waiting for a diagnosis. They were then asked to choose a preferred diagnosis strategy. At the end of the questionnaire, respondents were required to estimate the number of years (ie, 5 years, 10 years, 15 years, 20 years, 30 years, 40 years, or never) it would take for AI clinicians to surpass human clinicians. The scenarios and the options for the different types of clinicians are presented in Multimedia Appendix 2.

Data Collection
In October 2017 and August 2020, we sent our website link to people of different age groups by using various social media platforms, such as WeChat (Tencent Inc) and QQ (Tencent Inc). People could use the link to access the DCE questionnaire, which was the same for each participant. To increase the response rate, we provided incentives (ie, a lottery for a Fitbit watch and cash prizes) for completing the questionnaire.

At the beginning of the questionnaire, we provided a brief background on the applications of AI in medicine. This included information on the potential advantages and disadvantages of AI clinicians and traditional clinicians, and the purpose of our DCE. The questionnaire only took 5-10 minutes to complete. Respondents had to click the “Agree to take the survey” button to start filling out the questionnaire. Once respondents clicked the “Agree to take the survey” button, they were notified that they willingly chose to participate in this study. Respondents were also notified that their privacy was protected by the law.

PSM
PSM is a regression method for identifying treatment group and control group patients with similar basic characteristics. This method is prevalently used in the study of impact factors and causal effects, such as those in medical treatments, policy decisions, or case studies. PSM involves the following five steps [18]: (1) estimating propensity scores; (2) choosing a matching algorithm; (3) checking for overlap/common support; (4) estimating the quality and effects of the matching results; and (5) conducting a sensitivity analysis. The mathematical theory for PSM is primarily based on the Roy-Robin model [19-21]. Our objective was to perform a PSM analysis in which participants who were recruited in 2017 were treated as the treatment group, and participants who were recruited in 2020 were treated as the control group. Participants’ PSM data are provided in Multimedia Appendix 3 [18]. We matched the respondents in each group according to their demographic characteristics, such as age, sex, and educational level. All demographic information was coded as dummy variables; for instance, male respondents were coded as “1,” and female respondents were coded as “0.”

Matching Algorithm
Although there are various matching algorithms [18], we used the nearest neighbor [22] algorithm because it was appropriate for identifying individuals in one group that best matched the individuals in another group. Another merit of the nearest neighbor algorithm is that it can differentiate between individuals in the control group and individuals in the treatment group, which guarantees that all treated individuals are successfully matched. Therefore, the nearest neighbor algorithm provides the most information on treatment groups and control groups. Additionally, we conducted a 1:1 matching analysis, which effectively reduces confounding bias [23] and improves research efficiency and credibility.

Statistical Analysis

MNL Model
There are various analysis models that can be used to conduct DCE-related statistical analyses, such as random effects binary probit and logit models, MNL models, and mixed logit models [16,24]. The theoretical model for a DCE is based on the random utility model (Multimedia Appendix 4) [16]. We assumed that respondents’ choices would maximize the utility of each question in the DCE questionnaire. The overall utility of decision makers is based on fixed utility and random utility, which are unobservable. We assessed respondents’ preferences by analyzing their comments. This allowed us to identify random utilities that could not be identified by analyzing a question.

We used the MNL model to analyze people’s preferences for different attribute levels. Our independent variable only accounted for attributes that were related to health care plans; it did not account for any information that was related to participants. The MNL model was used to analyze respondents’ health care plans, which were chosen based on the relative importance of the plans’ attributes and the “none” option. The coded value of each participants’ chosen health care plan was calculated based on participants’ coded responses to questions about queuing times, diagnosis times, and diagnostic costs. We used a maximum likelihood approach to analyze MNL model data.

The results from the MNL model were determined by the options for health care plans, as the data for this attribute were grouped before analysis. In the MNL model, “effect” is synonymous with “utility.” Therefore, positive MNL model coefficients indicated that individuals preferred one level of service over other levels for the same attribute. The MNL model in this study was based on a similar logistic regression model. The MNL model–based observations correlated with those in blocks that corresponded with the same individual. Instead of having 1 level line per individual like in the classical logit model, the MNL model had 1 level line per attribute level of interest (ie, for each individual). For example, in this study, we analyzed three types of diagnoses (ie, clinician diagnoses, AI and clinician diagnoses, and AI diagnoses), and each type had its own characteristics. However, an individual could only choose 1 of the 3 types of diagnoses. As per the characteristics of the MNL model, all three options were presented to each respondent, and all respondents could choose their preferred option. We reported the odds ratios (ORs) of respondents’ preferences for different attribute levels.
**LCM**

We used an LCM [11] to create different classes for individuals with similar preferences. The purpose of the LCM was to identify correlations among explicit variables, create the fewest number of classes, and achieve local independence. An LCM initially assumes that the null model is the hypothesized model and that local independence exists among explicit variables. Afterward, the LCM increases the number of latent categories in the null model and uses a maximum likelihood approach to create various models, which are based on parameters' limitations. The LCM then tests the hypothesized model and observed data, compares the hypothesized model to the other models, and identifies the most appropriate model. Although there are different types of model information evaluation criteria, Akaike information criteria [25] and Bayesian information criteria [26] are the most prevalently used criteria for selecting LCMs. After the model was created, observed data were classified into the appropriate latent classes.

**Willingness to Pay**

Willingness to pay (WTP) is an efficient metric for measuring how much an individual is willing to sacrifice (ie, economic sacrifices) to choose one diagnosis attribute level over another (ie, the reference attribute level). We analyzed participants’ WTP to identify homogeneity and heterogeneity in participants’ preferences.

**Software**

Propensity score matching was conducted with Stata 16 (StataCorp LLC), and the MNL model and LCMs were created with Lighthouse Studio version 9.8.1 (Sawtooth Software).

**Results**

**Data Collection**

Of the 1520 individuals who visited our DCE website in 2017, 1317 (86.6%) completed the questionnaire and were included in the analysis. Of these 1317 respondents, 1317 (100%) were aged 18-85 years, 731 (55.5%) were female, and 1115 (84.7%) believed that AI clinicians would surpass or replace human clinicians.

Of the 874 individuals who visited our new DCE website in 2020, 528 (60.4%) completed the questionnaire. Of these 528 participants, 272 (51.5%) were female and 482 (91.3%) were confident that AI diagnoses were better than traditional diagnoses.

**General PSM and MNL Model Results**

Of the 1317 respondents who were recruited in 2017, 528 (40.1%) were matched (ie, via PSM) to the 528 respondents who were recruited in 2020. The PSM procedure is presented in Figure 1, and the demographic characteristics of respondents before and after PSM are presented in Table 1. The general MNL model results for the 2017 and 2020 groups are presented in Table 2, which shows estimated average preference weights (ie, effect weights), P values, ORs, and 95% confidence intervals. Generally, individuals in the 2017 and 2020 groups believed that accuracy was the most important diagnosis attribute (Figure 2). The weighted importance value of accuracy was 38.53% in the 2017 group and 40.55% in the 2020 group. Respondents believed that diagnosis time was the least important attribute (weighted importance in 2017: 2.69%; weighted importance in 2020: 1.16%). Additionally, individuals in the 2017 and 2020 groups preferred to receive combined diagnoses from both AI and human clinicians over AI-only diagnoses or human clinician–only diagnoses (2017: OR 1.645, 95% CI 1.535-1.763; 2020: OR 1.513, 95% CI 1.413-1.621; reference: clinician diagnosis; Table 2). In addition, the ORs for the levels of diagnosis accuracy increased as the accuracy increased, which indicated that people will always prefer diagnosis methods with high accuracy. For instance, in the 2017 group, 100% accuracy had an OR of 5.043 (95% CI 4.534-5.609). In the 2020 group, 100% accuracy had an OR of 5.263 (95% CI 4.734, 5.852). The preferences of the matched respondents in the 2017 group were very similar to those of the respondents in the 2020 group.
Figure 1. Propensity score matching procedure.

Table 1. Demographic characteristics of nonmatched and propensity score–matched respondents.

<table>
<thead>
<tr>
<th>Baseline matching characteristics</th>
<th>Nonmatched respondents</th>
<th>Propensity score–matched respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017 group (n=1317), n (%)</td>
<td>2020 group (n=528), n (%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>586 (44.5)</td>
<td>256 (48.48)</td>
</tr>
<tr>
<td>Female</td>
<td>731 (55.5)</td>
<td>272 (51.52)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;35</td>
<td>1106 (83.98)</td>
<td>348 (65.91)</td>
</tr>
<tr>
<td>≥35</td>
<td>211 (16.02)</td>
<td>180 (34.09)</td>
</tr>
<tr>
<td>Highest education level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school graduate to</td>
<td>1033 (78.44)</td>
<td>336 (63.64)</td>
</tr>
<tr>
<td>undergraduate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bachelor’s degree to doctorate</td>
<td>284 (21.56)</td>
<td>192 (36.36)</td>
</tr>
<tr>
<td>degree</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2. General results of the multinomial logit model. Data on propensity score–matched respondents’ preferences for diagnosis attributes in 2017 and 2020 are reported (N=528).

<table>
<thead>
<tr>
<th>Attributes and levels</th>
<th>2017 group</th>
<th></th>
<th>2020 group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinician</td>
<td>-0.15</td>
<td>&lt;.001</td>
<td>Reference</td>
<td>-0.05</td>
</tr>
<tr>
<td>Artificial intelligence and clinician</td>
<td>0.35</td>
<td>&lt;.001</td>
<td>1.64 (1.535-1.763)</td>
<td>0.36</td>
</tr>
<tr>
<td>Artificial intelligence</td>
<td>-0.20</td>
<td>&lt;.001</td>
<td>0.95 (0.885-1.016)</td>
<td>-0.31</td>
</tr>
<tr>
<td>Outpatient waiting time (minutes)</td>
<td>0</td>
<td>0.31</td>
<td>&lt;.001</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>0.12</td>
<td>.03</td>
<td>0.82 (0.741-0.914)</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>-0.03</td>
<td>.57</td>
<td>0.71 (0.639-0.789)</td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>-0.08</td>
<td>.12</td>
<td>0.67 (0.606-0.748)</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>-0.31</td>
<td>&lt;.001</td>
<td>0.54 (0.482-0.595)</td>
</tr>
<tr>
<td>Diagnosis time (minutes)</td>
<td>0</td>
<td>0.05</td>
<td>.19</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>-0.07</td>
<td>.06</td>
<td>0.89 (0.834-0.957)</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>0.02</td>
<td>.53</td>
<td>0.98 (0.912-1.046)</td>
</tr>
<tr>
<td>Diagnosis accuracy (% accuracy)</td>
<td>60</td>
<td>-0.83</td>
<td>&lt;.001</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>-0.35</td>
<td>&lt;.001</td>
<td>1.62 (1.458-1.802)</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>0.07</td>
<td>.16</td>
<td>2.47 (2.235-2.737)</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>0.32</td>
<td>&lt;.001</td>
<td>3.18 (2.867-3.526)</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>0.79</td>
<td>&lt;.001</td>
<td>5.04 (4.534-5.609)</td>
</tr>
<tr>
<td>Follow-up after diagnosis</td>
<td>Yes</td>
<td>0.20</td>
<td>&lt;.001</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>-0.20</td>
<td>&lt;.001</td>
<td>0.67 (0.620-0.698)</td>
</tr>
<tr>
<td>Diagnosis expenses (¥)</td>
<td>0</td>
<td>0.42</td>
<td>&lt;.001</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>0.28</td>
<td>&lt;.001</td>
<td>0.87 (0.769-0.976)</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>-0.01</td>
<td>.82</td>
<td>0.65 (0.576-0.730)</td>
</tr>
<tr>
<td></td>
<td>150</td>
<td>0.03</td>
<td>.66</td>
<td>0.67 (0.599-0.760)</td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>-0.24</td>
<td>&lt;.001</td>
<td>0.52 (0.459-0.585)</td>
</tr>
<tr>
<td></td>
<td>250</td>
<td>-0.47</td>
<td>&lt;.001</td>
<td>0.41 (0.363-0.465)</td>
</tr>
</tbody>
</table>

a A currency exchange rate of ¥1=US $0.16 is applicable.
Figure 2. General estimated weighted importance of diagnosis attributes in 2017 and 2020.

**Overall WTP**

In 2017, respondents were willing to pay ¥13.99 to receive combined diagnoses from AI and human clinicians. Additionally, people were not willing to pay for longer outpatient waiting times, but they were willing to pay for higher diagnosis accuracy (ie, ¥1.60 per 1% increase in accuracy). In 2020, respondents were willing to pay ¥0.79 to receive combined diagnoses from AI and human clinicians instead of clinician-only diagnoses. Compared to respondents’ WTP for certain diagnosis methods in 2017, respondents’ WTP in 2020 was lower. Furthermore, similar to the 2017 group, respondents in the 2020 group were also not willing to pay for longer outpatient waiting times. However, they were willing to pay for higher diagnosis accuracy.
LCM Results

After comparing the Akaike information criteria, Bayesian information criteria, and Akaike/Bayesian information criteria of the various potential classes, we chose three classes that were the most appropriate for the matched respondents in the 2017 and 2020 groups. The proportions of matched respondents from the 2017 group in each of the three classes were 43.2% (class 1: 228/528), 42.2% (class 2: 223/528) and 14.6% (class 3: 77/528). The proportions of matched respondents from the 2020 group in each of the three classes were 44.8% (class 1: 237/528), 48.2% (class 2: 254/528) and 7% (class 3: 37/528).

With regard to class 1 (n=228), Figure 3 shows that matched respondents in the 2017 group believed that diagnosis method was the most important attribute (weighted importance: 32.95%), followed by diagnosis expenses (weighted importance: 18.14%). In class 2, matched respondents from the 2017 group believed that diagnosis accuracy (weighted importance: 49.92%) and diagnosis expenses (weighted importance: 19.84%) were the most important attributes. In class 3, matched respondents from the 2017 group believed that diagnosis accuracy (weighted importance: 25.66%) and diagnosis expenses (weighted importance: 23.21%) were the most important attributes. In class 1, the respondents from the 2020 group believed that diagnosis expenses (weighted importance: 29.99%) and diagnosis method (weighted importance: 28.99%) were the most important attributes. In class 2, the respondents from the 2020 group believed that diagnosis accuracy (weighted importance: 52.34%) was the most important attribute, followed by diagnosis expenses (weighted importance: 14.44%). In class 3, the respondents from the 2020 group believed that diagnosis expense (weighted importance: 36.21%) was the most important attribute, followed by diagnosis accuracy (weighted importance: 32.84%). It was obvious that the three factors that respondents believed were the most important were diagnosis accuracy, diagnosis expenses, and diagnosis methods. In some classes, respondents believed that diagnosis method was the most important attribute. However, respondents typically believed that diagnosis accuracy was the most important attribute and diagnosis expense was the second most important attribute.
Figure 3. Weighted importance of diagnosis attributes in 2017 and 2020, as determined by the latent class model.

According to our ORs for classes 1 and 2, the respondents in the 2017 group (Table S1 in Multimedia Appendix 5) preferred the combined diagnosis method (class 1: OR 2.479, 95% CI 0.997-2.743; class 2: OR 1.204, 95% CI 1.039-1.394) over the other two methods. This was not true for respondents in class 3. Respondents in classes 1 and 3 preferred an outpatient waiting time of 0 minutes, and respondents in classes 1 and 2 preferred a diagnosis time of 0 minutes. Respondents across all classes preferred a diagnosis cost of ¥0. Furthermore, respondents in the 2017 group (ie, those in all classes) preferred high diagnosis accuracy (eg, 100% accuracy in class 3: OR 4.899, 95% CI 3.631-6.611). Respondents in all classes believed that follow-ups after diagnosis were important.

In classes 1 and 2, the respondents from the 2020 group (Table S2 in Multimedia Appendix 5) preferred the combined diagnosis method (class 1: OR 1.135, 95% CI 0.997-1.293; class 2: OR 2.009, 95% CI 1.826-2.211). This was not true for class 3. Respondents in class 2 preferred an outpatient waiting time of
20 minutes (OR 1.488, 95% CI 1.287-1.721). Additionally, similar to the 2017 group, the respondents in the 2020 group (ie, those in all classes) preferred high accuracy. Follow-ups after diagnosis were important to the respondents in the 2020 group (ie, those in all classes). The strength of respondents’ preferences is visually presented in Figure 4; preference strength was quantified by calculating the preference weight (ie, coefficient) of each attribute’s level.

Figure 4. Preference weights stratified by year (ie, 2017 and 2020) and class (ie, classes 1, 2, and 3), as determined by the latent class model.

We found that respondents’ WTP was highly consistent with the corresponding ORs of each attribute. In classes 1 and 2, the respondents from the 2017 group (Table 3) were willing to pay for the combined diagnosis method. This was not true for class 3. Additionally, in class 3, the respondents from the 2017 group were the only respondents who were willing to pay for longer diagnosis times. The respondents from the 2017 group (ie, those in all classes) were willing to pay for higher diagnosis accuracy and follow-ups after diagnosis.

In classes 1 and 2, the respondents from the 2020 group (Table 4) were willing to pay for the combined diagnosis method. This was not true for class 3, in which respondents were willing to pay more for the AI diagnosis method. The respondents from the 2020 group (ie, those in all classes) were willing to pay for shorter outpatient waiting times, higher diagnosis accuracy, and follow-ups after diagnosis.
Table 3. Respondents’ WTPa in 2017.b

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Overall WTP (N=528), ¥ (US $)</th>
<th>WTP in class 1 (n=228), ¥ (US $)</th>
<th>WTP in class 2 (n=223), ¥ (US $)</th>
<th>WTP in class 3 (n=77), ¥ (US $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artificial intelligence and clinician</td>
<td>−13.99 (−2.24)</td>
<td>−3.03 (−0.48)</td>
<td>−0.22 (−0.04)</td>
<td>0.31 (0.05)</td>
</tr>
<tr>
<td>Artificial intelligence</td>
<td>1.50 (0.24)</td>
<td>−0.52 (−0.08)</td>
<td>0.25 (0.04)</td>
<td>1.22 (0.20)</td>
</tr>
<tr>
<td>Outpatient waiting time</td>
<td>8.92 (1.43)</td>
<td>0.62 (0.10)</td>
<td>0.96 (0.15)</td>
<td>0.53 (0.09)</td>
</tr>
<tr>
<td>Diagnosis time</td>
<td>−0.57 (−0.09)</td>
<td>0.07 (0.01)</td>
<td>0.07 (0.01)</td>
<td>−0.44 (−0.07)</td>
</tr>
<tr>
<td>Diagnosis accuracy</td>
<td>−1.14 (−0.18)</td>
<td>−0.44 (−0.07)</td>
<td>−2.85 (−0.46)</td>
<td>−1.20 (−0.19)</td>
</tr>
<tr>
<td>Follow-up after diagnosis</td>
<td>11.32 (1.81)</td>
<td>1.22 (0.20)</td>
<td>0.95 (0.15)</td>
<td>0.62 (0.10)</td>
</tr>
<tr>
<td>Diagnosis expenses</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
</tr>
</tbody>
</table>

aWTP: willingness to pay.
bNegative currency values refer to the amount that respondents were willing to pay for another level.

Table 4. Respondents’ WTPa in 2020.b

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Overall WTP (N=528), ¥ (US $)</th>
<th>WTP in class 1 (n=237), ¥ (US $)</th>
<th>WTP in class 2 (n=254), ¥ (US $)</th>
<th>WTP in class 3 (n=37), ¥ (US $)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artificial intelligence and clinician</td>
<td>−0.79 (−0.13)</td>
<td>−0.17 (−0.03)</td>
<td>−1.33 (−0.21)</td>
<td>−1.31 (−0.21)</td>
</tr>
<tr>
<td>Artificial intelligence</td>
<td>0.48 (0.07)</td>
<td>0.54 (0.09)</td>
<td>0.42 (0.07)</td>
<td>−1.62 (−0.26)</td>
</tr>
<tr>
<td>Outpatient waiting time</td>
<td>0.38 (0.06)</td>
<td>0.70 (0.11)</td>
<td>0.19 (0.03)</td>
<td>0.61 (0.10)</td>
</tr>
<tr>
<td>Diagnosis time</td>
<td>−0.05 (−0.01)</td>
<td>−0.04 (−0.01)</td>
<td>0.004 (0.001)</td>
<td>0.06 (0.01)</td>
</tr>
<tr>
<td>Diagnosis accuracy</td>
<td>−1.60 (−0.26)</td>
<td>−3 (−0.48)</td>
<td>−0.44 (−0.07)</td>
<td>−5.65 (−0.90)</td>
</tr>
<tr>
<td>Follow-up after diagnosis</td>
<td>0.73 (0.12)</td>
<td>1.46 (0.23)</td>
<td>0.25 (0.04)</td>
<td>2.31 (0.37)</td>
</tr>
<tr>
<td>Diagnosis expenses</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
</tr>
</tbody>
</table>

aWTP: willingness to pay.
bNegative currency values refer to the amount that respondents were willing to pay for another level.

According to the LCM, which stratified data according to sex, male respondents in the 2017 group (Figure 5) believed that the most important attribute was diagnosis accuracy (weighted importance: 39.14%), followed by diagnosis expenses (weighted importance: 21.39%). Female respondents in the 2017 group also thought that diagnosis accuracy (weighted importance: 37.41%) and diagnosis expenses (weighted importance: 20.74%) were the most important attributes. Male respondents in the 2020 group thought that diagnosis accuracy (weighted importance: 36.74%) was the most important attribute, followed by diagnosis expenses (weighted importance: 23.84%). Additionally, female respondents in the 2020 group believed that diagnosis accuracy (weighted importance: 41.69%) was the most important attribute, followed by diagnosis expenses (18.96%). The LCM for male and female respondents in the 2017 and 2020 groups showed that there was no obvious heterogeneity among these respondents’ preferences.
Figure 5. Weighted importance of diagnosis attributes in 2017 and 2020, as determined by the latent class model, which stratified data according to sex (ie, male and female respondents).

Discussion

Principal Results

In this study, we collected information on people’s preferences for AI-based diagnosis by analyzing two different groups of individuals who were recruited in 2017 and 2020 (ie, before and during the COVID-19 pandemic). We used the PSM method to match two groups of respondents with similar demographic characteristics (ie, age, sex, and educational level). After comparing the demographically similar respondents in the 2017 and 2020 groups, we did not find any substantial differences in respondents’ preferences. Diagnosis accuracy and diagnosis expenses were the most important factors that influenced respondents’ preferences. Diagnosis accuracy and diagnosis expenses were the most important factors that influenced respondents’ preferences.

The success of a DCE questionnaire always depends on the response rate. In other words, people who actively click the website link and complete the questionnaire are essential for expanding sample sizes and the scope of a study. By using the PSM method, we were able to easily assess whether people’s preferences during normal times changed during unusual times (ie, the COVID-19 pandemic).

In this study, we used two different models—the MNL model and the LCM. Both models have various advantages and drawbacks with regard to quantifying respondents’ preferences. According to the general PSM logit model, respondents in both groups consistently believed that accuracy was the most important diagnosis attribute, regardless of their preferences for diagnosis methods. Moreover, diagnosis expense was an important factor that influenced respondents’ decisions in both 2017 and 2020. Respondents believed that this attribute was the second most important attribute. The limited accessibility and availability of medical resources are big problems in China, especially in several rural areas of China. These problems are the result of insufficient medical insurance distribution [27,28] and the country’s low per capita income.

We found that people’s preferences for different diagnoses were largely similar. This indicates that people’s decisions and their preferences for different diagnoses are not considerably affected by pandemic-related factors. However, according to our LCM, there was slight heterogeneity in the preferences of different groups of respondents (eg, male and female respondents). This heterogeneity was not observed in the logit model. Although the weighted importance of accuracy remained consistent across all classes, it might not be the most important factor that affects people’s decisions. In class 1, the respondents from the 2017 and 2020 groups believed that diagnosis expense was the most important factor that affected their decisions, followed by diagnosis method. Based on the LCM results, male respondents in the 2017 and 2020 groups believed that diagnosis accuracy was the most important attribute to consider when choosing a diagnosis strategy.

With regard to attribute levels, we found that respondents typically preferred to receive a combined diagnosis from both AI and human clinicians over a diagnosis from a single source (ie, AI diagnoses or human clinician diagnoses). This is understandable, since respondents typically believed that diagnosis accuracy could be improved by combining different...
modes of diagnosis. Additionally, it should be noted that several respondents preferred longer diagnosis and outpatient queuing times. Although no studies have reported that diagnosis time and outpatient time correlate with diagnosis accuracy, it is possible that some patients prefer waiting for a doctor over receiving a quicker diagnosis, as they may believe that waiting results in more accurate diagnoses. The low accessibility and high price of AI services are important issues, especially in rural or low-income areas. Therefore, before pricing an AI technology–based service, it is advisable to survey residents and analyze their disposable income. With regard to residents in rural areas, governments should consider adding AI diagnoses to health insurance plans or related subsidy projects. Another AI diagnosis factor that should be considered is accuracy, since companies should only promote and advertise products/services with a high accuracy. When an AI technology–based service enters the market, relevant users should consider combining AI technology with human wisdom during the early stage of market penetration. Therefore, in the future, AI diagnosis technology developers should focus on improving diagnosis accuracy and reducing the cost of diagnoses to make such technology accessible to a wide range of patients.

Limitations
Our study has several shortcomings and limitations, especially with regard to our data collection process. It was clear that our small sample size limited the power of our analyses. Additionally, our sample might not be representative of the entire Chinese population. Furthermore, the deployment/distribution of AI technology–based medical services is limited, especially in rural areas [29] and areas that consist of uneducated residents. Thus, there are still many obstacles to overcome before AI technology becomes popular; many developments are still needed to popularize conceptual projects.

Conclusion
Our study shows that respondents’ preferences for AI clinicians in 2017 did not substantially differ from those in 2020. Therefore, people’s preferences for AI diagnoses and clinical diagnoses were unaffected by the COVID-19 pandemic. However, preferences for high diagnostic accuracy and low diagnosis expenses were evident, regardless of people’s preferences for diagnosis methods, waiting times, and follow-up services.

In summary, affordability and accuracy are the two principal factors that should be considered when promoting AI-based health care. The combination of AI-based and professional health care will be more easily accepted by the general public as AI technology develops.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Survey introduction.
[DOCX File, 15 KB - jmir_v23i3e26997_app1.docx]

Multimedia Appendix 2
Supplementary questionnaire.
[DOCX File, 75 KB - jmir_v23i3e26997_app2.docx]

Multimedia Appendix 3
Propensity score matching method.
[DOCX File, 18 KB - jmir_v23i3e26997_app3.docx]

Multimedia Appendix 4
Random utility model.
[DOCX File, 18 KB - jmir_v23i3e26997_app4.docx]

Multimedia Appendix 5
Supplementary tables.
[DOCX File, 35 KB - jmir_v23i3e26997_app5.docx]

References


16. A user guide with case studies: How to conduct a discrete choice experiment for health workforce recruitment and retention in remote and rural areas. World Health Organization. URL: https://www.who.int/hrh/resources/DCE_UserGuide_WEB.pdf?ua=1 [accessed 2021-02-09]


Abbreviations

AI: artificial intelligence
DCE: discrete choice experiment
LCM: latent class model
MNL: multinomial logit
OR: odds ratio
PSM: propensity score matching
WTP: willingness to pay
Artificial Intelligence Techniques That May Be Applied to Primary Care Data to Facilitate Earlier Diagnosis of Cancer: Systematic Review

Owain T Jones¹, MPhil; Natalia Calanzani¹, PhD; Smiji Saji¹, MBBCHIR; Stephen W Duffy², MSc; Jon Emery³, DPhil; Willie Hamilton⁴, MD; Hardeep Singh⁵, MD, MPH; Niek J de Wit⁶, MD; Fiona M Walter¹, MD

¹Primary Care Unit, Department of Public Health & Primary Care, University of Cambridge, Cambridge, United Kingdom
²Wolfson Institute for Preventive Medicine, Queen Mary University of London, London, United Kingdom
³Centre for Cancer Research and Department of General Practice, University of Melbourne, Victoria, Australia
⁴College of Medicine and Health, University of Exeter, Exeter, United Kingdom
⁵Center for Innovations in Quality, Effectiveness and Safety, Michael E DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX, United States
⁶Julius Center for Health Sciences and Primary Care, UMC Utrecht, Utrecht, Netherlands

Abstract

Background: More than 17 million people worldwide, including 360,000 people in the United Kingdom, were diagnosed with cancer in 2018. Cancer prognosis and disease burden are highly dependent on the disease stage at diagnosis. Most people diagnosed with cancer first present in primary care settings, where improved assessment of the (often vague) presenting symptoms of cancer could lead to earlier detection and improved outcomes for patients. There is accumulating evidence that artificial intelligence (AI) can assist clinicians in making better clinical decisions in some areas of health care.

Objective: This study aimed to systematically review AI techniques that may facilitate earlier diagnosis of cancer and could be applied to primary care electronic health record (EHR) data. The quality of the evidence, the phase of development the AI techniques have reached, the gaps that exist in the evidence, and the potential for use in primary care were evaluated.

Methods: We searched MEDLINE, Embase, SCOPUS, and Web of Science databases from January 01, 2000, to June 11, 2019, and included all studies providing evidence for the accuracy or effectiveness of applying AI techniques for the early detection of cancer, which may be applicable to primary care EHRs. We included all study designs in all settings and languages. These searches were extended through a scoping review of commercial AI technologies. The main outcomes assessed were measures of diagnostic accuracy for cancer.

Results: We identified 10,456 studies; 16 studies met the inclusion criteria, representing the data of 3,862,910 patients. A total of 13 studies described the initial development and testing of AI algorithms, and 3 studies described the validation of an AI algorithm in independent data sets. One study was based on prospectively collected data; only 3 studies were based on primary care data. We found no data on implementation barriers or cost-effectiveness. Risk of bias assessment highlighted a wide range of study quality. The additional scoping review of commercial AI technologies identified 21 technologies, only 1 meeting our inclusion criteria. Meta-analysis was not undertaken because of the heterogeneity of AI modalities, data set characteristics, and outcome measures.

Conclusions: AI techniques have been applied to EHR-type data to facilitate early diagnosis of cancer, but their use in primary care settings is still at an early stage of maturity. Further evidence is needed on their performance using primary care data,
implementation barriers, and cost-effectiveness before widespread adoption into routine primary care clinical practice can be recommended.

(J Med Internet Res 2021;23(3):e23483) doi:10.2196/23483

KEYWORDS
artificial intelligence; machine learning; electronic health records; primary health care; early detection of cancer

Introduction

Background
Cancer control is a global health priority, with 17 million new cases diagnosed worldwide in 2018. In high-income countries such as the United Kingdom, approximately half the population over the age of 50 years will be diagnosed with cancer in their lifetime [1]. Although the National Health Service (NHS) currently spends approximately £1 billion (US $1.37 billion) on cancer diagnostics per year [2], the United Kingdom lags behind comparable European nations with their cancer survival rates [3].

In gatekeeper health care systems such as the United Kingdom, most people diagnosed with cancer first present in primary care [4], where general practitioners evaluate (often vague) presenting symptoms and decide on an appropriate management strategy, including investigations, specialist referral, or reassurance. More accurate assessment of these symptoms, especially for patients with multiple consultations, could lead to earlier diagnosis of cancer and improved outcomes for patients, including improved survival rates [5,6].

There is accumulating evidence that artificial intelligence (AI) can assist clinicians in making better clinical decisions or even replace human judgment, in certain areas of health care. This is due to the increasing availability of health care data and the rapid development of big data analytic methods. There has been increasing interest in the application of AI in medical diagnosis, including machine learning and automated analysis approaches. Recent studies have applied AI to patient symptoms to improve diagnosis [7,8], to retinal images for the diagnosis of diabetic retinopathy [9], to mammography images for breast cancer diagnosis [10,11], to computed tomography (CT) scans for the diagnosis of intracranial hemorrhages [12], and to images of blood films for the diagnosis of acute lymphoblastic leukemia [13].

Few AI techniques are currently implemented in routine clinical care. This may be due to uncertainty over the suitability of current regulations to assess the safety and efficacy of AI systems [14-16], a lack of evidence about the cost-effectiveness and acceptability of AI systems [14], challenges to implementation into existing electronic health records (EHRs) and routine clinical care, and uncertainty over the ethics of using AI systems. A recent review of AI and primary care reported that research on AI for primary care is at an early stage of maturity [17], although research on AI-driven tools such as symptom checkers for patient and clinical users are more mature [18-21].

The CanTest framework [22] (Figure 1) establishes the developmental phases required to ensure that new diagnostic tests or technologies are fit for purpose when introduced into clinical practice. It provides a roadmap for developers and policy makers to bridge the gap from the development of a diagnostic test or technology to its successful implementation. We used this framework to guide the assessment of the studies identified in this review.
Objectives

Few studies of AI-based techniques for the early detection of cancer have been undertaken in primary care settings [17]. Therefore, the aim of this systematic review is to identify AI techniques that facilitate the early detection of cancer and could be applied to primary care EHR data. We also aim to summarize the diagnostic accuracy measures used to evaluate existing studies and evaluate the quality of the evidence, the phase of development the AI technologies have reached, the gaps that exist in the evidence, and the potential for use in primary care. As many commercial technological developments are not documented in academic publications, we also performed a parallel scoping review of commercially available AI-based technologies for the early detection of cancer that may be suitable for implementation in primary care settings.

Methods

Search Strategy and Selection Criteria

This study was conducted in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) guidelines [23], and the protocol was registered with PROSPERO (an international prospective register of systematic reviews) before conducting the review (CRD42020176674) [24]. All aspects of the protocol were reviewed by the senior research team.

We included all primary research articles published in peer-reviewed journals, without language restrictions, from January 01, 2000, to June 11, 2019. Studies were included if they provided evidence around the accuracy, utility, acceptability, or cost-effectiveness of applying AI techniques to facilitate the early detection of cancer and could be applied to primary care EHRs (ie, to the types of data found in primary care EHRs) [22]. We included AI techniques based on any type of data that were relevant to primary care settings, including coded data and free text. We included all types of study design, as we anticipated that there would be few relevant randomized controlled trials. We kept our search terms broad to not miss relevant studies and carefully considered evidence from any health care system to assess whether the evidence could be applied to primary care settings.

As our aim is to identify AI techniques that would be applicable in primary care clinical settings, we excluded studies that incorporated data not typically available in primary care EHRs in the early diagnostic stages (eg, histopathology images, magnetic resonance imaging, or CT scan images). We also excluded studies that only described the development of an AI technique without any testing or evaluation data, studies that did not incorporate an element of machine learning (ie, with training and testing or validation steps), studies that used AI techniques for biomarker discovery alone, and studies that were based on sample sizes of less than 50 cases or controls. Machine learning techniques and neural networks have been described since the 1960s [25,26]; however, they were initially limited by computing power and data availability. We chose to start our search in 2000, as this was when the earliest research describing the new wave of machine learning techniques emerged [27].

We searched MEDLINE, Embase, SCOPUS, and Web of Science bibliographic databases, using keywords related to AI, cancer, and early detection. We extended these systematic
searches through manual searching of the reference lists of the included studies. We contacted study authors, where required. Where studies were not published in English, we identified suitably qualified native speakers to help assess these studies. We performed a parallel scoping review to look for commercially developed AI technologies that were not identified through systematic searches, thus unpublished and not scientifically evaluated. This included manually searching commercial research archives and networks (eg, arXiv [28], Google [29], Microsoft [30], and IBM [31]), reviewing the computer-based technologies identified in 3 recent reviews [19-21], and manually searching for further technologies mentioned in the text or references of the studies and websites included in these reviews.

Following duplicate removal, 1 author (OJ) screened titles and abstracts to identify studies that fit the inclusion criteria. Of the titles and abstracts, 17.42% (1838/10,456) were checked by 2 other authors (SS and NC); interrater reliability was excellent at 96.24% (1769/1838). Any disagreements were discussed by the core research team (OJ, SS, NC, and FW), and a consensus was reached. Three reviewers (OJ, SS, and NC) independently assessed the full-text articles for inclusion in the review. Any disagreements were resolved by a consensus-based decision.

Data Analysis
Data extraction was undertaken independently by at least two reviewers (OJ, SS, and NC) into a predesigned data extraction spreadsheet. The research team met regularly to reach consensus by discussing and resolving any differences in data extraction. One author (OJ) amalgamated the data extraction spreadsheets, summarizing the data where possible.

The main summary measures collected included sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), area under the receiver operating characteristic (AUROC) curve, and any other diagnostic accuracy measures of the AI techniques. Secondary outcomes include the types of AI used, the type of data used to train and test the algorithms, and how these algorithms were evaluated. We also collected data, where identified, on cost-effectiveness and patient or clinician acceptability.

Risk of bias assessment was undertaken for all full-text papers by 2 independent researchers (OJ and NC) using the quality assessment of diagnostic accuracy studies-2 (QUADAS-2) critical appraisal tool [32]. OJ assessed all studies, and 50% (40/79) of them were cross-checked by NC. Any disagreements in the assessment were resolved by consensus discussion.

The studies identified were heterogeneous, employing various AI techniques and using different outcome measures for evaluation. Hence, a meta-analysis of the data was not possible, and we chose to use a narrative synthesis approach, following established guidance on its methodology [33]. We aimed to summarize the findings of the identified studies using primarily a textual approach, while also providing an overview of the quantitative outcome measures used in the studies. Once data extraction was completed, we explored the relationships that emerged within the data.

Full details of our review question, search strategy, inclusion or exclusion criteria, and data extraction methodology are described in Multimedia Appendices 1 [1-5,7-9,11-13,34-38] and 2, and the full list of excluded studies is provided in Multimedia Appendix 3 [34,39-114].

Results
A total of 13,004 articles were identified in database searches (including 2548 duplicates), and 793 articles underwent full-text review. Of the 79 articles that were related to EHRs, 16 met the inclusion criteria and were included in this analysis (Figure 2), representing the data of 3,862,910 patients. No articles identified through other sources or reference lists met the inclusion criteria.
Tables 1 and 2 show the main study characteristics for the 16 included studies, including the modality of AI used. Supplementary information on the variables included in the AI techniques is available in Multimedia Appendix 4 [34,39-53]. We categorized the variables included into the following categories: demographics, symptoms, comorbidities, lifestyle history, examination findings, blood results, and other. Most studies (n=13) described the initial development and testing of an AI technique [39-51]. Three studies validated the AI technique developed by Kinar et al [48] in independent data sets from 3 different countries (Israel, United States, and United Kingdom) [34,52,53].
Table 1. Study details including modality of artificial intelligence and adopted comparison or control.

<table>
<thead>
<tr>
<th>Study</th>
<th>Authors’ origin</th>
<th>Cancer</th>
<th>Modality of artificial intelligence</th>
<th>Comparison or control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Histopathology</td>
</tr>
<tr>
<td><strong>Development studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alzubi et al, 2019 [39]</td>
<td>Jordan and India</td>
<td>Lung cancer</td>
<td>WONN-MLB(^a)</td>
<td>X(^b)</td>
</tr>
<tr>
<td>Chang et al, 2009 [40]</td>
<td>Taiwan</td>
<td>Pancreatic Cancer</td>
<td>BPNN(^e); LR(^f)</td>
<td>—</td>
</tr>
<tr>
<td>Cooper et al, 2018 [41]</td>
<td>United Kingdom</td>
<td>Colorectal Cancer</td>
<td>ANN(^i); CVT(^j); LR</td>
<td>X</td>
</tr>
<tr>
<td>Cowley et al, 2013 [42]</td>
<td>United Kingdom</td>
<td>Colorectal Cancer</td>
<td>BPANN(^l)</td>
<td>—</td>
</tr>
<tr>
<td>Goryński et al, 2014 [44]</td>
<td>Poland</td>
<td>Lung cancer</td>
<td>MLP-ANN(^q)</td>
<td>X</td>
</tr>
<tr>
<td>Hart et al, 2018 [45]</td>
<td>United States</td>
<td>Lung cancer</td>
<td>BPANN</td>
<td>—</td>
</tr>
<tr>
<td>Kang et al, 2017 [47]</td>
<td>China</td>
<td>Any cancer</td>
<td>BPNN; CVT; SVM; DT</td>
<td>X</td>
</tr>
<tr>
<td>Kinar et al, 2016 [48]</td>
<td>Israel and United States</td>
<td>Colorectal Cancer</td>
<td>DT/RF(^s); GBM; CVT</td>
<td>X</td>
</tr>
<tr>
<td>Kop et al, 2016 [49]</td>
<td>The Netherlands</td>
<td>Colorectal Cancer</td>
<td>CART(^u); RF; LR; CVT</td>
<td>X</td>
</tr>
<tr>
<td>Miotto et al, 2016 [50]</td>
<td>United States</td>
<td>Multiple diseases and cancers</td>
<td>DNN(^v); RF</td>
<td>—</td>
</tr>
<tr>
<td>Payandeh et al, 2009 [51]</td>
<td>Iran</td>
<td>CML(^w) and lymphoproliferative disorders</td>
<td>MLP-ANN</td>
<td>X</td>
</tr>
<tr>
<td><strong>Validation studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birks et al, 2017 [52]</td>
<td>United Kingdom</td>
<td>Colorectal Cancer</td>
<td>DT/RF; GBM; CVT</td>
<td>X</td>
</tr>
<tr>
<td>Hornbrook et al, 2017 [34]</td>
<td>United States</td>
<td>Colorectal Cancer</td>
<td>DT/RF; GBM; CVT</td>
<td>X</td>
</tr>
<tr>
<td>Kinar et al, 2017 [53]</td>
<td>Israel</td>
<td>Colorectal Cancer</td>
<td>DT/RF; GBM; CVT</td>
<td>X</td>
</tr>
</tbody>
</table>

\(^a\)WONN-MLB: weight optimized neural network with maximum likelihood boosting.
\(^b\)X: corresponding control used in this study.
\(^c\)Not used in this study.
\(^d\)1: previously developed artificial intelligence methods.
\(^e\)BPNN: back propagation neural network.
\(^f\)LR: logistic regression.
\(^g\)2: other artificial intelligence methods developed by this author.
\(^h\)3: other statistical (ie, non-artificial intelligence) techniques.
\(^i\)ANN: artificial neural network.
\(^j\)CVT: cross-validation techniques.
\(^k\)4: colonoscopy.
\(^l\)BPANN: back propagation artificial neural network.
n°5: primary care clinicians.

n°SVM: support vector machine.

n°DT: decision tree.

n°K-NN: K-nearest neighbor.

n°MLP-ANN: multilayer perceptron artificial neural network.

n°6: screening tests (eg, low-dose computed tomography scan and fecal occult blood test).

n°RF: random forest.

n°GBM: gradient boosting model.

n°CART: classification and regression trees.

n°DNN: deep neural network.

n°CML: chronic myeloid leukemia.

The study authors originated from a variety of countries, including the United States (n=5), countries in the Middle East (n=5), Europe (n=5), and Asia (n=3), with some studies involving multiple countries. The AI techniques were most commonly developed to identify colorectal cancer (n=7) [34,41,42,48,49,52,53], although they also addressed lung cancer (n=3) [39,44,45], hematological cancers (n=2) [43,51], pancreatic cancer (n=1) [40], prostate cancer (n=1) [46], and multiple cancers (n=2) [47,50].

Neural networks were the dominant technique employed (n=10) [39-42,44-50,51], with many neural network subtypes mentioned. The study by Miotto et al [50] was the only study to include a processed form of the free text notes in the data used by the AI technique, although the work described by Kop et al [49] was developed in a subsequent study to include clinical free text data [115].

The majority of studies (n=9) used a combination of histopathological diagnoses and expert opinion as the control for their study [34,41,44,47-49,51-53]. The clinical control group was unclear in 2 studies [40,45]. Many studies used multiple AI techniques and then compared them with each other (n=8) [40,42,43,45-47,49,50]. Some studies used non-AI techniques, such as logistic regression and screening tests, as comparators for the performance of the AI technique that was being developed [40,41,45,46,48-51].
Table 2. Study details: patient variables.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patient variables</th>
<th>Age</th>
<th>Sex</th>
<th>Demographics</th>
<th>Symptoms</th>
<th>Comorbidities</th>
<th>Lifestyle</th>
<th>Examination</th>
<th>Other blood tests</th>
<th>Other b</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Development studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alzubi et al, 2019 [39]</td>
<td></td>
<td>X</td>
<td>d</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Chang et al, 2009 [40]</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td>Cooper et al, 2018 [41]</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hart et al, 2018 [45]</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Kang et al, 2017 [47]</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Kinjar et al, 2016 [48]</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Kop et al, 2016 [49]</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Miotto et al, 2016 [50]</td>
<td></td>
<td>—</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td><strong>Validation studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birks et al, 2017 [52]</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hornbrook et al, 2017 [34]</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Kinjar et al, 2017 [53]</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
</tbody>
</table>

*aFBC: full blood count.
*bMore detail on other variables included is available in Multimedia Appendix 4.
*cX: corresponding variable used in this study.
*dNot used in this study.

Most of the studies (n=12) included blood test results, all suitable for use in primary care settings. Age was also commonly included (n=12). Other variables used were sex (n=10), demographics (n=5), symptoms (n=7), comorbidities (n=8), lifestyle history (n=7), examination findings (n=6), medication or prescription history (n=3), spirometry results (n=2), urine dipstick results (n=1), fecal immunochemical test results (n=1), X-ray text reports (n=1), and referrals (n=1).

Table 3 shows the study designs and populations. Most studies used data sets originating from specialist care settings (n=7) [39,40,42-44,46,51], with only 3 studies using solely primary care patient data [41,49,52]. Kinjar et al [48] included a follow-up validation study based on the health improvement network (THIN) database, also using primary care data. Several studies used a mixture of primary and secondary care patient data (n=5) [34,47,48,50,53].
<table>
<thead>
<tr>
<th>Study details</th>
<th>Population from health care setting</th>
<th>Database used</th>
<th>Disease positive population (patients)</th>
<th>Disease negative population (patients)</th>
<th>Training set (patients)</th>
<th>Testing set (patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Development studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alzubi et al, 2019 [39]</td>
<td>Specialist care</td>
<td>Wroclaw Thoracic Surgery Centre</td>
<td>1200 in total; numbers of disease positive and negative unclear</td>
<td>1200 in total; numbers of disease positive and negative unclear</td>
<td>N/S^a</td>
<td>1000</td>
</tr>
<tr>
<td>Chang et al, 2009 [40]</td>
<td>Specialist care (unclear)</td>
<td>“a certain medical center”</td>
<td>194</td>
<td>157^b</td>
<td>234</td>
<td>117</td>
</tr>
<tr>
<td>Cooper et al, 2018 [41]</td>
<td>Primary care</td>
<td>NHS Bowel Cancer Screening Programme comparative study [116]</td>
<td>549</td>
<td>1261</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>Cowley et al, 2013 [42]</td>
<td>Specialist care</td>
<td>2-week wait colorectal referrals to Castle Hill Hospital</td>
<td>74</td>
<td>703</td>
<td>777</td>
<td>100</td>
</tr>
<tr>
<td>Goryński et al, 2014 [44]</td>
<td>Specialist care</td>
<td>Patients treated at Kuyavia and Pomerania Centre of pulmonology</td>
<td>103</td>
<td>90</td>
<td>97</td>
<td>48</td>
</tr>
<tr>
<td>Kalra et al, 2003 [46]</td>
<td>Specialist care</td>
<td>Men whose samples were tested at 6 sites in the United States^d</td>
<td>348</td>
<td>N/S</td>
<td>218</td>
<td>144</td>
</tr>
<tr>
<td>Kinar et al, 2016 [48]^e</td>
<td>Mixed</td>
<td>Maccabi Health Services EMRs^f linked to the Israel Cancer Registry</td>
<td>2437</td>
<td>463,670</td>
<td>466,107</td>
<td>139,205</td>
</tr>
<tr>
<td>Kop et al, 2016 [49]</td>
<td>Primary care</td>
<td>6 anonymized data sets from 3 urban regions, each covering a GP^g recording system</td>
<td>1292</td>
<td>263,879</td>
<td>N/S</td>
<td>N/S</td>
</tr>
<tr>
<td>Miotto et al, 2016 [50]</td>
<td>Mixed</td>
<td>Mount Sinai Data Warehouse</td>
<td>276,214 patients with 78 diseases</td>
<td>276,214 patients with 78 diseases</td>
<td>200,000</td>
<td>76,214</td>
</tr>
<tr>
<td>Payandeh et al, 2009 [51]</td>
<td>Specialist care</td>
<td>Blood test results from patients at the Taleghani Hospital</td>
<td>450</td>
<td>N/S</td>
<td>360</td>
<td>132</td>
</tr>
<tr>
<td><strong>Validation studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birks J et al, 2017 [52]</td>
<td>Primary care</td>
<td>Clinical Practice Research Datalink</td>
<td>5141</td>
<td>2,220,108</td>
<td>N/A^h</td>
<td>N/A</td>
</tr>
<tr>
<td>Hornbrook et al, 2017 [34]</td>
<td>Mixed</td>
<td>Kaiser Permanente North West EHR^i system, Kaiser Permanente Tumor Registry</td>
<td>900</td>
<td>16,195</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Kinar et al, 2017 [53]</td>
<td>Mixed</td>
<td>Maccabi Health Services EMRs, linked to the Israel Cancer Registry</td>
<td>133</td>
<td>112,451</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

^a N/S: not stated.

^b Cases of acute pancreatitis.

^c NHS: National Health Service.

^d Hospitals included: Northwest Prostate Institute Seattle, the University of Washington Seattle, the Johns Hopkins Hospital Baltimore, Memorial Sloan-Kettering Cancer Institute New York, Brigham and Women’s Hospital Boston, and The University of Texas MD Anderson Cancer Center

^e NB: this study also included a small validation study in the Health Improvement Network database in the United Kingdom (n=25,613)
Almost all the studies used different data sets, with the exception of the Maccabi Health Services EHR, which was used in 2 studies [48,53]. The data set sizes ranged from 193 to 2,225,249 patients, with a mean of 241,585 (SD 555,953), median of 3,150, and IQR of 267,237 patients. The wide range is primarily due to the large data set used by Birks et al [52]. Of the 13 development studies, 3 provided no information on the control population used [39,46,51]. Five of the development studies did not provide full information on how they partitioned their data set for the training and testing of the algorithm [39,41,43,47,49]. Five studies appeared to have independent training and testing data sets, with most split in ratios ranging from 60:40 to 70:30 [40,44-46,50].

Three studies [34,52,53] validated a previously developed AI technique [48] in independent data sets. Kinar et al [48] reported both the initial development of an AI technique and a subsequent validation study in an independent data set. The study by Cooper et al [41] was the only study that developed an AI technique based on prospectively collected clinical data, with the data originating from a pilot study of fecal immunochemical testing by the NHS Bowel Cancer Screening Programme [116].

Table 4 summarizes the main reported outcome measures. Specificity (n=11), AUROC (n=11), and sensitivity (n=10) were the most frequently reported; others included PPV (n=6), NPV (n=5), diagnostic accuracy (n=4), and odds ratios (n=3). Specificity results range from 80.6% [45] to 100% [51], sensitivity results from 0% [51] to 96.7% [40], and AUROC results from 0.55 [45] to 0.9896 [44].
<table>
<thead>
<tr>
<th>Study</th>
<th>Cancer type</th>
<th>Outcome measures for each modality of AIa</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Development studies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alzubi et al, 2019 [39]</td>
<td>Lung cancer</td>
<td>• Specificity: 92%, Accuracy: 93%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• False positive rate: 9%; F-1 score: 92%</td>
</tr>
<tr>
<td>Chang et al, 2009 [40]</td>
<td>Pancreatic cancer</td>
<td>• Sensitivity: BPNNb 88.3%, genetic algorithm LRc 96.7%, stepwise LR 96.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity: BPNN 84.2%, genetic algorithm LR 82.5%, stepwise LR 73.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• AUROC:d BPNN 0.895, genetic algorithm LR 0.921, stepwise LR 0.882</td>
</tr>
<tr>
<td>Cooper et al, 2018 [41]</td>
<td>Colorectal cancer</td>
<td>• Sensitivity: 35.15% (at FITe threshold 160 µg g⁻¹)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity: 85.57%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PPVe: 51.47%, NPVe: 75.19%, AUROC: 0.69, cancer detection rate: 10.66%</td>
</tr>
<tr>
<td>Cowley et al, 2013 [42]</td>
<td>Colorectal cancer</td>
<td>• Sensitivity: 90%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity: 96%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PPV: 62%, NPV: 99%</td>
</tr>
<tr>
<td>Daqqa et al, 2017 [43]</td>
<td>Leukemia</td>
<td>• Sensitivity: SVMh 69.7%, K-NNi 60.0%, decision tree 62.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity: SVM 81.5%, K-NN 82.8%, decision tree 87.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PPV: SVM 71.3%, K-NN 68.1%, decision tree 76.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• NPV: SVM 80.4%, K-NN 74.1%, decision tree 87.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Accuracy: SVM 76.82%, K-NN 72.15%, decision tree 77.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• F-measure: SVM 70%, K-NN 60%, decision tree 67%</td>
</tr>
<tr>
<td>Goryński et al, 2014 [44]</td>
<td>Lung cancer</td>
<td>• AUROC: 0.9896</td>
</tr>
<tr>
<td>Hart et al, 2018 [45]</td>
<td>Lung cancer</td>
<td>• Sensitivity: ANNj 75.30%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity: ANN 80.60%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• AUROC: ANN 0.86, RFk 0.81, SVM 0.55</td>
</tr>
<tr>
<td>Kalra et al, 2003 [46]</td>
<td>Prostate cancer</td>
<td>• Specificity: 92%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• AUROC: 0.825</td>
</tr>
<tr>
<td>Kang et al, 2017 [47]</td>
<td>Any cancer</td>
<td>• Sensitivity: DNNl 64.07%, SVM 54.46%, decision tree 60.00%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Specificity: DNN 94.77%, SVM 95.27%, decision tree 91.50%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• AUROC: DNN 0.882, SVM 0.928, decision tree 0.824</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Accuracy: DNN 86.00%, SVM 83.83%, decision tree 83.60%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Using fuzzy interval of threshold with DNN achieves sensitivity 90.20%, specificity 94.22%, accuracy 93.22%</td>
</tr>
<tr>
<td>Kinar et al, 2016 [48]</td>
<td>Colorectal cancer</td>
<td>• Specificity: Testing set 88% overall (at a sensitivity of 50%). Higher for proximal colon tumors. Validation set 94% (at a sensitivity of 50%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• AUROC: Testing set 0.82, validation set 0.81</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ORm 26 at false +ve rate of 0.5% (testing set), OR 40 at false +ve rate of 0.5% (validation set). Algorithm identified 48% more CRCn cases than gFOBTO</td>
</tr>
<tr>
<td>Kop et al, 2016 [49]</td>
<td>Colorectal cancer</td>
<td>• Sensitivity: CARTo 53.9%, RF 63.7%, LR 64.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PPV: CART 2.6%, RF 3%, LR 3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• AUROC: CART 0.885, RF 0.889, LR 0.891</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• F1-score: CART 0.049, RF 0.057, LR 0.058</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Drugs for constipation most important predictor of CRC, followed by iron deficiency anemia</td>
</tr>
</tbody>
</table>
Outcome measures for each modality of AI

- Specificity: 92%
- AUROC: 0.773 for classification of all diseases (cancer and other diagnoses). Rectal or anal cancer 0.887, liver or intrahepatic bile duct cancer 0.886, prostate cancer 0.859, multiple myeloma 0.849, ovarian cancer 0.824, bladder cancer 0.818, testicular cancer 0.811, pancreatic cancer 0.795, leukemia 0.774, uterine cancer 0.771, non-Hodgkin lymphoma 0.771, bronchial or lung cancer 0.770, colon cancer 0.767, breast cancer 0.762, kidney or renal pelvis cancer 0.753, brain or nervous system cancer 0.742, Hodgkin disease 0.731, cervical cancer 0.675
- Accuracy index: 0.929 overall for classification of all diseases
- F-score: 0.181 for classification of all diseases
- Deep patient obtained approximately 55% correct predictions when suggesting 3 or more diseases per patient, regardless of time interval

Multiple diseases and cancers

Miotto et al, 2016 [50]

- Specificity: 92%
- AUROC: 0.773 for classification of all diseases (cancer and other diagnoses). Rectal or anal cancer 0.887, liver or intrahepatic bile duct cancer 0.886, prostate cancer 0.859, multiple myeloma 0.849, ovarian cancer 0.824, bladder cancer 0.818, testicular cancer 0.811, pancreatic cancer 0.795, leukemia 0.774, uterine cancer 0.771, non-Hodgkin lymphoma 0.771, bronchial or lung cancer 0.770, colon cancer 0.767, breast cancer 0.762, kidney or renal pelvis cancer 0.753, brain or nervous system cancer 0.742, Hodgkin disease 0.731, cervical cancer 0.675
- Accuracy index: 0.929 overall for classification of all diseases
- F-score: 0.181 for classification of all diseases
- Deep patient obtained approximately 55% correct predictions when suggesting 3 or more diseases per patient, regardless of time interval

Payandeh et al, 2009 [51]

- Sensitivity: CML 0%, lymphoproliferative disorder 0%
- Specificity: CML 100%, lymphoproliferative disorder 99.2%
- PPV: CML 0%, lymphoproliferative disorder 0%
- NPV: CML 99.2%, lymphoproliferative disorder 100%
- Error % for convoluted neural network 0.33, error % for LR 0.78

Validation studies

Birks et al, 2017 [52]

- Sensitivity: 0-180 days (test to diagnosis): 50-75 years: 34.5%, 40-89 years: 39.9%; 181-360 days: 50-75 years: 18.8%, 40-89 years: 27.4%
- AUROC: 0.80, OR: 34.7 at 99% specificity, 19.7 at 97%, 14.6 at 95%, 10.0 at 90%

Hornbrook et al, 2017 [34]

- Sensitivity: 0-180 days (test to diagnosis): 50-75 years: 34.5%, 40-89 years: 39.9%; 181-360 days: 50-75 years: 18.8%, 40-89 years: 27.4%
- AUROC: 0.80, OR: 34.7 at 99% specificity, 19.7 at 97%, 14.6 at 95%, 10.0 at 90%

Kinar et al, 2017 [53]

- Sensitivity: 17.0% at 1% +ve rate, 24.4% at 3% +ve rate
- PPV: 2.1% at 1% +ve rate, 1.0% at 3% +ve rate
- NPV: 99.9% at 1% +ve rate, 99.9% at 3% +ve rate
- OR: 21.8% at 1% +ve rate, 10.9% at 3% +ve rate

We looked for other secondary outcomes, including implementation barriers to AI techniques in primary care settings, but did not find any evidence related to patient or clinician acceptability or cost-effectiveness.

Table 5 shows the outcomes of the risk of bias assessment using the QUADAS-2 tool. The studies demonstrated a wide range in quality; however, no studies were excluded based on their risk of bias assessment. The identified limitations were acknowledged in the relative contribution of the studies to the conclusions of the review.
Table 5. Critical appraisal results using the Quality Assessment of Diagnostic Accuracy Studies-2 tool.

<table>
<thead>
<tr>
<th>Study</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
<th>Risk of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient</td>
<td>Index test</td>
<td>Reference</td>
<td>Flow and</td>
<td>Patient</td>
<td>Index test</td>
<td>Reference</td>
<td>Patient</td>
<td>Index test</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Alzubi et al, 2019 [39]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Birks et al, 2017 [52]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Chang et al, 2009 [40]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Cooper et al, 2018 [41]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Cowley et al, 2013 [42]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Daqqa et al, 2017 [43]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Gorynski et al, 2014 [44]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Hart et al, 2018 [45]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Hornbrook et al, 2017 [34]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Kalra et al, 2003 [46]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Kang et al, 2017 [47]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Kinar et al, 2016 [48]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Kinar et al, 2017 [53]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Kop et al, 2016 [49]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Miotto et al, 2016 [50]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
<tr>
<td>Payandeh et al, 2009 [51]</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
<td>a</td>
<td>b</td>
<td>c</td>
</tr>
</tbody>
</table>

aHigh risk.  
bLow risk.  
cUnclear risk.

Table 6 summarizes the computer-based technologies identified in our parallel scoping review of commercial AI technologies. We identified 21 commercial computer-based technologies. Of these, 11 were clinician-facing differential diagnosis technologies that did not appear to be integrated into the EHR [117-127]. Ten of the technologies were linked to, or integrated into, the EHR in some way [8,128-136]. Nine of the technologies did not use AI algorithms incorporating an element of machine learning, as was required in our inclusion criteria [118,120-127]. It was also not clear from the websites and studies of 3 further technologies whether they met our AI inclusion criteria [117,130,134]. There were 8 technologies that met our inclusion criteria for AI (Abtrace [128], Babylon [8], Cthesigns [129], Isabel [131], Medial EarlySign [132], symcat [119], symptomate [135], and the unnamed technology evaluated by Liang et al [136]). Only the Medial EarlySign tool was evaluated for its performance in the diagnosis or triage of potential cancer [132]; 4 of the studies developing and validating this technology were included in this systematic review [34,48,52,53]. Cthesigns is specifically designed to aid the early diagnosis of cancer but has not been the subject of any studies we could identify [129].
Table 6. Summarizing scoping review of commercial artificial intelligence technologies.

<table>
<thead>
<tr>
<th>Technology identified (origin) websites and associated academic studies</th>
<th>Not AI(^a)</th>
<th>Not cancer</th>
<th>Not primary care based</th>
<th>Not early detection or diagnosis</th>
<th>Early research</th>
<th>Not published</th>
<th>Not primary research</th>
<th>&lt;50 cases or controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abtrace (United Kingdom)</strong></td>
<td>Abtrace website [128]</td>
<td>_(^b)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X(^c)</td>
<td>—</td>
</tr>
<tr>
<td><strong>Babylon (United Kingdom)</strong></td>
<td>Babylon health website [8]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Zhelezniak et al [137]</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Douglas et al [138]</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Smith et al [139]</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>National Health Service 111 powered by Babylon - Outcomes Evaluation [140]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Middleton et al [141]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Cthesigns (United Kingdom)</strong></td>
<td>Cthesigns website [129]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td><strong>Diagnosis Pro (United States)</strong></td>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Bond et al [117]</td>
<td>N/C(^d)</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>DocResponse (United States)</strong></td>
<td>Docresponse website [130]</td>
<td>N/C</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
</tr>
<tr>
<td><strong>DxPlain (United States)</strong></td>
<td>Dxplain website [118]</td>
<td>N/C</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Barnett et al [142]</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Barnett et al [143]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Bauer et al [144]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Berner et al [145]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Bond et al [117]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Elhanan et al [146]</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Elkin et al [147]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Feldman et al [148]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Hammersley et al [149]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Hoffer et al [150]</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>London et al [151]</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Iliad (United States)</strong></td>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Berner et al [145]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Elstein et al [152]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Friedman et al [153]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Gozum et al [154]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Graber et al [155]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Heckerling et al [120]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Lange et al [156]</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Lau et al [157]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Li et al [158]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Technology identified (origin) websites and associated academic studies</td>
<td>Not AI¹</td>
<td>Not cancer</td>
<td>Not primary care based</td>
<td>Not early detection or diagnosis</td>
<td>Early research</td>
<td>Not published</td>
<td>Not primary research</td>
<td>&lt;50 cases or controls</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lincoln et al [159]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Murphy et al [160]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Wolf et al [161]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Internist-1 (United States)</td>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Miller et al [121]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Miller et al [122]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Isabel (United Kingdom)</td>
<td>Isabel healthcare website – Isabel pro [131]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Bond et al [117]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Ramnarayan et al [162]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Ramnarayan et al [163]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Carlson et al [164]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Graber et al [165]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Graber et al [166]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Ramnarayan et al [167]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Bavdekar et al [168]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Ramnarayan et al [169]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Semigran et al [20]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Meyer et al [170]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Meditel (United States)</td>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Berner et al [145]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hammersley et al [149]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Waxman et al [171]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Wexler et al [123]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Medial Early sign (United States/Israel)</td>
<td>Earlysign website [132]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Kinar et al [53]²</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Birks et al [52]²</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hornbrook et al [34]²</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Goshen et al [172]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Zack et al [173]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cahn et al [174]</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Multilevel Diagnosis Decision Support System (Spain)</td>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Rodriguez-Gonzalez et al [124]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Online webGP (United Kingdom; later became eConsult)</td>
<td>Emis health online-triage website [175]²</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hurleygroup website [176]²</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

¹ Not AI = not identified as artificial intelligence
² Website not found

https://www.jmir.org/2021/3/e23483
<table>
<thead>
<tr>
<th>Technology identified (origin) websites and associated academic studies</th>
<th>Not AI⁶</th>
<th>Not cancer</th>
<th>Not primary care based</th>
<th>Not early detection or diagnosis</th>
<th>Early research</th>
<th>Not published</th>
<th>Not primary research</th>
<th>&lt;50 cases or controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edwards et al [133]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Carter et al [177]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cowie et al [178]</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Pepid (United States)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pepid website [125]ᵇ</td>
<td>N/C</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Bond et al [117]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Problem Knowledge Couplers (PKC; United States)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Apkon et al [126]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Quick Medical Reference (QMR) (United States; developed from Internist-1)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Arene et al [179]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Bacchus et al [180]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Bankowitz et al [181]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Berner et al [145]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Berner et al [182]</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Friedman et al [153]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Gozum et al [154]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Graber et al [155]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Miller et al [122]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Lemaire et al [183]</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reconsider (United States)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Nelson et al [127]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Symcat (United States)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symcat website [119]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Symptify (United States)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptify website [134]</td>
<td>N/C</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Symptomate (Poland)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomate website [135]</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Unnamed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No website identified</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Liang H et al [136]</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

⁶AI: artificial intelligence.

ᵇNot applicable or no data.

ᶜStudy excluded for the reason specified in the column label.

dN/C: not clear.

ᵉThese studies met the inclusion criteria of the systematic review and were therefore included.

ᶠEdwards et al [133] suggests that this Egton Medical Information Systems (EMIS) application is powered by the eConsult system.

ᵍCarter et al [177] suggests that this is the group who developed webGP.

ʰSeveral published studies are linked in the research section of the website, none involved use of the differential diagnosis or decision support tools. Some case studies audited the use of these tools.
Discussion

Principal Findings
We identified 16 studies reporting AI techniques that could facilitate the early detection of cancer and could be applied to the types of data found in primary care EHRs. However, heterogeneity of AI modalities, data set characteristics, outcome measures, conduct of these studies, and quality assessment meant that we were unable to draw strong conclusions about the utility of these techniques in primary care settings. There was a notable paucity of evidence on performance using primary care data. Coupled with the lack of evidence on implementation barriers or cost-effectiveness, this may help explain why AI techniques have not been adopted widely into primary care clinical practice to date. The study by Kinar et al [48] and its subsequent validation in independent data sets [34,52,53], including primary care data sets, is a valuable example of a staged evaluation of an AI technique from early development, via validation data sets, to evaluation in the population for intended use [22]. The work by Kop and collaborators [49,115,184] also represents a good example of the staged development of an AI technique, with sequential peer-reviewed, published evaluations at each stage.

We also identified 21 commercial AI technologies, many of which have not been evaluated and reported in peer-reviewed, published studies. Many other technologies that were patient-facing and designed for the triage of symptoms were identified but had not been applied to EHRs. Eight of these technologies appeared to be based on newer machine learning AI techniques, with the majority appearing to be driven by knowledge-based decision tree algorithms. Only one of the identified technologies has been evaluated specifically for cancer, although it may be more efficacious for these technologies to be very general in scope and to be widely used, rather than to have a narrow focus on cancer alone. With wider adoption, these technologies have a greater potential for raising patient and clinician awareness of cancer. However, it remains important to fully understand their diagnostic accuracy and safety, including for the triage of potential cancer symptoms. AI technologies applied to EHRs are potentially useful for primary care clinicians; however, they need to be designed in a way that is appropriate for the type and origin of the data found in primary care EHRs and to have been thoroughly and transparently evaluated in the population the technology is intended for.

Strengths and Limitations
The strengths of this systematic review include the following: a broad and inclusive search strategy to avoid missing studies; guidance of an international expert panel in the development of the protocol and search strategy; independent screening, quality assessment, and data extraction processes; followed PRISMA guidance; and a parallel scoping review for commercial AI technologies. As only a few heterogeneous studies were identified, it was not possible to synthesize the data and evaluate the utility of these AI techniques. Furthermore, only one commercially available AI technology was identified via the systematic review. Many of the technologies identified in the parallel scoping review lacked sufficient academic detailing and evidence for their accuracy or safety. This is a rapidly evolving research area, which will require further review over time.

Conclusions
Worldwide, there is a great deal of interest in AI techniques and their potential in medicine, not least in the United Kingdom where politicians and NHS leaders have publicly prioritized the incorporation of AI into clinical settings. Our findings support those of Kueper et al [17], namely, that although some AI techniques have good initial validation reports, they have not yet been through the steps for full application in clinical practice. Validation using independent data is preferable to splitting a single data set [185] and could be the next step in the development of many AI techniques identified in this review. Much of the research is at an early stage, with variable reporting and conduct, and requires further validation in prospective clinical settings and assessment of cost-effectiveness after clinical implementation before it can be incorporated into daily practice safely and effectively [186].

Consensus is required on how AI techniques designed for clinical use should be developed and validated to ensure their safety for patients and clinicians in their intended settings. Good internal and external validity is required in these experiments to avoid bias, most notably spectrum bias [187] and distributional shift [16], and to ensure that the appropriate data are used to develop the AI technique in keeping with its anticipated clinical setting and diagnostic function. The CanTest framework provides an outline for further studies aiming to develop this evidence base for AI techniques in clinical settings; to prove their safety and efficacy to commissioners, clinicians, and patients; and to enable them to be implemented in clinical practice [22]. Prospective evaluation in the clinical setting for which the AI technique is intended is essential: AI aimed at primary care clinics must be evaluated in primary care settings, where cancer prevalence is low compared with specialist settings, to accurately evaluate their future performance [187,188]. Further research around the acceptability of AI techniques for patients and clinicians and their cost-effectiveness will also be important to facilitate rapid implementation. Once these AI techniques are ready for implementation, they will require careful design to ensure effective integration into health information systems [189]. Data governance and protection must also be addressed, as they may present significant barriers to the implementation of these technologies [190,191].

In conclusion, AI techniques have the potential to aid the interpretation of patient-reported symptoms and clinical signs and to support clinical management, doctor-patient communication, and informed decision making. Ultimately, in the context of early cancer detection, these techniques may help reduce missed diagnostic opportunities and improve safety netting. However, although there are a few good examples of staged validation of these AI techniques, most of the research is at an early stage. We found numerous examples of the implementation of AI technologies without any or sufficient evidence for their accuracy or safety. Further research is required to build up the evidence base for AI techniques applied to EHRs.
and to reassure commissioners, clinicians, and patients that they are safe and effective enough to be incorporated into routine clinical practice.

Acknowledgments
This research was funded by the National Institute for Health Research (NIHR) Policy Research Programme, conducted through the Policy Research Unit in Cancer Awareness, Screening, and Early Diagnosis, PR-PRU-1217-21601. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. This work was also supported by the CanTest Collaborative (funded by Cancer Research UK C8640/A23385), of which FW and WH are directors and JE, HS, and NdW are associate directors. HS is additionally supported by the Houston Veterans Administration Health Services Research and Development Center for Innovations in Quality, Effectiveness, and Safety (CIN13-413) and the Agency for Healthcare Research and Quality (R01HS27363). The funding sources had no role in the study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit for publication. The authors would like to thank Isla Kuhn, Reader Services Librarian, University of Cambridge Medical Library, for her help in developing the search strategy.

Authors’ Contributions
OJ developed the protocol, completed the search, screened the articles for inclusion, extracted the data, synthesized the findings, interpreted the results, and drafted the manuscript. NC screened the articles for inclusion, extracted the data, and critically revised the manuscript. SS screened the articles for inclusion, extracted the data, and critically revised the manuscript. WH developed the protocol, interpreted the results, and critically revised the manuscript. SD, JE, HS, and NdW critically revised the manuscript. FW developed the protocol, synthesized the findings, interpreted the results, and critically revised the manuscript. All authors approved the final version.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Protocol for the study.
[DOCX File, 34 KB - imir_v23i3e23483_app1.docx ]

Multimedia Appendix 2
Search strategies.
[DOCX File, 16 KB - imir_v23i3e23483_app2.docx ]

Multimedia Appendix 3
Results of the full-text article review.
[DOCX File, 38 KB - imir_v23i3e23483_app3.docx ]

Multimedia Appendix 4
Supplementary information to table 1.
[DOCX File, 36 KB - imir_v23i3e23483_app4.docx ]

References


27. AI in the UK?: Ready, Willing and Able. HOUSE OF LORDS: Select Committee on Artificial Intelligence. 2018. URL: https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf [accessed 2021-01-25]


36. NHS Long Term Plan. URL: https://www.longtermplan.nhs.uk/ [accessed 2021-02-08]


123. Check your symptoms online. Symptomate. URL: https://symptomate.com/


131. C the signs. C the Signs. URL: https://cthesigns.co.uk/ [accessed 2020-11-30]


Abbreviations

AI: artificial intelligence
AUROC: area under the receiver operating characteristic
CT: computed tomography
EHR: electronic health record
NHS: National Health Service
Artificial Intelligence Techniques That May Be Applied to Primary Care Data to Facilitate Earlier Diagnosis of Cancer: Systematic Review

J Med Internet Res 2021;23(3):e23483
URL: https://www.jmir.org/2021/3/e23483
doi:10.2196/23483
PMID:33656443
Future Medical Artificial Intelligence Application Requirements and Expectations of Physicians in German University Hospitals: Web-Based Survey

Oliver Maassen\textsuperscript{1,2}, MSc; Sebastian Fritsch\textsuperscript{1,2,3}, MD; Julia Palm\textsuperscript{2,4}, MSc; Saskia Deffge\textsuperscript{1,2}, MSc; Julian Kunze\textsuperscript{1,2}, MD; Gernot Marx\textsuperscript{1,2}, MD, Prof Dr; FRCA; Morris Riedel\textsuperscript{2,3,5}, Prof Dr; Andreas Schuppert\textsuperscript{1,6}, Prof Dr; Johannes Bickenbach\textsuperscript{1,2}, MD, Prof Dr

\textsuperscript{1}Department of Intensive Care Medicine, University Hospital RWTH Aachen, Aachen, Germany
\textsuperscript{2}SMITH Consortium of the German Medical Informatics Initiative, Leipzig, Germany
\textsuperscript{3}Jülich Supercomputing Centre, Forschungszentrum Jülich, Jülich, Germany
\textsuperscript{4}Institute of Medical Statistics, Computer and Data Sciences, Jena University Hospital, Jena, Germany
\textsuperscript{5}School of Natural Sciences and Engineering, University of Iceland, Reykjavik, Iceland
\textsuperscript{6}Institute for Computational Biomedicine II, University Hospital RWTH Aachen, Aachen, Germany

Corresponding Author:
Oliver Maassen, MSc
Department of Intensive Care Medicine
University Hospital RWTH Aachen
Pauwelsstraße 30
Aachen, 52074
Germany
Phone: 49 2418080444
Email: oliver.maassen@rwth-aachen.de

Abstract

Background: The increasing development of artificial intelligence (AI) systems in medicine driven by researchers and entrepreneurs goes along with enormous expectations for medical care advancement. AI might change the clinical practice of physicians from almost all medical disciplines and in most areas of health care. While expectations for AI in medicine are high, practical implementations of AI for clinical practice are still scarce in Germany. Moreover, physicians’ requirements and expectations of AI in medicine and their opinion on the usage of anonymized patient data for clinical and biomedical research have not been investigated widely in German university hospitals.

Objective: This study aimed to evaluate physicians’ requirements and expectations of AI in medicine and their opinion on the secondary usage of patient data for (bio)medical research (eg, for the development of machine learning algorithms) in university hospitals in Germany.

Methods: A web-based survey was conducted addressing physicians of all medical disciplines in 8 German university hospitals. Answers were given using Likert scales and general demographic responses. Physicians were asked to participate locally via email in the respective hospitals.

Results: The online survey was completed by 303 physicians (female: 121/303, 39.9%; male: 173/303, 57.1%; no response: 9/303, 3.0%) from a wide range of medical disciplines and work experience levels. Most respondents either had a positive (130/303, 42.9%) or a very positive attitude (82/303, 27.1%) towards AI in medicine. There was a significant association between the personal rating of AI in medicine and the self-reported technical affinity level ($\chi^2=48.3$, $P<.001$). A vast majority of physicians expected the future of medicine to be a mix of human and artificial intelligence (273/303, 91.1%) but also requested a scientific evaluation before the routine implementation of AI-based systems (276/303, 91.1%). Physicians were most optimistic that AI applications would identify drug interactions (280/303, 92.4%) to improve patient care substantially but were quite reserved regarding AI-supported diagnosis of psychiatric diseases (62/303, 20.5%). Of the respondents, 82.5% (250/303) agreed that there should be open access to anonymized patient databases for medical and biomedical research.

Conclusions: Physicians in stationary patient care in German university hospitals show a generally positive attitude towards using most AI applications in medicine. Along with this optimism comes several expectations and hopes that AI will assist...
physicians in clinical decision making. Especially in fields of medicine where huge amounts of data are processed (eg, imaging procedures in radiology and pathology) or data are collected continuously (eg, cardiology and intensive care medicine), physicians’ expectations of AI to substantially improve future patient care are high. In the study, the greatest potential was seen in the application of AI for the identification of drug interactions, assumedly due to the rising complexity of drug administration to polymorbid, polypharmacy patients. However, for the practical usage of AI in health care, regulatory and organizational challenges still have to be mastered.

( J Med Internet Res 2021;23(3):e26646 ) doi:10.2196/26646

KEYWORDS
artificial intelligence; AI; machine learning; algorithms; clinical decision support; physician; requirement; expectation; hospital care

Introduction
While a balance between the increasing amount of documented data on the one hand and the demographic change and aging populations on the other hand challenges our health care systems, big data and artificial intelligence (AI) in medicine offer a huge potential to relieve physicians from the increasing complexity of today’s health care and information overload when treating patients [1,2]. Over the last decade, research on AI in medicine and biomedicine and the number of publications in these fields have substantially increased [3,4]. Research has come up with promising AI developments in general machine learning (ML) algorithms, for manifold applications to predict clinical events, to improve diagnoses accuracy as well as treatments, and to reduce the burden of disease [5,6]. Well-known examples for AI in medicine are the application of deep learning as a subfield of ML in medical imaging for disease detection from X-rays [7]. Thus, it is expected that AI in medical practice will meet higher expectations of medical treatment and physicians and will increase the efficiency of clinical care. AI is perceived as the next big thing that will sustainably change medicine towards precision and personalized medicine [8] and change health care and with it, the role of physicians. It is believed that physicians will not be replaced by AI, but AI will make lives easier and focussed where human interaction is really required.

Big Data and AI in Medicine: Definition and Application Areas

An ever-increasing amount of medical data is being recorded by monitoring patient care devices, enabling big data analysis in health care [9]. This paves the way for the application of different ML techniques like deep learning [7], traditional shallow neural networks, support vector machines, and random forests, which are specific models for using AI in practice [10]. Besides conventional ML techniques, deep learning in particular offers advantages for understanding and manipulating the highly relevant class of data, especially for images, language, and speech recognition [11]. However, while deep learning is superior for specific applications, it has limitations for other applications where conventional ML techniques are superior [12]. Examples include cases where large datasets are not available to study a specific medical condition, as deep learning generally requires a large dataset to perform well in practice.

Despite its widespread use, a holistic definition of the term “artificial intelligence” is challenging. This can be partly explained by the fact that it is a “high-level” term, often not mentioning concrete ML algorithms or models in a clear context. Examples of AI in medicine are AI applications to support diagnostic procedures, predict the course of the disease [13-17], enhance the potential of clinical decision support [18], and support the management of hospital workflows [19,20]. Thereby, AI offers the possibility to support physicians in delivering high-quality medicine and increasing medical care efficiency.

Preconditions for AI Development for Health Care

One essential precondition for the development of AI in medical practice is data availability to develop and train the algorithms. Therefore, the creation of research databases with consolidated anonymized patient data, ideally from multiple locations making clinical routine data available for so called “secondary usage,” is desirable. One very prominent example of such a database is the freely accessible critical care database MIMIC-III (Medical Information Mart for Intensive Care) [21]. After accepting a data use agreement, researchers are granted unrestricted access for analysis. Since its publication in August 2015, the respective publication was cited more than 850 times, showing the great interest in this database and its wide scientific usage [22]. Nevertheless, due to different health care systems and information systems used for patient care, the structure and content of patient data from German hospitals are not in accordance with data from US hospitals. Consequently, there is an urgent need to establish research databases that are applicable to the situation in Germany.

Challenges of Big Data and AI in Medicine

Today, the widespread practical implementation of AI and AI-based decision support into hospital care has not yet become reality [23]. Especially in radiology and other medical imaging procedures, vendors of medical technology have predominantly integrated some kind of AI (eg, ML algorithms) into their products [24]. In addition, in the field of medical prediction, there are cases that have already been applied to electronic health records to complete prospective verification studies [25,26]. Cabitza et al [27] described the sociotechnical elements that must be mastered to successfully implement potentially effective AI in real-world clinical settings, which they call the “last mile” gap of AI implementation. Further multifaceted technical, regulatory, social, and human factors hinder the practical application of AI in clinical care [23].
Tremendous efforts have already been made to evaluate AI in health care and AI-enabled clinical decision support [28]. However, only a few medical AI applications are really used in clinical practice. As physicians are supposed to be the primary users of AI in medicine, there is a need to investigate physicians’ requirements and expectations for future developments of AI in health care. In addition, regulatory questions, like the liability for medical errors, must be regulated if AI is to be used in physician practice and patient care [29].

Another often observed challenge in applying AI is the availability of sensitive patient datasets due to General Data Protection Regulation constraints, mostly when AI is used beyond just one health care organization. In this context, federated ML [30] is a promising approach to obtain powerful, accurate, safe, robust, and unbiased models by enabling multiple organizations to train collaboratively without the need to exchange or centralize datasets. Also, a federated ML approach can be useful where datasets within one organization might not be enough to train good models (eg, rare diseases). In this context, transfer learning approaches [31] are feasible, too, whereby medical AI models are created using a pretrained, state-of-the-art AI model from a different larger medical dataset or otherwise openly available data (eg, ImageNet dataset).

Both are not often applied in Germany today. To address the multifaceted complexity of AI, the purpose of our study was to evaluate the general perception towards AI in medicine among physicians, but also towards concrete application and the opinion on the usage of anonymized patient data for (bio)medical research and AI development.

To achieve this, we developed a web-based survey for physicians in German academic hospitals. The results should also help researchers and data scientists to better understand physicians’ needs regarding AI systems and to boost their use in clinical care.

**Methods**

**Study Design, Data Collection, and Recruitment**

For the survey's conceptualization, open and explorative interviews were carried out with 3 junior and 3 senior physicians. The results were structured and then utilized to frame the survey questions in German. These questions were integrated into an open web-based survey (LimeSurvey) to be conducted among our study population in 8 German university hospitals consisting exclusively of physicians from the full range of medical disciplines. The local ethics committee and local data protection officer did not express objections to the publication of the collected survey data. For verification and functionality validation, we performed a test phase of the online survey with 25 anesthesiologists and critical care physicians in June 2019. Minor adaptations were added in the final survey version before its link was sent to physicians in 8 university hospitals via email by local persons in charge.

The survey was available for 19 weeks from June 2019 till October 2019. Within the data collection period, no content modifications nor bug fixes were necessary, and we did not identify any unforeseen events like system errors or server downtime.

The survey was separated into 2 sections. The first section was comprised of questions about AI in medicine, and the second contained general biographical questions.

A translated, English version of the survey is attached in Multimedia Appendix 1. We only included completely filled out questionnaires in the statistical analysis. However, this might include some questions that were not answered (no response).

The questions about AI in medicine are separated into 3 sections: (1) personal opinion about AI in health care (Q1.1–Q1.16; Q4), (2) fields of application of AI in medicine (Q2.1–Q2.25), (3) usage of anonymized patient data for research purposes (Q3.1–Q3.4)

The question groups 1, 2, and 3 were phrased as single-choice questions asking physicians about their personal view on given statements using a 4-point Likert scale without a neutral option. The first set of questions (Q1.1–Q1.16) in the survey explored the attitudes towards AI in medicine. The second set of questions focused on fields of AI application in medicine. In total, 25 AI applications were given, and physicians were asked to rate if the proposed applications could substantially improve patient care in the future. The third set of questions explored physicians' opinions on the secondary usage of anonymized patient data for research purposes (eg, for AI development for medical practice). Physicians were asked whether they agreed or disagreed with the statements on the usage of anonymized patient data for clinical and biomedical research. Finally, we asked physicians how positively or negatively they evaluated the use of AI in medicine on a 5-point Likert scale. This question (Q4) was assigned to the first section, “Personal opinion about AI in health care.” Biographical answers were mostly conceptualized as closed-ended, single-choice questions (eg, demographic questions), but were also presented as multiple choice questions (eg, medical discipline and predominant workplace).

**Statistical Analysis**

For the statistical analysis, we stratified the potential fields of AI applications in medicine into 6 categories: (1) imaging procedures, (2) other diagnostic procedures, (3) intensive care unit (ICU)/anesthesia, (4) medication and therapy, (5) workflow support and education, (6) prognosis assessment (Textbox 1). Here, we partly reference peer-reviewed publications of AI algorithms, comparing AI algorithms with physicians cited by Topol [32]. In addition, we categorized the 33 medical disciplines into 6 categories for further subgroup analysis (see Table S1 in Multimedia Appendix 2). We analyzed most of the data descriptively using graphics produced by the R packages sjPlot [33] and ggplot2 [34]. Where appropriate in the survey data analysis, we conducted Kruskal-Wallis tests to investigate the relationship between AI rating and biographical data. All analyses were conducted in R version 4.0.3 [35].
Textbox 1. Categories of artificial intelligence (AI) applications in stationary hospital care.

- 1. Imaging procedures
  - 1.1 Analysis of x-rays, computed tomography (CT), magnetic resonance tomography (MRT), sonographies [36-38]
  - 1.2 Analysis of histopathologic fine cuts [39,40]
  - 1.3 Analysis of endoscopic pictures or videos [41-43]
  - 1.4 Analysis of dermatologic reflected light microscopy [44,45]

- 2. Other diagnostic procedures
  - 2.1 Analysis of electroencephalography (EEG)/electrocardiography (ECG) [46,47]
  - 2.2 Diagnosing rare diseases [48,49]
  - 2.3 Triage in emergency care [50,51]
  - 2.4 Diagnosing psychiatric diseases [52,53]
  - 2.5 Subspecification of hematologic diseases [54-56]

- 3. Intensive care unit (ICU)/anesthesia
  - 3.1 Early alarm of the deterioration of patient status [57]
  - 3.2 Reduction of false alarms in intensive care medicine [58]
  - 3.3 Automatic mechanical ventilation [59,60]
  - 3.4 Support of parenteral or enteral nutrition [61]
  - 3.5 Automatic anesthesia administration [62]

- 4. Medication and therapy
  - 4.1 Oncologic therapy planning [18,63]
  - 4.2 Antibiotic stewardship [64]
  - 4.3 Identification of drug interactions [65-67]
  - 4.4 Medication for geriatric patients [68]
  - 4.5 Medication for pediatric patients [69]

- 5. Workflow support and education
  - 5.1 Education and training of medical students and physicians [70]
  - 5.2 Workflow support in stationary hospital care [19,20]
  - 5.3 Medical recording or discharge letters [71,72]

- 6. Prognosis assessment
  - 6.1 Prediction of effects of therapeutic interventions [73]
  - 6.2 Assessment of prognosis of malignant diseases [13-15]
  - 6.3 Assessment of prognosis of nonmalignant diseases [16,17]

**Results**

**Demographic and Professional Characteristics**

The online survey was finished by 121 (121/303, 39.9%) female and 173 (173/303, 57.1%) male physicians (no response: 9/303, 3.0%). Their mean length of clinical work experience was 12.7 years. In particular, physicians from the age groups of 25-34 years (98/303, 32.3%), 35-44 years (103/303, 34.0%), and 45-54 years (69/303, 22.8%) participated. Physicians from a wide range of medical disciplines and from all proposed clinical hierarchical levels took part in the survey (Table 1). Additionally, all proposed operational areas (hospital ward, operating theater, outpatient clinic, ICU, office, laboratory, functional area, others areas) are represented in the survey (Table 1).
Table 1. Demographic and professional characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Values (n=303)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age range (years), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>25-34</td>
<td>98 (32.3)</td>
</tr>
<tr>
<td>35-44</td>
<td>103 (34.0)</td>
</tr>
<tr>
<td>45-54</td>
<td>69 (22.8)</td>
</tr>
<tr>
<td>55-65</td>
<td>21 (6.9)</td>
</tr>
<tr>
<td>&gt;65</td>
<td>3 (1.0)</td>
</tr>
<tr>
<td>No response</td>
<td>8 (2.6)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>121 (39.9)</td>
</tr>
<tr>
<td>Male</td>
<td>173 (57.1)</td>
</tr>
<tr>
<td>No response</td>
<td>9 (3.0)</td>
</tr>
<tr>
<td><strong>Current occupation, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Assistant physician</td>
<td>101 (33.3)</td>
</tr>
<tr>
<td>Medical specialist</td>
<td>49 (16.2)</td>
</tr>
<tr>
<td>Senior physician</td>
<td>108 (35.6)</td>
</tr>
<tr>
<td>Clinic director</td>
<td>28 (9.2)</td>
</tr>
<tr>
<td>Others</td>
<td>6 (2.0)</td>
</tr>
<tr>
<td>No response</td>
<td>11 (3.6)</td>
</tr>
<tr>
<td><strong>Medical field or discipline, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Anesthesiology/intensive care medicine</td>
<td>75 (24.8)</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>53 (17.5)</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>25 (8.3)</td>
</tr>
<tr>
<td>Surgery</td>
<td>22 (7.3)</td>
</tr>
<tr>
<td>Neurology</td>
<td>14 (4.6)</td>
</tr>
<tr>
<td>Dermatology</td>
<td>12 (4.0)</td>
</tr>
<tr>
<td>Microbiology, virology, infectiology</td>
<td>10 (3.3)</td>
</tr>
<tr>
<td>Psychiatry and psychotherapy</td>
<td>10 (3.3)</td>
</tr>
<tr>
<td>Psychosomatic medicine and psychotherapy</td>
<td>8 (2.6)</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>8 (2.6)</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>7 (2.3)</td>
</tr>
<tr>
<td>Pathology</td>
<td>7 (2.3)</td>
</tr>
<tr>
<td>Otorhinolaryngology</td>
<td>5 (1.7)</td>
</tr>
<tr>
<td>Child and adolescent psychiatry and psychotherapy</td>
<td>5 (1.7)</td>
</tr>
<tr>
<td>Laboratory medicine</td>
<td>5 (1.7)</td>
</tr>
<tr>
<td>Radiology</td>
<td>5 (1.7)</td>
</tr>
<tr>
<td>Urology</td>
<td>5 (1.7)</td>
</tr>
<tr>
<td>Other disciplines/ specialization</td>
<td>43 (14.2)</td>
</tr>
<tr>
<td><strong>Predominant workplace, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Hospital ward</td>
<td>123 (40.6)</td>
</tr>
<tr>
<td>Operating theater</td>
<td>106 (35.0)</td>
</tr>
<tr>
<td>Outpatient clinic</td>
<td>100 (33.0)</td>
</tr>
</tbody>
</table>
Physicians’ Attitudes Towards AI in Medicine

A majority of physicians reported either a positive (130/303, 42.9%) or a very positive attitude (82/303, 27.1%) towards AI in medicine (Q4; see Multimedia Appendix 3), representing more than two-thirds of the respondents; 18.2% (55/303) rated it neutral, and just 5.6% (17/303) rated it either negative or very negative.

As described in the Methods, we categorized the first question group into 3 subcategories. The first category focused on the rules and regulatory requirements of AI in medicine (see Figure 1). We found strong agreement (ie, “rather applies” and “fully applies”) among physicians (276/303, 91.1%) for a scientific evaluation before the implementation of an AI-based system. Furthermore, the requirement for special “AI training” for physicians before usage of an AI-based decision support system was clearly favored (207/303, 68.3%).

Figure 1. Rules and regulatory requirements of artificial intelligence (AI) usage in medicine.

The statements regarding the responsibility for AI decisions and the influence of algorithms’ lack of logical comprehensibility returned a much less clear picture with answers split nearly in half.

In the second subcategory of questions, “effect of AI on medical treatment” (see Figure 2), respondents mostly agreed with the statement “The future or medicine will be shaped by a mix of human and artificial intelligence” (273/303, 90.1%). Most physicians also expected a reduction of malpractice through the use of AI (204/303, 67.3%). At the same time, a majority didn’t expect (ie, “doesn’t apply at all” and “rather doesn’t apply”) that AI would give them more time for their patients (203/303, 67.0%) or that they would play a minor role in the treatment of patients (219/303, 72.3%).
Figure 2. Effect of artificial intelligence (AI) on medical treatment.

The third subcategory of questions (see Figure 3) focused on the effect of AI in physicians’ work. Here, respondents agreed that the usage of AI in healthcare would increase physicians’ dependence on computer systems (267/303, 88.1%). They also agreed that AI-based decision support systems would change their work as a physician (264/303, 87.1%). The clear majority also anticipated a change of physicians’ job requirements (252/303, 83.2%). For the statement “Usage of AI prevents doctors from learning to correctly assess a patient,” agreement and disagreement were roughly evenly distributed (agreement: 146/303, 48.2%; disagreement: 144/303, 47.5%).

Figure 3. Effect of artificial intelligence (AI) on physicians’ work.
The Kruskal-Wallis test revealed no significant difference in the personal rating of AI between the current occupations of assistant physician, medical specialist, senior physician, and clinic director ($H_3=6.39$, $P=.09$; see Multimedia Appendix 4). We could also not find a strong association between the AI score and the medical discipline groups described in the Methods section ($H_5=5.92$, $P=.31$; see Multimedia Appendix 5).

As expected, we found a significant association between the personal rating of AI in medicine and the self-reported technical affinity level ($H_4=48.3$, $P<.001$; Figure 4).

Figure 4. Personal rating of artificial intelligence (AI) stratified by technical affinity score.

### AI in Medicine: Fields of Application With the Potential to Improve Clinical Practice

In the second section of the survey, we asked the physicians for their appraisal of the potential of AI in medicine to improve clinical care in various fields of application. In total, 25 AI applications were proposed. As described in the Methods section, we also stratified the applications for analysis into 6 categories (Textbox 1, Figure 5).

In the first category, “AI for imaging procedures,” a large majority of physicians agreed that all proposed applications had the potential to improve patient care substantially in the future. There was especially high agreement among respondents for the potential of AI to enhance the analysis of x-rays, computed tomography, magnetic resonance tomography, and sonographies (263/303, 86.8%). However, there was less agreement for the future potential of AI in the analysis of endoscopic images and videos (194/303, 64.0%) than for other applications.

In the second category, “AI for other diagnostic procedures,” most physicians expected patient care to be improved significantly by using AI for the analysis of electroencephalograms and electrocardiograms and subspecification of hematologic diseases (257/303, 84.8%). Only a minority of respondents saw a role of AI in the diagnosis of psychiatric diseases (62/303, 20.5%) and in triage in emergency care (142/303, 46.9%).

The application of AI for ICU and anesthesia was assessed in the third category of AI applications for medicine. The majority of physicians agreed that all applications would improve patient care, even though the agreement for the potential of automatic anesthesia administration (172/303, 56.8%) was rated much lower than for the application of AI for an early alarm of the deterioration of patient status (267/303, 88.1%).

Furthermore, in the fourth and fifth categories “AI for medication and therapy” and “AI for workflow support and education,” respectively, a majority of respondents expected an improvement of daily practice through the listed AI applications. While AI’s potential for the identification of drug interactions was outstandingly high (280/303, 92.4%), fewer physicians were convinced that AI for oncology therapy planning will advance patient care (199/303, 65.7%). Also, workflow support in stationary hospital care was expected and rated as beneficial for patient care in the future (240/303, 79.2%).
In the sixth category, regarding usage of AI for prognosis assessment, therapeutic interventions, and prognosis of malignant and nonmalignant diseases, we received lower agreement than in most other categories regarding an expected improvement in patient care.

In sum, in almost all categories of AI applications in medicine, physicians saw a high potential to improve patient care. A ranking of all proposed applications across all categories with the highest number of answers for "rather applies" and “fully applies” can be found in Table S2 in Multimedia Appendix 2. A short version, including the highest-rated applications and the lowest-rated potential to improve patient care in the future, is presented in Table 2. This table shows that the most frequently mentioned application to improve patient care was “Identification of drug interactions.” On the other side of the scale, the 2 least often mentioned AI applications with the highest number of answers for "rather doesn’t apply at all" and “fully doesn’t apply” can be found in Table S2 in Multimedia Appendix 2.
applications with potential for the future of health care were the usage of AI for “diagnosis of psychiatric diseases” and for “triage in emergency care.” Beside those applications, there were also high numbers of “no responses” for specific applications like the application of AI for “Subspecification of hematologic diseases” (No response: 64/303, 21.1%).

<table>
<thead>
<tr>
<th>Rating</th>
<th>Artificial intelligence (AI) application</th>
<th>Field of application</th>
<th>Responses of “rather applies” or “fully applies”, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identification of drug interactions</td>
<td>Medication and therapy</td>
<td>280 (92.4)</td>
</tr>
<tr>
<td>2</td>
<td>Early alarming of deterioration of patient status</td>
<td>ICU³/anesthesia</td>
<td>267 (88.1)</td>
</tr>
<tr>
<td>3</td>
<td>Analysis of x-rays, CTb, MRTc, sonographies</td>
<td>Imaging procedures</td>
<td>263 (86.8)</td>
</tr>
<tr>
<td>4</td>
<td>Analysis of ECGs³ and EEGs⁵</td>
<td>Other diagnostic procedures</td>
<td>257 (84.8)</td>
</tr>
<tr>
<td>[...]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Assessment of prognosis of nonmalignant diseases</td>
<td>Prognosis assessment</td>
<td>177 (58.4)</td>
</tr>
<tr>
<td>23</td>
<td>Automatic anesthesia administration</td>
<td>ICU/anesthesia</td>
<td>172 (56.8)</td>
</tr>
<tr>
<td>24</td>
<td>Triage in emergency care</td>
<td>Other diagnostic procedures</td>
<td>142 (46.9)</td>
</tr>
<tr>
<td>25</td>
<td>Diagnosis of psychiatric diseases</td>
<td>Other diagnostic procedures</td>
<td>62 (20.5)</td>
</tr>
</tbody>
</table>

²ICU: intensive care unit.
³CT: computed tomography.
⁴MRT: magnetic resonance tomography.
⁵ECG: electrocardiogram.
⁶EEG: electroencephalogram.

**Personal Opinion of Physicians on the Secondary Usage of Anonymized Patient Data for Medical Research**

In the third group of questions, we investigated physicians’ attitudes on the secondary usage of anonymized patient data for medical data research, which in sum, was positive for the majority of respondents (see [Figure 6](#)). Solely for the question regarding balancing better treatment of diseases versus individual data protection, controversial answers were given. Most physicians thought that anonymized patient data should be freely available in Germany for research purposes (250/303, 82.5%), and 83.2% of respondents (252/303) agreed or fully agreed that they wished to be able to use anonymized patient data for their own research.
**Discussion**

**Principal Findings**

In our study, we could demonstrate that most physicians reported a positive or a very positive attitude towards AI in medicine. Physicians expect that AI will be used in clinical practice for various applications and will substantially improve patient care. There was agreement among the majority of physicians that AI will change their work as a physician. Participants also had a positive attitude towards using anonymized patient data for research purposes as a precondition for the development of algorithms for medical practice. Nevertheless, the usage of AI in medicine in today’s clinical practice in hospitals and health care in Germany is rare.

Shaw et al [74] investigated the challenges of implementing AI in health care compared with other technologies, suggesting that AI implementation in medicine poses novel difficulties. Specific hurdles to be mastered are the absence of interoperability standards and missing regularities in cases of AI-driven, wrong decisions [23].

To overcome the problem of missing interoperability and improve access to health care data for clinical and biomedical research in Germany, the Ministry of Research and Education has initiated the German Medical Informatics Initiative to make clinical health data from patient care available for medical research [75]. Four consortia (Smart Medical Information Technology for Healthcare [SMITH] [76], Medical Informatics in Research and Care in University Medicine [MIRACUM] [77], HiGHmed [78], and Data Integration for Future Medicine [DIFUTURE] [79]) that include all German university hospitals are conceptualizing, developing, and operating so-called data integration centers in the university medical centers to make health care data from health information systems accessible for medical research. Beyond that, the initiative aims to create the regulatory framework and prerequisites for the secondary usage of routine health care data for (bio)medical data research [75].

**Physicians’ Attitudes Towards AI in Medicine**

Physicians participating in our survey had a positive attitude towards the usage of AI in medicine. Nevertheless, they emphasized the need for scientific proof prior to broad implementation of AI-based systems. Besides the obligatory medical device instruction for AI in medicine, physicians want to have dedicated professional training to use AI in medicine. Another precondition for clinical usage of AI is clarity about the legal liability for its usage, especially when the basis of AI recommendations might not be easy to comprehend at once. Our survey’s controversial answers to legal and regulatory questions show that rules and regulatory requirements are either not clear or nonexistent. Sullivan and Schweikart [29] described the complexity of legal responsibilities of health professionals and technology manufacturers, especially if the AI technology recommendations are not explainable. The authors highlighted one major problem: If the reasoning for recommendations is unknown, the AI is a black box, and there is a need for new legal solutions for AI usage in medicine.

While most physicians expect the future of medicine to be characterized by the combination of human and artificial intelligence, AI has already been proven to be able to outperform human physicians in specific tasks [80]. Nevertheless, human intelligence also learns from AI systems. As a restriction, the
authors think that an AI system making fully autonomous decisions would be neither desirable nor acceptable for the public.

Therefore, a hybrid solution of human and artificial intelligence can form a symbiotic relationship. Physicians expect that AI will significantly impact them and introduce changes for their daily work. This also includes the dependency of physicians on computer systems and new job requirements for physicians. Yu et al. [81] described that AI can improve the quality of care by reducing human error and reducing human fatigue from a routine clinical task, but will probably not reduce physicians' workload, because medical guidelines might suggest higher frequencies of examinations for vulnerable patients. The authors Magrabi et al. [28] described the challenges of evaluating AI-based decision support and AI's practical implications for medical practice. Due to the actual small number of AI applications, there is only little evidence to describe the concrete implications of AI for the clinical work of physicians. Nevertheless, it can be expected that analogously to the variety of AI applications in medical disciplines, physicians' work will change according to the task supported by the AI application. However, we see a general urgent need to integrate AI in medical education and professional training curricula [82,83].

**Fields of AI Application With the Potential to Improve Clinical Practice**

Currently, AI usage in medicine is one of the most promoted topics in medicine as a new technology that will fundamentally change physicians’ clinical practice [32,84]. On the one hand, there are enormous expectations on AI-based decision support systems for better diagnosis, treatment, and clinical documentation facilitation. On the other hand, only a few AI applications have passed the regulatory requirements and have been implemented in clinical routine practice [85]. Participants in our study were optimistic that most proposed AI applications for medicine would improve patient care substantially in the future. The majority rated 23 of 25 applications positively, and 14 of these applications were evaluated by more than 70% of respondents to substantially enhance patient care. The highest potential was given for the AI application “identification of drug interactions,” while the AI application for “diagnosis of psychiatric diseases” received the least positive evaluations. We assume that due to the increasing complexity of medication administration, physicians hope to be supported by AI-based decision support systems to avoid drug interactions especially when treating polymorbid, polypharmacy patients. The low rating of AI’s potential for psychiatric diseases is remarkable as there are several AI applications for this medical field as described for ML in recent publications [52,53]. Respondents in the study population might not yet be completely informed about all potential AI applications, like in this context as well as the application of AI for speech or voice analysis using a recording.

Recently, Laguarta et al. [86] from the Massachusetts Institute of Technology successfully developed and applied an AI model for diagnosing COVID-19 using only cough recordings, achieving a COVID-19 sensitivity of 98.5% with a specificity of 94.2% (area under the curve: 0.97). For asymptomatic subjects, the AI model achieved a sensitivity of 100% with a specificity of 83.2% [86]. The press release about the Massachusetts Institute of Technology Open Voice approach and the application of AI for voice analysis for the diagnosis of COVID-19 will contribute to informing physicians and the general population about less-known applications of AI for health care. To give physicians a basic understanding of AI for medical practice as well as its limitations and opportunities, Meskó and Görög [84] published a guide for medical professionals in the era of AI.

Table 2 shows that those applications using (sensor-based) continuously collected data in particular (eg, in ICUs or cardiology and neurology, imaging and video diagnostic procedures) and AI applications for workflow support were considered promising to substantially improve future patient care. In this context, Rush et al. [87] argued that the data-rich ICU environment has massive AI usage potential. We can see that those fields were rated with high potential for future medicine improvement where information technology usage is high and structured data are documented. Less agreement among respondents was reached for fields with less structured data like therapeutic interviews in psychiatry.

**Personal Opinion of Physicians on the Secondary Usage of Anonymized Patient Data for AI Development and Other Research Purposes**

Access to clinical research databases like the MIMIC database is an elementary precondition for AI development for medicine. We found very positive attitudes towards the secondary usage of anonymized patient data for clinical and biomedical research. The fact that many researchers are positive about the anonymization and disclosure of their data after research can be a solution to the lack of publicly open medical data. Physicians’ attitudes are in line with the general movement of science and engineering to make research data “findable, accessible, interoperable, and reusable”—according to the FAIR data principles [88,89]. A European initiative applying the FAIR data principles is the European Open Science Cloud (EOSC), providing services to find and reuse each other’s research objects under optimal and well-defined conditions [90]. The EOSC-Hub offers a wide selection of freeware services for researchers (eg, in the fields of data management, storage, data sharing, discovery, processing, and analysis) under one federated identity security system [90].

For the question addressing the trade-off between individual data protection and improvement of medical diagnosis or therapy, no uniform opinion nor tendency was found. To avoid such issues, various privacy-preserving technologies have been developed for clinical and biomedical research, such as record linkage, synthetic data generation, and genomic data privacy [91]. Price and Cohen [92] described the legal and ethical challenges of big data for data privacy and how to handle patient data for the best conception of health privacy. The authors concluded that “Privacy underprotection and overprotection each create cognizable harms to patients both today and tomorrow,” highlighting the enormous complexity of privacy in big data research.
Strengths and Limitations

We conducted a web-based survey among hospital physicians about their opinion of AI applications for different fields of applications and the attitudes of physicians towards the secondary usage of patient data for medical research. To our knowledge, this is the first survey to interrogate physicians’ expectations and opinions of AI usage in medicine across German university hospitals. Yet, we did not investigate the usability of specific AI-based applications or decision support systems in our survey.

A limitation of our online survey is possible recruitment bias, as participating physicians may have had a particular interest or were involved in research on AI in medicine. The majority of respondents reported a positive attitude towards AI in healthcare. In addition, we found a positive association between self-reported technical affinity and attitude towards AI in medicine (Figure 4). Therefore, participants in our survey might have a more positive attitude towards technology and AI in healthcare than the whole population of physicians in German university hospitals. Even though physicians from almost every medical discipline participated in our survey, 42.2% (128/303) were internal medicine and anesthesia department clinicians. This might have had an impact on the rating of the potential of AI application to improve health care in the future (Figure 5, Table 2). In consequence, AI applications performing tasks, which are common in these dominating disciplines, like identification of potential drug interactions and usage of continuous patient data monitoring could have received higher ratings than in a fully balanced population. Further studies on the usability and added value of AI applications in healthcare are needed prior to implementation in hospitals and medical practice in general. According to Magrabi et al [28], a rigorous initial and ongoing evaluation is essential for the safety and effectiveness of AI integration in sociotechnical settings like healthcare. Due to the huge variety and high complexity of AI applications, this paper may not take all regulatory issues into account.

Conclusions

Most physicians expect that medicine’s future will be characterized by a combination of human and artificial intelligence. The participating physicians evaluated that most of the proposed AI applications will substantially improve patient care in the future. The highest potential is given to AI applications using sensor-based, continuously collected data like electrocardiogram and electroencephalogram or continuous patient monitoring in ICUs, imaging procedures in diagnostics, and workflow support. Physicians have the greatest expectation in the use of AI for the identification of drug interactions, reflecting the rising complexity of drug administration. Thus, future clinical AI users in hospitals seem to be ready for this new technology's clinical usage. We expect that AI applications will support imaging diagnostics and that AI applications for sensor-based, continuously collected data will be used in healthcare in the near future. In other medical disciplines with less standardization of data processing and collection, like in the German outpatient sector, AI applications will be developed and used in clinical practice later.

In general, the secondary usage of patient data and open access to databases for medical research were seen very positively by the physicians in our survey. Researchers in clinical and biomedical research would like to benefit from better access to research databases to generate new insights for improved patient care. Thus, initiatives like the German Medical Informatics Initiative, EOSC, and FAIR data principles will improve data usage from clinical care for clinical and (bio)medical research and facilitate researchers’ access to clinical research data. In turn, that will fundamentally enhance the conditions of clinical data analysis and, as a consequence, enable better and personalized treatments for patients. Nevertheless, before new AI applications are implemented in clinical practice, the regulatory, legal, and ethical challenges must be mastered. Legislators and regulators must create the necessary framework for anonymous patient data exchange for clinical care and research, development of medical AI applications, and finally, its practical bedside use by physicians in healthcare.

Acknowledgments

This publication of the SMITH consortium was supported by the German Federal Ministry of Education and Research, grant numbers 01ZZ1803B, 01ZZ1803C, and 01ZZ1803M.

Authors’ Contributions

OM and SF designed the survey and set up the web-based survey. OM, JP, and SF analyzed the data. OM wrote the manuscript. SF, JP, SD, JK, GM, MR, AS, and JB revised the article. All authors approved the final draft.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey on the usage of artificial intelligence in stationary hospital care.
[DOCX File, 36 KB - jmir_v23i3e26646_app1.docx ]

Multimedia Appendix 2
Additional tables.

Multimedia Appendix 3
Personal rating of the usage of AI in medicine? (Scale: 1 – 5; 1 = very negative; 3 = neutral; 5 = very positive).

Multimedia Appendix 4
Overall rating of artificial intelligence (AI) stratified by current occupation.

Multimedia Appendix 5
Artificial intelligence (AI) affinity score stratified by medical discipline group.

References


35. R-Core-Team. R: A language and environment for statistical computing (Version 4.0.3). The R Foundation. URL: https://www.r-project.org/


https://www.jmir.org/2021/3/e26646

J Med Internet Res 2021 | vol. 23 | iss. 3 | c26646 | p.507

(page number not for citation purposes)


Abbreviations

AI: artificial intelligence  
DIFUTURE: Data Integration for Future Medicine  
EOSC: European Open Science Cloud  
ICU: intensive care unit  
MIMIC: Medical Information Mart for Intensive Care  
MIRACUM: Medical Informatics in Research and Care in University Medicine  
ML: machine learning  
SMITH: Smart Medical Information Technology for Healthcare

©Oliver Maassen, Sebastian Fritsch, Julia Palm, Saskia Deffge, Julian Kunze, Gernot Marx, Morris Riedel, Andreas Schuppert, Johannes Bickenbach. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 05.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Natural Language Processing and Machine Learning for Identifying Incident Stroke From Electronic Health Records: Algorithm Development and Validation

Yiqing Zhao¹, PhD; Sunyang Fu¹, MHI; Suzette J Bielinski¹, PhD; Paul A Decker¹, MSc; Alanna M Chamberlain¹, PhD; Veronique L Roger¹, MD; Hongfang Liu¹, PhD; Nicholas B Larson¹, PhD

Department of Health Sciences Research, Mayo Clinic, Rochester, MN, United States

Corresponding Author:
Nicholas B Larson, PhD
Department of Health Sciences Research
Mayo Clinic
205 3rd Ave SW
Rochester, MN, 55905
United States
Phone: 1 507 293 1700
Email: Larson.Nicholas@mayo.edu

Abstract

Background: Stroke is an important clinical outcome in cardiovascular research. However, the ascertainment of incident stroke is typically accomplished via time-consuming manual chart abstraction. Current phenotyping efforts using electronic health records for stroke focus on case ascertainment rather than incident disease, which requires knowledge of the temporal sequence of events.

Objective: The aim of this study was to develop a machine learning–based phenotyping algorithm for incident stroke ascertainment based on diagnosis codes, procedure codes, and clinical concepts extracted from clinical notes using natural language processing.

Methods: The algorithm was trained and validated using an existing epidemiology cohort consisting of 4914 patients with atrial fibrillation (AF) with manually curated incident stroke events. Various combinations of feature sets and machine learning classifiers were compared. Using a heuristic rule based on the composition of concepts and codes, we further detected the stroke subtype (ischemic stroke/transient ischemic attack or hemorrhagic stroke) of each identified stroke. The algorithm was further validated using a cohort (n=150) stratified sampled from a population in Olmsted County, Minnesota (N=74,314).

Results: Among the 4914 patients with AF, 740 had validated incident stroke events. The best-performing stroke phenotyping algorithm used clinical concepts, diagnosis codes, and procedure codes as features in a random forest classifier. Among patients with stroke codes in the general population sample, the best-performing model achieved a positive predictive value of 86% (43/50; 95% CI 0.74-0.93) and a negative predictive value of 96% (96/100). For subtype identification, we achieved an accuracy of 83% in the AF cohort and 80% in the general population sample.

Conclusions: We developed and validated a machine learning–based algorithm that performed well for identifying incident stroke and for determining type of stroke. The algorithm also performed well on a sample from a general population, further demonstrating its generalizability and potential for adoption by other institutions.

(J Med Internet Res 2021;23(3):e22951) doi:10.2196/22951

KEYWORDS
stroke; natural language processing; electronic health records; machine learning

Introduction

Stroke is a syndrome involving a rapid loss of cerebral function with vascular origin [1]. The loss of function can result in deep coma or subarachnoid hemorrhage. There are two broad categories of stroke: hemorrhagic and ischemic stroke [2]. Hemorrhage is caused by bleeding within the skull cavity, while ischemia is characterized by inadequate blood to supply a part of the brain. Stroke identification is an important outcome for various cardiovascular studies [3-5]. However, a challenge with stroke ascertainment is the inconsistent use of International
Classification of Diseases (ICD) codes [6], which may result in inaccurate code-based ascertainment of cases [7]. Therefore, the time-consuming process of electronic health record (EHR) abstraction remains the gold standard of stroke ascertainment [8,9].

Machine learning has recently gained popularity for its ability to classify patients or make predictions on various aspects of diseases. In contrast to manually curated algorithms based on domain expertise, machine learning is a data-driven approach that can be trained on large data sets to identify and leverage complex feature relationships and improve classification and prediction tasks thereby. In terms of stroke, machine learning algorithms have been applied to predict future stroke cases [10], mortality and recurrent strokes [11,12], and treatment outcomes [13,14]. Most existing phenotyping algorithms have been developed to only differentiate between cases and noncases of diseases [15-18]; however, ascertaining incident disease (ie, first occurrence of disease) in a population is a more difficult task [8,19,20]. A recent study by Ni et al [21] examined potential predictive features of stroke occurrence including demographic, clinical, and diagnostic characteristics of patients. The authors found that diagnostic tests for stroke, such as computed tomography (CT) and magnetic resonance imaging (MRI), contributed to most of the model performance, and that the optimal feature set included imaging findings, signs and symptoms, interventions, emergency department assessments, findings from angiography and carotid ultrasound tests, ICD codes, substance use (smoking, alcohol, and street drugs) characteristics, and demographics. However, features such as signs and symptoms, substance use characteristics, and demographics may not be specific enough for disease ascertainment, as there is a high prevalence of stroke-like symptoms among people without a diagnosis of stroke [22]. In addition, incorporating too many features in the model may result in overfitting without appropriate regularization. Another study [7] also used ICD and Current Procedural Terminology (CPT) [23] codes as features to classify positive, possible, and negative stroke cases. However, stroke-related clinical concepts (including both disease name concepts and symptom concepts) in unstructured clinical notes were not included in this model.

Rapid adoption of EHRs has enabled secondary use of the EHR data in epidemiological research [24-26]. Previous studies noted the existence of bias using a single type of EHR data (ie, diagnosis codes) [27-29]. To avoid this bias, the Electronic Medical Records and Genomics (eMERGE) consortium [30,31] has piloted the development of EHR-based phenotyping algorithms using multiple types of EHR data [32-34]. This has given rise to a number of phenotyping algorithms that use both structured EHR data (eg, demographics, diagnosis and procedure codes, laboratory test results, and medications) and unstructured EHR data (eg, clinical notes, imaging reports, and discharge summaries) [35-38]. However, the eMERGE consortium algorithms are typically focused on identifying cases and noncases rather than characterizing a new-onset (ie, incident) disease in a population. Moreover, extracting information from unstructured clinical text is a nontrivial task that involves natural language processing techniques [39-41].

In our paper, we address existing challenges for stroke ascertainment, specifically for incident stroke. Our research objective is to develop and validate a machine learning–based phenotyping algorithm to identify incident stroke and detailed stroke subtypes based on three major EHR-derived data elements: clinical concepts extracted from clinical notes; ICD, Ninth Revision (ICD-9) diagnosis codes; and CPT procedure codes.

### Methods

This study was approved by the Mayo Clinic Institutional Review Board (no. 17-008818) and is in accordance with the ethical standards mandated by the committee on responsible human experimentation. The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Study Design

This was a predictive modeling study that used observational cohort data for training and validation. We employed an atrial fibrillation (AF) cohort, in which all incidences of stroke were manually ascertained in a previous study [4], to train and test our phenotyping algorithm for the date of incident stroke events. We then evaluated the generalizability of our algorithm in a general population cohort.

### The AF Cohort

The AF cohort comprised a patient population from Olmsted County, Minnesota, USA [4,42]. Olmsted County is an area relatively isolated from other urban centers with only a few providers delivering most care to residents, primarily Mayo Clinic and Olmsted Medical Center [43-45]. Extracting all health care–related events was completed through the Rochester Epidemiology Project (REP), a records linkage system [43,44]. The REP is a records linkage system that allows retrieval of nearly all health care utilization and outcomes of residents living in Olmsted County. The electronic indexes of the REP include demographic information, diagnostic and procedure codes, health care utilization data, outpatient drug prescriptions, results of laboratory tests, and information about smoking, height, weight, and body mass index. ICD-9 codes and the Mayo Clinic electrocardiograms were obtained among adults aged ≥18 years from 2000 to 2014 to ascertain AF. Patients were identified by the presence of an ICD-9 code for stroke through March 31, 2015, and then validated by manual review of the EHR. Strokes were classified as ischemic strokes/transient ischemic attack or hemorrhagic strokes [4,46]. The first (incident) event of each type of stroke after the incident AF date was ascertained, regardless of whether a patient had a prior stroke. The AF cohort included 4914 validated patients with AF, 1773 of whom were screened for a possible stroke. Table 1 shows the cohort characteristics. Manual abstraction of the EHR validated the stroke code in 740 patients. Manual ascertainment of stroke and the dates of the events were used as a gold standard to train and test the stroke algorithm.
### Table 1. Atrial fibrillation cohort characteristics.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Cohort (n=4914)</th>
<th>Screened (n=1773)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2309 (46.99)</td>
<td>869 (49.01)</td>
</tr>
<tr>
<td>Male</td>
<td>2605 (53.01)</td>
<td>904 (50.99)</td>
</tr>
<tr>
<td><strong>Age at diagnosis of AF(^a) (years), mean</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>76</td>
<td>80</td>
</tr>
<tr>
<td>Male</td>
<td>70</td>
<td>74</td>
</tr>
<tr>
<td><strong>ICD-9(^b) diagnosis codes(^c), n</strong></td>
<td>27,243</td>
<td>27,243</td>
</tr>
</tbody>
</table>

\(^a\)AF: atrial fibrillation.  
\(^b\)ICD-9: International Classification of Diseases, Ninth Revision.  
\(^c\)ICD retrieval was from AF incidence date to March 31, 2015. AF validations were from 2000 to 2014.

### Candidate Predictive Features

The proposed algorithm aimed to identify first (incident) stroke events within a certain time frame. The three major data elements we used were clinical concepts, ICD-9 codes, and CPT codes. To align with the manual review process, only codes and clinical notes from the AF incident date to March 31, 2015, were retrieved and processed. In our analyses, we constructed different models by varying the inclusion of CPT codes and symptom-related clinical concepts in the model feature set and compared different models’ performances.

Both ICD-9 and CPT codes were extracted from the REP database. Clinical concepts were identified from the major and secondary problem list section of Mayo Clinic EHR, and from clinical notes from other REP sites using a natural language processing system, MedTagger\([47]\). Expert-provided vocabulary was adopted from a previous study\([48]\) to extract clinical concepts from unstructured clinical notes. MedTagger enables a series of natural language processing processes, including regular expression matching and positive, negative, or probable identification with ConText\([49,50]\), and is insensitive to upper and lower case. MedTagger is also able to determine if the extracted clinical concepts are referring to the patients or their family members, or if the extracted clinical concepts are in present tense and thus are referring to a current event rather than a past medical condition. We considered only documents with positive, present-tense stroke mentions that were referring to patients themselves. Table S1 in Multimedia Appendix 1 lists clinical concepts for 2 major stroke subtypes and stroke-related symptoms. Table S2 in Multimedia Appendix 1 lists ICD-9 codes for 2 stroke subtypes and stroke-related symptoms. Table S3 in Multimedia Appendix 1 lists the CPT codes used in the stroke algorithm.

Clinical concept dates were determined by the date of the clinical notes from which clinical concepts were extracted, while ICD-9 and CPT code dates were extracted from the REP. Each visit was characterized by clinical concepts, ICD-9, and CPT codes within a 60-day window. The visit date was determined by the earliest date of any of the 3 elements in the 60-day window. If visit dates were within a 60-day window of a confirmed stroke incidence date, they were considered positive instances; otherwise, they were considered negative instances. Figure 1 demonstrates an example with an incident stroke on July 4, 2004. All visits were extracted and included in our data set if there was at least one key word or code during a 60-day window. Nurse abstractors reviewed every visit sequentially until they determined the incidence date to be July 4, 2004. All subsequent visits after a positive stroke incident were not reviewed and thus were not included in our analyses. Since the confirmed stroke incidence date fell in the date range of the third visit (June 24, 2004–August 22, 2004), we considered the combination of codes and clinical concepts in this visit to be predictive of a positive stroke incidence.

**Figure 1.** Inclusion of clinical concepts and codes on a patient visit timeline. CPT: Current Procedural Terminology; ICD-9: International Classification of Diseases, Ninth Revision.
Data Analysis

After incident stroke was confirmed, visits afterwards were not reviewed by abstractors and thus excluded from our overall data set. Figure 2 shows the workflow of the algorithm training and testing process. We created a data set with 9130 confirmed visits (with stroke vs nonstroke labels) among the 1773 patients. In total, there were 746 stroke visits and 8384 nonstroke visits. The stroke incidence count (n=746) was larger than the number of patients with confirmed stroke incidence (740) because incidence dates for different subtypes of stroke (ischemic stroke/transient ischemic attack and hemorrhagic stroke) were all recorded, such that patients might have had multiple incidence dates. We included data from a randomly selected 79.98% of our screened patients (1418/1773 patients; 7253 visits) as a training set and the remaining 20.02% of our screened patients (355/1773 patients; 1877 visits) were retained as an independent testing set. Due to the outcome imbalance in the data set (positive:negative ratio of about 1:10), we used the synthetic minority oversampling technique [51] to create oversampled training data sets with an oversampling percentage of 1000%.

Figure 2. Stroke algorithm training and testing workflow. AF: atrial fibrillation.

We considered two machine learning classifiers, logistic regression and random forest [52], to train our phenotyping models. Logistic regression served as a baseline modeling algorithm. Random forest was also chosen because of its high performance with structured input features and better model flexibility. We also considered the influence of feature groups by varying the inclusion of CPT codes and symptom terms in the input feature set. The hyperparameter tuning of the machine learning models was performed using 10-fold cross-validation. The performance metrics adopted for the machine learning task in the test set were precision, recall, and F score. The oversampling and machine learning modeling training and testing processes were implemented in Weka 3 (University of Waikato) [53]. Additional statistical summaries were performed using the R statistical software version 3.6.2 (The R Foundation for Statistical Computing). Quantitative variables are summarized as means, while nominal variables are expressed by counts and percentages.

Validation Cohort

We evaluated the generalizability of our model on a sample from a general population cohort of 71,429 patients. This cohort consisted of individuals sampled in Olmsted County, Minnesota on January 1, 2006, with an age ≥30 years and with no prior history of cardiovascular disease. We applied the best performing model based on the leave-out test set to this entire population cohort to generate incident stroke predictions. We then randomly selected 50 patients from those who had no stroke-related features (i.e., de facto negative stroke predictions), 50 patients from those who were shown to have negative stroke
predictions, and 50 patients from those who were shown to have positive stroke predictions and a predicted incident stroke for evaluation. This verification-based sampling strategy allowed for estimates of positive and negative predictive values (PPVs and NPVs, respectively) by conditioning on algorithm predictions. Under these conditions (n=50), the half-width of the 95% Wilson score CI for the PPVs and separate NPVs would be approximately 0.1 for a true value of 0.85.

All 150 patient cases were reviewed by 1 nurse abstractor to confirm incident stroke, which served as our gold standard. We recorded model prediction outputs on all patient visits in the 150-patient validation set. We combined visit-level true predictions to generate patient-level incidence predictions by saving only the earliest date of positive predictions as stroke incidences. We compared patient-level incidence predictions with our gold standard. True prediction in our evaluation meant the date of the predicted incident stroke was within 60 days of the abstracted stroke date. A 2 x 2 confusion matrix was used to calculate performance scores for prediction evaluation. Model performance metrics included PPV and NPV using manual evaluation as the gold standard and patient-level predictions to calculate true positives, false positives, true negatives, and false negatives. The uncertainty of these performance estimates was calculated using Wilson score 95% CI for proportions.

In addition, we developed heuristic rules to distinguish stroke subtype (ischemic stroke/transient ischemic attack or hemorrhagic stroke) of each identified stroke incidence by analyzing the composition of keyword or code input feature sets (in a window of 60 days). We counted the number of keywords or codes for each ischemic stroke/transient ischemic attack and hemorrhagic stroke. If an input feature set contained more keywords or codes for ischemic stroke/transient ischemic attack, then this incidence was considered an ischemic stroke incidence; otherwise, it was considered a hemorrhagic stroke incidence. We only evaluated correct incident stroke predictions from the previous step in the evaluation data set with manually ascertained subtypes as the gold standard. Accuracy was calculated to measure performance of the subtype identification.

Results

Model Selection and Subtype Identification

Table 2 shows the algorithm performance measured on the test set for 8 models run on 4 input combinations and 2 classifiers (logistic regression and random forest). The random forest classifier outperformed the logistic classifier regardless of the feature sets used. Inclusion of CPT codes as features improved the performance for the random forest model with F score increased from 0.836 (Model 3) to 0.905 (Model 1). However, in the logistic model, the inclusion of CPT codes slightly improved the F score from 0.772 (Model 4) to 0.793 (Model 2). Using comparisons to all features (Model 1 and 2) and excluding the symptom terms (Model 6 and 7) achieved better F score (values italicized in Table 2).

Table 2. Stroke algorithm performance.

<table>
<thead>
<tr>
<th>Model</th>
<th>ICD-9a</th>
<th>Clinical concept</th>
<th>CPTb</th>
<th>Classifier</th>
<th>Precision</th>
<th>Recall</th>
<th>F score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>Symptoms + disease concepts</td>
<td>Yes</td>
<td>Random forest</td>
<td>0.912</td>
<td>0.906</td>
<td>0.905</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>Symptoms + disease concepts</td>
<td>Yes</td>
<td>Logistic</td>
<td>0.807</td>
<td>0.795</td>
<td>0.793</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>Symptoms + disease concepts</td>
<td>No</td>
<td>Random forest</td>
<td>0.835</td>
<td>0.845</td>
<td>0.836</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>Symptoms + disease concepts</td>
<td>No</td>
<td>Logistic</td>
<td>0.791</td>
<td>0.777</td>
<td>0.772</td>
</tr>
<tr>
<td>5</td>
<td>Yes</td>
<td>Disease-only concept</td>
<td>Yes</td>
<td>Random forest</td>
<td>0.920</td>
<td>0.915</td>
<td>0.915</td>
</tr>
<tr>
<td>6</td>
<td>Yes</td>
<td>Disease-only concept</td>
<td>Yes</td>
<td>Logistic</td>
<td>0.809</td>
<td>0.798</td>
<td>0.796</td>
</tr>
<tr>
<td>7</td>
<td>Yes</td>
<td>Disease-only concept</td>
<td>No</td>
<td>Random forest</td>
<td>0.856</td>
<td>0.847</td>
<td>0.846</td>
</tr>
<tr>
<td>8</td>
<td>Yes</td>
<td>Disease-only concept</td>
<td>No</td>
<td>Logistic</td>
<td>0.779</td>
<td>0.767</td>
<td>0.763</td>
</tr>
</tbody>
</table>

aICD-9: International Classification of Diseases, Ninth Revision.

Model Generalizability

Table 3 shows the distribution of stroke features in the AF cohort and the general population cohort. The AF cohort had a higher proportion of stroke-related codes and concepts. Results from the evaluation of the 150 selected patient records are presented in Table 4. Prediction performance corresponded to a PPV of 0.86 (95% CI 0.74-0.93), an NPV without ICD codes of 1.00 (95% CI 0.92-1.00), and an NPV with codes of 0.92 (95% CI 0.90-0.98). No strokes were observed among patients with no eligible stroke ICD codes. For subtype characterization, we achieved an accuracy of 80% (95% CI 0.68-0.89) in the general population sample.
Table 3. Patient feature distribution post-AF.

<table>
<thead>
<tr>
<th>Stroke feature distribution</th>
<th>AF(^a) screened</th>
<th>No stroke (n=1033), n (%)</th>
<th>AF nonscreened (n=3141), n (%)</th>
<th>AF cohort total (n=4914), n (%)</th>
<th>Olmsted County cohort (N=71,429), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-9(^b)+CPT(^c)+CC(^d)</td>
<td>654 (88.37)</td>
<td>379 (36.69)</td>
<td>0 (0)</td>
<td>1033 (21.02)</td>
<td>2726 (3.82)</td>
</tr>
<tr>
<td>ICD-9+CPT</td>
<td>66 (8.92)</td>
<td>596 (57.70)</td>
<td>0 (0)</td>
<td>662 (13.47)</td>
<td>1018 (1.42)</td>
</tr>
<tr>
<td>ICD-9+CC</td>
<td>9 (1.22)</td>
<td>12 (1.16)</td>
<td>0 (0)</td>
<td>21 (0.43)</td>
<td>48 (0.067)</td>
</tr>
<tr>
<td>CPT+CC</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>167 (5.32)</td>
<td>167 (3.40)</td>
<td>1595 (2.23)</td>
</tr>
<tr>
<td>ICD-9</td>
<td>11 (1.49)</td>
<td>46 (4.45)</td>
<td>0 (0)</td>
<td>57 (1.16)</td>
<td>194 (0.27)</td>
</tr>
<tr>
<td>CPT</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1736 (55.27)</td>
<td>1736 (35.33)</td>
<td>17,433 (24.40)</td>
</tr>
<tr>
<td>CC</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>11 (0.35)</td>
<td>11 (0.24)</td>
<td>566 (0.79)</td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1227 (39.06)</td>
<td>1227 (24.97)</td>
<td>47,849 (66.99)</td>
</tr>
</tbody>
</table>

\(^a\)AF: atrial fibrillation.
\(^b\)ICD-9: International Classification of Diseases, Ninth Revision.
\(^d\)CC: clinical concepts.

Table 4. Generalizability analysis results from the Olmsted County cohort.

<table>
<thead>
<tr>
<th>Gold standard</th>
<th>Stroke algorithm prediction (N=150)</th>
<th>No ICD-9(^a) codes (n=50)</th>
<th>Predicted no stroke (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative (n=100)</td>
<td>0 stroke (n=25)</td>
<td>4</td>
<td>43</td>
</tr>
<tr>
<td>Positive (n=50)</td>
<td>50</td>
<td>46</td>
<td>7</td>
</tr>
</tbody>
</table>

\(^a\)ICD-9: International Classification of Diseases, Ninth Revision.

Discussion

Principal Findings

The rapid expansion of information available in EHRs opens new opportunities to combine structured and unstructured data for research. Advances in machine learning methods and tools facilitate the combination of multimodal clinical data for effective development of phenotyping algorithms. However, performance of stroke electronic phenotyping algorithms varies by stroke subtypes [25] and phenotyping tasks (ie, case vs noncase or incident stroke phenotyping). Our previous study showed that when naïve ICD codes with clinical concept matching were used, stroke incidence identification had a PPV of 60.6% while case-versus-noncase identification had a much higher PPV of 88.7% [20].

In this study, we included clinical concepts extracted from clinical notes along with ICD-9 and CPT codes for incident stroke ascertainment. The rationale to add CPT codes is that diagnosis of stroke usually needs to be confirmed by imaging evidence and will probably be followed by therapeutic procedures. Thus, the addition of CPT codes in the model could potentially help to reduce the information redundancy effect by distinguishing between past and current events recorded in clinical notes. Our algorithm closely resembles the ascertainment process (chart review) of clinicians, which uses multiple types of EHR data (eg, diagnoses and procedure codes, unstructured clinical notes) in a parsimonious manner. Due to the redundancy and temporal ambiguity in unstructured clinical notes, we needed to construct a data set with sufficient and interpretable features from multimodal clinical data.

We found that the random forest generated better results, while the addition of CPT codes improved overall performance. This may be because imaging procedures, especially head CT or MRI, are critical in the diagnosis of stroke. Therefore, CPT codes of such procedures can be important indicators for distinguishing between incident and historical events. In addition, ICD codes and therapeutic procedures can vary significantly between incident and recurrent events. Meanwhile, we observed that the additions of stroke-related symptom concepts were not helpful for the phenotyping task. This may be due to the fact that our stroke incidence ascertainment depends largely on the ubiquitous nature of many stroke-related symptoms: they may be stroke-related but not necessarily stroke specific. Additionally, ascertainment requires well-documented evidence, such as imaging or imaging reports. Without properly recorded evidence, patients are not likely to be ascertained as stroke.

Our generalizability evaluation demonstrates that models trained using a specific disease cohort for incident stroke ascertainment can generalize well to a general patient population. This is very...
encouraging given there are many existing patient cohorts available. Secondary use of these patient cohorts would be a cost-effective way for developing machine learning–based phenotyping algorithms. The study also illustrates that incorporating structured EHR data, such as CPT codes, can effectively distinguish incident stroke mentions from historical events in the clinical notes.

One limitation of our study is the dependence of domain experts to provide relevant clinical concepts, ICD-9 codes, and CPT codes. In the future, we will explore advance feature engineering approaches to identify those relevant concepts or codes automatically or semiautomatically. We are also aware that our imbalance cohort data and oversampling strategies might have introduced overfitting. Although our evaluation in the general population proved the performance of the algorithm, in the future, we can adopt a case–control matching strategy to deal with imbalanced data and mitigate the potential overfitting issue. In addition, new treatment strategies (mechanical thrombectomy) to treat stroke have been in the market in recent years, and thus the features used in our algorithm could have different weights for predictions of events in different temporal settings. A more precise strategy could consider using different features for prediction tasks in different time frames, where variations in clinical knowledge and care path have been considered.

Conclusions
In conclusion, the high prevalence of stroke and the lack of an efficient algorithm to confirm incident stroke events necessitate the development of an effective and interpretable algorithm to identify incident stroke occurrences. In this paper, we described our efforts to develop and validate an EHR-based algorithm that accurately identifies incident stroke events and goes beyond typical case-versus-noncase stroke identification. Our algorithm’s good performance in a general population sample demonstrates its generalizability and potential to be adopted by other institutions.

Acknowledgments
The authors thank the other investigators, the staff, and the participants of the stroke phenotyping study for their valuable contributions. The stroke phenotyping study was conducted by a collaborative team of researchers from the Department of Health Sciences Research at Mayo Clinic and used 2 cohorts: the AF cohort and the Olmsted County cohort. This study was supported by grants from the National Institutes of Health (no. R01 HL136659 and R21 AG062580) and the American Heart Association (no. 11SDG7260039), and was made possible using the resources of the Rochester Epidemiology Project (no. R01 AG034676).

Authors’ Contributions
YZ had full access to all study data and takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors were responsible for study concept; design, acquisition, analysis, or interpretation of data; critical revision of the manuscript for important intellectual content; and administrative, technical, or material support. YZ was responsible for the drafting of the manuscript. YZ and NBL were responsible for statistical analysis. SB and AMC were responsible for obtaining funding. HL, SB, and NBL were responsible for study supervision.

Conflicts of Interest
None declared.

Multimedia Appendix 1
ICD-9, CPT codes, and clinical concepts for two major stroke subtypes and stroke-related symptoms.

References


Abbreviations

AF: atrial fibrillation
CT: computed tomography
EHR: electronic health record
eMERGE: Electronic Medical Records and Genomics
ICD: International Classification of Diseases
ICD-9: International Classification of Diseases, Ninth Revision
MRI: magnetic resonance imaging
NPV: negative predictive value
PPV: positive predictive value
REP: Rochester Epidemiology Project

©Yiqing Zhao, Sunyang Fu, Suzette J Bielinski, Paul A Decker, Alanna M Chamberlain, Veronique L Roger, Hongfang Liu, Nicholas B Larson. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 08.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Abstract

**Background:** Social media platforms provide an easily accessible and time-saving communication approach for individuals with mental disorders compared to face-to-face meetings with medical providers. Recently, machine learning (ML)-based mental health exploration using large-scale social media data has attracted significant attention.

**Objective:** We aimed to provide a bibliometric analysis and discussion on research trends of ML for mental health in social media.

**Methods:** Publications addressing social media and ML in the field of mental health were retrieved from the Scopus and Web of Science databases. We analyzed the publication distribution to measure productivity on sources, countries, institutions, authors, and research subjects, and visualized the trends in this field using a keyword co-occurrence network. The research methodologies of previous studies with high citations are also thoroughly described.

**Results:** We obtained a total of 565 relevant papers published from 2015 to 2020. In the last 5 years, the number of publications has demonstrated continuous growth with *Lecture Notes in Computer Science* and *Journal of Medical Internet Research* as the two most productive sources based on Scopus and Web of Science records. In addition, notable methodological approaches with data resources presented in high-ranking publications were investigated.

**Conclusions:** The results of this study highlight continuous growth in this research area. Moreover, we retrieved three main discussion points from a comprehensive overview of highly cited publications that provide new in-depth directions for both researchers and practitioners.

(J Med Internet Res 2021;23(3):e24870) doi:10.2196/24870

**KEYWORDS**

bibliometric analysis; machine learning; mental health; social media

Introduction

**Background**

Artificial intelligence (AI) has permeated various daily sectors that are directly related to our lives [1,2]. With this trend, AI for health, which refers to applying AI to real-world health care, has become one of the most important social issues at present [3,4]. With privacy and security as the bedrock of AI-based health care, there have been many attempts to employ AI and its applications in health care services [5,6]. As a representative example, Rizwan Malik, a radiologist in the United Kingdom, adopted a unique AI-based chest X-ray system to reduce patient waiting time in the COVID-19 pandemic scenario [4]. Furthermore, Microsoft [2] has invested approximately US $20 million to aid the collaboration teams of health care professionals and data science/AI experts in COVID-19–related research.
Extensive efforts have been put forward to employ AI technologies in health care services in addressing issues related to physical health, involving several medical centers, researchers, and organizations, as well as for mental health as a rapidly growing social issue. Although mental health is a pervasive and comprehensive issue, its detection and exposure are challenging. The World Health Organization estimates that approximately 1 billion people worldwide have mental disorders [7]. Moreover, 264 million people have been globally affected by depression, a common mental disorder [8]. However, more than 75% of people in underdeveloped countries (ie, low-income countries) suffering from mental disorders do not receive any treatments [7]. Several scholars have also revealed that individuals who suffer from mental disorders tend to prefer sharing their personal information and seeking assistance to reduce their concerns through online channels rather than with medical providers such as counselors or therapists [9-11].

Considering this tendency, social media represents a supportive tool for these individuals [11], where users are allowed to generate content, share information, and communicate [12]. Many researchers have attempted to explore the large-scale user-generated content in social media by means of machine learning (ML), which is a robust data-engineering technique, to analyze hidden information and knowledge on mental health. Therefore, we provide a theoretical background of related studies in the following subsections.

Related Review Papers

Higgins et al [13] define a systematic review as

\textit{a study that is composed of a search for scientific publications related to various topics in accordance with systematic guidelines including the search queries, the scientific databases, and the assessment criteria.}

With this concept, several prior mental health studies have investigated how to utilize ML in social media datasets. For instance, Seabrook et al [14] examined a systematic approach to provide an overview of prior research that focused on depression and anxiety in social media contexts between 2005 and 2016 with 8 identified databases. To objectively evaluate and summarize the literature, each case was evaluated by three unique dimensions: how to include psychological/cognitive measures, how to use external measurements for mental health criteria, and how to collect user activities in social media. Subsequently, 70 cases were selected, examined, and reviewed for both the implications and future directions regarding the application of ML to mental health in social media.

In addition to a systematic review approach, a scoping review may be performed, which is defined as “a type of research synthesis that aims to map the literature on a particular topic or research area and provide an opportunity to identify key concepts” [15]. This implies that a scoping review provides a bird’s eye view of key concepts in specific research areas, main sources, findings, and implications. For instance, Shatte et al [16] adopted a scoping review approach including 300 papers that focused on ML and big data applications in mental health, and concluded that the majority of these papers considered depression, schizophrenia, and Alzheimer disease as their main mental illnesses. Moreover, 89% of the papers analyzed utilized supervised learning approaches such as support vector machine (SVM), naïve Bayes, or decision trees to examine their selected illness.

Chancellor et al [17] also performed a thematic discourse analysis on 55 scientific papers with the goal of predicting mental health status in social media, and demonstrated that interdisciplinary researchers have different perspectives toward users’ datasets; these perspectives were classified as “human-centered machine learning” (HCML). Based on these findings and the concept of HCML, Chancellor and De Choudhury [18] subsequently categorized a total of 75 papers with five discourses: disorder/patient, social media, scientific, data/ML, and person. Based on this categorization, a total of 75 cases in which mental health status was assessed using social media datasets within 41 conference/journal papers published from 2013 to 2018 retrieved through academic databases (eg, ACM Digital Library and Google Scholar) were reviewed with respect to data annotation methods, data collection/quality management, preprocessing procedures, feature selections, model selection, and verification.

As presented in numerous prior studies, ML and mental health in social media have gained exponential attention in both practical and academic fields. Thus, we aimed to perform a bibliometric analysis to provide an overview and recent trends of this field.

Related Bibliometric Analyses

Bibliometric analysis is an extensive and widely used approach “to shed light on the processes of written communication and of the nature and course of development of a discipline” [19]. A bibliometric analysis thus allows researchers to understand the trends of specific research areas with several primary publications, including collaboration relations [20,21], core research themes [20], and scientific techniques [22].

Several scholars have performed bibliometric analyses on AI/ML in health care areas, including public and mental health, as well as in areas of specific mental illnesses. For example, dos Santos et al [22] performed a bibliometric analysis of data mining and ML techniques applied to public health issues based on papers published between 2009 and 2018 retrieved from three academic databases: Web of Science (WoS), Scopus, and ScienceDirect.

In the case of depression specifically, Tran et al [23] used a bibliometric approach to examine AI applications presented in publications indexed in WoS, evaluated the productivity of AI research through statistical analyses, and performed an exploratory factor analysis on the contexts of paper abstracts to present the most relevant and popular research issues. Moreover, Wang et al [24] performed a bibliometric analysis of natural language processing in various medical research areas including papers retrieved from PubMed data engines published from 1999 to 2018.

With respect to social media, several bibliometric analyses have closely evaluated relevant publications and their effects on society. As a representative example, Chen et al [20] adopted
both quantitative and statistical approaches with the WoS database to detect specific events in social media within the period of 2009-2017, investigated the number of publications and degree of collaboration, and further used clustering analysis to identify the main research themes. Another bibliometric study conducted by Sa’ed et al [21] focused on social media in psychology over 12 years based on records retrieved from WoS, and identified bibliometric indicators, including international collaboration/research networks.

Based on this background, the use of ML in medical fields and social media has been extensively explored using bibliometric approaches with notable implications and future directions. Therefore, this is an appropriate time to provide more detailed observations on ML with respect to the relation of specific medical areas with social media. Specifically, we examined the trends of research using ML for mental health in social media by employing (1) a bibliometric analysis to determine the publication distributions on sources (journals or conferences), authors, institutions, countries, research subjects, and author keywords; and (2) a trend review analysis to determine the distributions of citation numbers, along with a comprehensive review of highly cited publications.

With these approaches, we aimed to identify overall research trends of this area in a quantitative manner, and to qualitatively identify the key methodologies used on diverse social media platforms. These findings can shed light on the recent trends in the field and highlight more detailed directions of future research areas.

**Methods**

**Data Collection**

We collected papers from two citation databases, Scopus and WoS. Scopus is one of the largest citation repositories that covers scientific journals, conference proceedings, and books. WoS stores high-quality publications evaluated by three main indices: Science Citation Index Expanded (SCIE), Social Sciences Citation Index (SSCI), or Art & Humanities Citation Index (A&HCI).

Relevant publications were obtained when the terms included in the search query appeared in the title, abstract, or keywords. We defined the search query of each topic based on prior research on ML, social media [17], and mental health [25]. We excluded papers that were not written in English or were categorized as other document types (Figure 1). As a result, a total of 565 papers published from 2016 to 2020 were obtained on July 21, 2020. To cover rapidly changing trends in ML areas, we also considered the year 2020, which is still open for new issues. The complete list of included publications is provided in Multimedia Appendix 1.

**Analysis Methodologies**

A bibliometric analysis includes the distribution exploration of publication and research subject, as well as citation quantities. Both the Python programming language and Microsoft Excel were employed to perform statistical analyses of the retrieved papers. We first analyzed the publication distributions of papers with several categories (eg, sources, countries, institutions, authors, and research subjects). We also performed a network analysis of frequently used keywords. Moreover, to identify the research trends in this area, we performed trend review analyses with highly cited papers covering the following topics: (i) ML techniques, (ii) specific mental illnesses, and (iii) social media.
Results

Publication Distribution Analysis

Overall Publication Trend

The continuous growth of publications from 2016 to 2020 (until July 2020) is illustrated in Table 1. In 2016, two papers were retrieved from WoS and 33 papers were retrieved from Scopus. The publication count demonstrates rapid growth in 2019 with 43 publications retrieved from WoS and 166 publications retrieved from Scopus. Considering the retrieved date (July 2020), we expect that more papers would be retrieved in the remainder of 2020 up to the present.

Table 1. Number of publications per year.

<table>
<thead>
<tr>
<th>Year</th>
<th>Scopus (N=450)</th>
<th>Web of Science (N=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>33 (7.3)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>2017</td>
<td>68 (15.1)</td>
<td>16 (13.9)</td>
</tr>
<tr>
<td>2018</td>
<td>88 (19.6)</td>
<td>21 (18.3)</td>
</tr>
<tr>
<td>2019</td>
<td>166 (36.9)</td>
<td>43 (37.4)</td>
</tr>
<tr>
<td>2020</td>
<td>95 (21.1)</td>
<td>33 (28.7)</td>
</tr>
</tbody>
</table>

Productive Publication Source

We considered several document types, including not only journal articles but also conference proceedings and book chapters. Tables 2 and 3 present the publication sources with high counts in Scopus and WoS, respectively. Lecture Notes in Computer Science was the most productive publication source in Scopus, followed by CEUR Workshop Proceedings, Neural Computing and Applications, and Journal of Medical Internet Research with more than 20 publication counts each. Journal of Medical Internet Research was selected as the most productive publication source in WoS with 15 publication counts, followed by IEEE Access.

Table 2. Top publication sources in Scopus (N=450).

<table>
<thead>
<tr>
<th>Rank</th>
<th>Source</th>
<th>Publication count, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lecture Notes in Computer Science</td>
<td>35 (7.8)</td>
</tr>
<tr>
<td>2</td>
<td>CEUR Workshop Proceedings</td>
<td>25 (5.6)</td>
</tr>
<tr>
<td>3</td>
<td>Neural Computing and Applications</td>
<td>22 (4.9)</td>
</tr>
<tr>
<td>4</td>
<td>Journal of Medical Internet Research</td>
<td>16 (3.6)</td>
</tr>
<tr>
<td>5</td>
<td>Advances in Intelligent Systems and Computing</td>
<td>13 (2.9)</td>
</tr>
<tr>
<td>6</td>
<td>ACM International Conference Proceeding Series</td>
<td>9 (2.0)</td>
</tr>
<tr>
<td>6</td>
<td>International Journal of Innovative Technology and Exploring Engineering</td>
<td>9 (2.0)</td>
</tr>
<tr>
<td>8</td>
<td>IEEE Access</td>
<td>7 (1.6)</td>
</tr>
<tr>
<td>9</td>
<td>Communications in Computer and Information Science</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>9</td>
<td>Frontiers in Psychiatry</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>9</td>
<td>International Journal of Environmental Research and Public Health</td>
<td>5 (1.1)</td>
</tr>
</tbody>
</table>
Table 3. Top publication sources in Web of Science (N=115).

<table>
<thead>
<tr>
<th>Rank</th>
<th>Source</th>
<th>Publication count, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Journal of Medical Internet Research</td>
<td>15 (13.0)</td>
</tr>
<tr>
<td>2</td>
<td>IEEE Access</td>
<td>7 (6.1)</td>
</tr>
<tr>
<td>3</td>
<td>BMJ Open</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>3</td>
<td>Computers in Human Behavior</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>3</td>
<td>Frontiers in Psychology</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>3</td>
<td>IEEE Transactions on Knowledge and Data Engineering</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>3</td>
<td>International Journal of Environmental Research and Public Health</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>8</td>
<td>BMC Medical Informatics and Decision Making</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Cyberpsychology Behavior and Social Networking</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Journal of Information Science</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Journal of Intelligent information Systems</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Multimedia Tools and Applications</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>NPJ Schizophrenia</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Scientific Reports</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Social Science Computer Review</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>8</td>
<td>Translational Behavioral Medicine</td>
<td>2 (1.7)</td>
</tr>
</tbody>
</table>

Predominant Countries

More than 30 countries were identified as the predominant nations performing research in this field in Scopus (n=59) and WoS (n=39). Table 4 illustrates the top productive countries based on the number of publications. The United States was the most productive nation in both databases, followed by China and India.
Table 4. Top productive countries.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Publication count, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Scopus (N=450)</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>United States</td>
<td>146 (32.4)</td>
</tr>
<tr>
<td>2</td>
<td>India</td>
<td>66 (14.7)</td>
</tr>
<tr>
<td>3</td>
<td>China</td>
<td>63 (14.0)</td>
</tr>
<tr>
<td>4</td>
<td>United Kingdom</td>
<td>34 (7.6)</td>
</tr>
<tr>
<td>5</td>
<td>Canada</td>
<td>22 (4.9)</td>
</tr>
<tr>
<td>6</td>
<td>Spain</td>
<td>18 (4.0)</td>
</tr>
<tr>
<td>7</td>
<td>Australia</td>
<td>17 (3.8)</td>
</tr>
<tr>
<td>8</td>
<td>Germany</td>
<td>16 (3.6)</td>
</tr>
<tr>
<td>9</td>
<td>Taiwan</td>
<td>14 (3.1)</td>
</tr>
<tr>
<td>10</td>
<td>France</td>
<td>13 (2.9)</td>
</tr>
<tr>
<td>10</td>
<td>Netherlands</td>
<td>13 (2.9)</td>
</tr>
<tr>
<td></td>
<td><strong>Web of Science (N=115)</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>United States</td>
<td>52 (45.2)</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>25 (21.7)</td>
</tr>
<tr>
<td>3</td>
<td>United Kingdom</td>
<td>12 (10.4)</td>
</tr>
<tr>
<td>4</td>
<td>Australia</td>
<td>11 (9.6)</td>
</tr>
<tr>
<td>5</td>
<td>Spain</td>
<td>6 (5.2)</td>
</tr>
<tr>
<td>6</td>
<td>Canada</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td>6</td>
<td>India</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td>6</td>
<td>Saudi Arabia</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td>7</td>
<td>South Korea</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>7</td>
<td>Taiwan</td>
<td>4 (3.5)</td>
</tr>
</tbody>
</table>

**Productive Institutions**

There were 391 different institutions associated with the 565 publications. The top-ranked institutions are presented in Table 5. Harvard University in the United States emerged as the most productive institution in WoS (13 publications), whereas Tsinghua University in China was selected as the most productive organization in Scopus (21 publications).
Table 5. Top productive institutions.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Scopus (N=450)</th>
<th>Web of Science (N=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tsinghua University</td>
<td>21 (4.7)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>Georgia Institute of Technology</td>
<td>12 (2.7)</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>Harvard University</td>
<td>14 (3.1)</td>
<td>13 (11.3)</td>
</tr>
<tr>
<td>University of Pennsylvania</td>
<td>13 (2.9)</td>
<td>5 (4.4)</td>
</tr>
<tr>
<td>Chinese Academy of Sciences</td>
<td>14 (3.1)</td>
<td>6 (5.2)</td>
</tr>
<tr>
<td>Johns Hopkins University</td>
<td>6 (1.3)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>King’s College London</td>
<td>6 (1.3)</td>
<td>—</td>
</tr>
<tr>
<td>University of Toronto</td>
<td>6 (1.3)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>National Tsing Hua University</td>
<td>6 (1.3)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>Northwestern University</td>
<td>5 (1.1)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Centre National de la Recherche Scientifique</td>
<td>5 (1.1)</td>
<td>—</td>
</tr>
<tr>
<td>Vrije Universiteit Amsterdam</td>
<td>5 (1.1)</td>
<td>—</td>
</tr>
<tr>
<td>The University of Arizona</td>
<td>5 (1.1)</td>
<td>—</td>
</tr>
<tr>
<td>National University of Singapore</td>
<td>5 (1.1)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Deakin University</td>
<td>5 (1.1)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>University of New South Wales</td>
<td>5 (1.1)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Ministry of Education China</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>Delhi Technological University</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>Cornell University</td>
<td>4 (0.9)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Radboud University Nijmegen</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>Russian Academy of Sciences</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>Microsoft Research</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>The University of Utah</td>
<td>4 (0.9)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Universidad Autónoma de Madrid</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>University of Rochester</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>University of Chinese Academy of Sciences</td>
<td>4 (0.9)</td>
<td>3 (2.6)</td>
</tr>
<tr>
<td>Université du Québec à Montréal</td>
<td>4 (0.9)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>King Faisal University</td>
<td>4 (0.9)</td>
<td>2 (1.7)</td>
</tr>
<tr>
<td>University of Texas System</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
<tr>
<td>Asia University Taiwan</td>
<td>4 (0.9)</td>
<td>—</td>
</tr>
</tbody>
</table>

—: no related records.

 Predominant Authors

The top 20 researchers contributing to the field are listed in Table 6 based on their number of publications. Twelve researchers are affiliated to US-based organizations and five belong to Chinese institutions. The institutions of productive authors include not only several academic institutions but also some well-known hospitals such as Zucker Hillside Hospital. The most productive researcher was Professor Munmun De Choudhury, affiliated with Georgia Institute of Technology (15 publications), followed by Professor Sharath Chandra Guntuku from the University of Pennsylvania.
<table>
<thead>
<tr>
<th>Author</th>
<th>Institution</th>
<th>Country</th>
<th>Publication count, n (%)</th>
<th>Scopus (N=450)</th>
<th>Web of Science (N=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M De Choudhury</td>
<td>Georgia Institute of Technology</td>
<td>United States</td>
<td>4 (3.5)</td>
<td>11 (2.4)</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>SC Guntuku</td>
<td>University of Pennsylvania</td>
<td>United States</td>
<td>5 (1.1)</td>
<td>1 (1.1)</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>HF Ahmad</td>
<td>King Faisal University</td>
<td>Saudi Arabia</td>
<td>4 (0.9)</td>
<td>3 (2.6)</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>SK Ernala</td>
<td>Georgia Institute of Technology</td>
<td>United States</td>
<td>4 (0.9)</td>
<td>3 (2.6)</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>LH Ungar</td>
<td>University of Pennsylvania</td>
<td>United States</td>
<td>4 (0.9)</td>
<td>3 (2.6)</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>T Nguyen</td>
<td>University of Pennsylvania</td>
<td>United States</td>
<td>5 (1.1)</td>
<td>2 (1.7)</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>S Venkatesh</td>
<td>University of Maryland</td>
<td>United States</td>
<td>5 (1.1)</td>
<td>2 (1.7)</td>
<td>5 (1.1)</td>
</tr>
<tr>
<td>ML Birnbaum</td>
<td>Zucker Hillside Hospital</td>
<td>United States</td>
<td>4 (0.9)</td>
<td>1 (1.7)</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>M Conway</td>
<td>University of Utah</td>
<td>United States</td>
<td>4 (0.9)</td>
<td>2 (1.7)</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>L Feng</td>
<td>Tsinghua University</td>
<td>China</td>
<td>4 (0.9)</td>
<td>2 (1.7)</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>D Phung</td>
<td>Deakin University</td>
<td>Australia</td>
<td>4 (0.9)</td>
<td>2 (1.7)</td>
<td>4 (0.9)</td>
</tr>
<tr>
<td>J Jia</td>
<td>Tsinghua University</td>
<td>China</td>
<td>6 (1.3)</td>
<td>—</td>
<td>6 (1.3)</td>
</tr>
<tr>
<td>T Zhu</td>
<td>Chinese Academy of Sciences</td>
<td>China</td>
<td>6 (1.3)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>RM Merchant</td>
<td>University of Pennsylvania</td>
<td>United States</td>
<td>2 (0.4)</td>
<td>3 (2.6)</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>H Christensen</td>
<td>University of New South Wales</td>
<td>Australia</td>
<td>3 (0.7)</td>
<td>2 (1.7)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>JM Kane</td>
<td>Zucker Hillside Hospital</td>
<td>United States</td>
<td>3 (0.7)</td>
<td>2 (1.7)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>Q Li</td>
<td>Tsinghua University</td>
<td>China</td>
<td>3 (0.7)</td>
<td>2 (1.7)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>AF Rizvi</td>
<td>Zucker Hillside Hospital</td>
<td>United States</td>
<td>3 (0.7)</td>
<td>2 (1.7)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>CY Shen</td>
<td>National Tsing Hua University</td>
<td>China</td>
<td>3 (0.7)</td>
<td>2 (1.7)</td>
<td>3 (0.7)</td>
</tr>
<tr>
<td>L Ungar</td>
<td>University of Pennsylvania</td>
<td>United States</td>
<td>3 (0.7)</td>
<td>2 (1.7)</td>
<td>3 (0.7)</td>
</tr>
</tbody>
</table>

---

Productive Research Subjects

The top 10 research subjects of each citation database are given in Figure 2. Among them, computer science was the most pivotal research subject in both databases (46, 40% in WoS; 292, 65% in Scopus). In Scopus, medicine (111, 25%), and engineering and mathematics (90, 20%) accounted for more than 10% of the total publications. In WoS, medical informatics (24, 21%), health care sciences services, engineering, and psychology constituted more than 10% of total publications.

Figure 2. Publication count of top 10 research subjects.
**Author Keyword Co-occurrence**

Along with research subjects, we investigated the keywords derived by the authors, which represent the main research topics of the publications [26]. The keyword co-occurrence is visualized using a network graph (Figure 3), which is a well-known bibliometric methodology, in which each node is a keyword, while an edge between two nodes indicates the co-occurrence of two words. After building a network graph, we excluded edges with less than 3 co-occurrences.

**Figure 3.** Keyword co-occurrence network graph; the color map on the right side represents the degree centrality.

![Keyword co-occurrence network graph](image)

Note that the keywords with a high frequency reflect the scope of the research area, which includes social media, ML, natural language processing, and mental health. In particular, in the case of mental health–related words, depression was the most frequently presented keyword, followed by suicide, consumer health information, social support, and stress detection. The main research methodologies of papers included natural language processing, sentiment analysis, classification, text mining, and stress detection in the ML field. Twitter and Reddit were identified as the most widely investigated social media platforms in this area.

As there are several approaches of text analysis using natural language processing techniques in this field, we believe that future studies may provide hybrid approaches using both textual- and visual-based data collected from several types of social
media data. In addition, validating ML models trained on mental health–related social media data in clinical settings needs to be further investigated.

### Overview of Highly Cited Publications

**Publication Citation Quantities**

The annual number of citations is presented in Table 7. Along with publication distributions, the annual number of citations has been consistently increasing. Up to July 21, 2020, more than 900 and 400 annual citations were recorded in Scopus and WoS, respectively.

**Table 7. Number of citations per year.**

<table>
<thead>
<tr>
<th>Year</th>
<th>Citation count, n</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Scopus</td>
</tr>
<tr>
<td>2016</td>
<td>14</td>
</tr>
<tr>
<td>2017</td>
<td>112</td>
</tr>
<tr>
<td>2018</td>
<td>349</td>
</tr>
<tr>
<td>2019</td>
<td>1000</td>
</tr>
<tr>
<td>2020</td>
<td>938</td>
</tr>
</tbody>
</table>

**Comprehensive Analysis of Highly Cited Papers**

We evaluated the overall academic output through bibliometric analysis. Due to the lack of observations in the content of the publications, as mentioned in previous studies [20,27], we extensively observed and reviewed the top five most highly cited papers per year to identify the comprehensive research methodologies in the field (Table 8). After excluding 7 duplicated papers, 39 papers were selected. Subsequently, a two-round filtering procedure was performed to determine whether a specific paper meets the following criteria: (i) addressing specific mental illness, (ii) using an ML technique, and (iii) utilizing datasets of social media. There were 15 papers that met these criteria. Subsequently, three experts in ML, medical services, and computer science, respectively, participated in the second-round filtering procedure. Following this, 10 papers that satisfied these criteria were selected.

**Table 8. Overview of the top 5 most cited papers by year.**

<table>
<thead>
<tr>
<th>Year</th>
<th>Top-cited papers (N=39), n</th>
<th>Reviewed papers (N=10), n</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Article</td>
<td>Conference paper</td>
</tr>
<tr>
<td>2016</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>2017</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>2018</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>2019</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>2020</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

An overview and the research methodologies of the 10 highly cited publications are listed in Table 9, which are categorized according to the data source: Twitter (n=4 publications), Instagram (n=3), Facebook (n=3), Reddit (n=3), Weibo (n=2), and other online community (n=1).
Table 9. Summary of research methodologies employed in highly cited publications.

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Reference</th>
<th>Mental Health</th>
<th>Data Description</th>
<th>Machine learning</th>
<th>Feature</th>
<th>Output</th>
<th>Annotation</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twitter</td>
<td>Budenz et al [28]</td>
<td>Mental illness, bipolar disorder</td>
<td>1,270,902 tweets including bipolar or mental health-related words</td>
<td>Logistic regression</td>
<td>Term frequency-inverse document frequency</td>
<td>Related to mental illness or bipolar disorder</td>
<td>Manually annotated 2047 tweets with topic, stigma, and social support messaging</td>
<td>10-fold cross validation (AUC=0.83)</td>
</tr>
<tr>
<td>Twitter</td>
<td>Du et al [29]</td>
<td>Suicide</td>
<td>1,962,766 tweets including 21 suicide-related keywords/phrases</td>
<td>CNN, SVM, extra trees, random forest, logistic regression, Bi-LSTM</td>
<td>One-hot-vector mapped to pre-trained GloVe Twitter embedding</td>
<td>Related to suicide</td>
<td>Manually annotated 3263 tweets and trained classifier to select 3000 additional suicide-related tweets</td>
<td>Accuracy 0.74, recall 0.96, precision 0.78, F1 0.83</td>
</tr>
<tr>
<td>Facebook, Twitter</td>
<td>Guntuku et al [30]</td>
<td>Psychological stress</td>
<td>601 users’ Facebook and Twitter posts</td>
<td>Linear regression with several regularization methods (eg, ridge, elastic-net, LASSO and L2 penalized SVMs)</td>
<td>LIWC, latent Dirichlet allocation topic modeling, stress lexicon, user engagement</td>
<td>Stress</td>
<td>Qualtrics survey; fill out the demographic questions and Cohen 10-item Stress Scale</td>
<td>5-fold cross-validation (Pearson r=0.24); trained on Facebook and Twitter, tested on Twitter</td>
</tr>
<tr>
<td>Facebook, Instagram</td>
<td>Shuai et al [31]</td>
<td>Social network mental disorders (eg, cyberrelationship addiction, information overload, and net compulsion)</td>
<td>3126 users’ Instagram and Facebook data</td>
<td>Decision tree learning, SVM, logistic regression, DTSVM, SNMDD (newly proposed model; tensor technique for deriving latent features)</td>
<td>Social interaction, personal profile, duration</td>
<td>Social network mental disorders</td>
<td>MTurk survey; fill out the standard social network mental disorder questionnaires; professional psychiatrists labeled users having a social network mental disorder</td>
<td>5-fold cross validation (accuracy 0.78 for Instagram and 0.83 for Facebook)</td>
</tr>
<tr>
<td>Instagram</td>
<td>Reece and Danforth [32]</td>
<td>Depression</td>
<td>43,950 users’ Instagram images</td>
<td>Random forest classifier</td>
<td>Number of comments and likes, number of faces in photograph, 3 color properties (hue, saturation, value)</td>
<td>Depression</td>
<td>MTurk survey; Center for Epidemiologic Studies Depression Scale to measure depression level</td>
<td>Recall: 0.697; precision: 0.604; F1: 0.647</td>
</tr>
<tr>
<td>Weibo</td>
<td>Lin et al [33]</td>
<td>Stress</td>
<td>1 billion Weibo posts</td>
<td>SVM, softmax regression, gradient-boosted decision tree, LASSO-MTL, L2-MTL, CA-SO-MTL</td>
<td>CNN features or word vector representations with hand-crafted features</td>
<td>12 stressor events (eg, marriage, financial, illness, school), 6 stressor subjects</td>
<td>30 volunteers manually annotated the stressor events and subjects</td>
<td>10-fold cross validation (F1&gt;0.80)</td>
</tr>
<tr>
<td>Weibo</td>
<td>Cheng et al [34]</td>
<td>Suicide risk, depression, anxiety, stress</td>
<td>974 participants’ Weibo posts, suicide probability, Weibo suicide communication (WSC), depression, anxiety, and stress.</td>
<td>SVM</td>
<td>Simplified Chinese-LIWC</td>
<td>Suicide risk, emotional distress (depression, anxiety, stress), WSC</td>
<td>Survey and psychological test tools (ie, Suicide Probability Scale, Depression Anxiety Stress Scales-21)</td>
<td>Leave-one-out cross-validation: suicide probability (AUC=0.61, P&lt;0.04), severe anxiety (AUC=0.75, P&lt;0.001)</td>
</tr>
<tr>
<td>Data Source</td>
<td>Reference</td>
<td>Mental Health</td>
<td>Data Description</td>
<td>Machine learning</td>
<td>Annotation</td>
<td>Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>------------------</td>
<td>---------------------------------</td>
<td>------------</td>
<td>-----------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reddit</td>
<td>Gkotsis et al [35]</td>
<td>Bipolar, schizophrenia, anxiety, depression, self-harm, suicide watch, addiction, crippling alcoholism, opiate, autism</td>
<td>1,014,660 posts</td>
<td>CNN, FF, linear regression, SVM</td>
<td>N/A^m</td>
<td>Accuracy: 91.8% (binary classification task), 79.8% (multiclass classification task)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facebook, Twitter, Instagram, Reddit</td>
<td>Coppersmith et al [36]</td>
<td>Suicide risk</td>
<td>197,615 posts from 418 users</td>
<td>LSTM with attention</td>
<td>One-hot-vector mapped to pre-trained GloVe</td>
<td>Suicide risk</td>
<td>Examining public self-stated data and using data donated through OurDataHelps.org</td>
<td>10-fold cross validation (AUC=0.94)</td>
</tr>
<tr>
<td>Online Community - Live Journal</td>
<td>Saha et al [37]</td>
<td>Mental health</td>
<td>620,060 posts from 78,647 users</td>
<td>MTL</td>
<td>Linguistic features of LIWC; topics by LDA^a</td>
<td>Mental health sub-reddit (eg, Abuse, Anorexia, Anxiety, Bipolar disorder, Cutting, Death, Drugs, Eating disorders, Insomnia, Pain, Self-injury, and Suicide)</td>
<td>N/A</td>
<td>AUC=0.94 with the community on eating disorders</td>
</tr>
</tbody>
</table>

^aAUC: area under the curve.  
^bCNN: convolutional neural network.  
^cSVM: support vector machine.  
^dBi-LSTM: bidirectional long short-term memory.  
^eLASSO: least absolute shrinkage and selection operator.  
^fLIWC: Linguistic Inquiry and Word Count.  
^gDT SVM: decision tree support vector machine.  
^hSNMDD: social network mental disorder detection.  
^iMTL: multitask learning.  
^jM2-TMTL: multitask learning considering l2 loss.  
^kCASO-MTL: clustered alternating structure optimization multitask learning.  
^lFF: feed-forward.  
^mN/A: not applicable.  
^nLDA: latent Dirichlet allocation.

In the case of Twitter, Budenz et al [28] analyzed 1,270,902 tweets by searching bipolar and mental health terms. Before using a logistic regression analysis to classify whether a specific tweet was asking for any help or included terms associated with mental illness stigma, they repeatedly performed a series of sentiment analyses on 2047 randomly sampled tweets. The results obtained through 10-fold cross-validation procedures showed an average area under the curve (AUC) of 0.83 when the term-frequency inverses document frequency weighted vector was employed as the input source. Twitter tweets were also used to predict an association with psychological stressors, as one of the major causes of suicide. To prevent suicidal behaviors [29], the authors retrieved 1,962,766 tweets based on 21 suicide-related keywords, manually annotated labels of a subset of 3263 tweets, and labeled the other 3000 tweets based on ML classifiers. A Twitter corpus–pretrained GloVe vector was employed to convert each token into a vector as an input of the convolutional neural network (CNN). The CNN model achieved an F1-score of 83%, which outperformed SVM, extra trees, and other ML algorithms.
In addition, stress level, as one of the pervasive causes of mental health conditions, was predicted on social media platforms, including Twitter and Facebook [30]. Linguistic characteristics were extracted from a total of 601 users’ social media posts using the Linguistic Inquiry and Word Count (LIWC) tool, latent Dirichlet allocation (LDA), and stress lexicon. To predict stress, the authors applied linear regression with regularization methods, and validated the model performance based on sociodemographic variables (eg age, gender, race, income, and education) and social media language using the Pearson correlation coefficient (r). The content analysis indicated significant differences in language expressions among social media platforms.

Shuai et al [31] collected posts from both Facebook and Instagram to detect social network mental disorders (SNMD), which include several side effects such as cyber-relationship addiction or net compulsion. They developed and employed SNMD questionnaire items to classify each participant into specific types of SNMD. Among more than 3100 participants, 389 respondents were regarded as having SNMD. Social interaction, personal profile, and duration extracted by each participant’s social activity logs were employed as input features of ML models. The proposed model, which was organized by new tensor techniques and latent features, achieved more than 83% accuracy in identifying whether a specific user has SNMD.

One of the notable approaches in this area is a visual-oriented approach. Reece and Danforth [32] employed 43,950 images from 166 Instagram users to detect posts related to depression. Based on the results of the Center for Epidemiologic Studies Depression Scale questionnaire (CES-D), a total of 71 users revealed that they experienced depression. Moreover, both Instagram usernames and history were collected from crowd workers who responded to the CES-D. They extracted metadata (eg, the number of comments, “likes”), color properties (eg, hue, saturation, value), and the total number of faces from the collected photographs to investigate whether users suffer from depression.

Based on the guidelines of De Choudhury et al [38], Reece and Danforth decided to integrate the users’ recent posts presented on a specific (single) day rather than using their entire posts. Through a random forest classifier, they achieved a relatively high recall score of identifying the target class at 70% in 100 observations. The results indicated that the photos posted by depressed users were more likely to be bluer, grayer, and darker, and to receive fewer likes. However, as a limitation of the study, they pointed out that depression is a form of general clinical status, indicating a need for fine-tuning the questionnaires for specific diagnosis.

Lin et al [33] collected approximately 1 billion tweets from the Chinese social media platform Weibo, and proposed ML multitask models to detect both stressor events and six subjects. The event was categorized into 12 different labels, including marriage, financial, illness, and school. Each tweet was first labeled as stress-related. The tweets were categorized into one of the stressor events and subject categories by 30 volunteers. The performance of classifying a stressor event or subject was represented with various classifiers such as SVM, softmax regression, and gradient decision. The model performance was not clearly presented; however, it was stated that the F1-score reached over 80% in the event detection task.

A mental illness is often accompanied by another mental illness as a so-called “comorbidity,” which refers to the simultaneous presence of one or more mental or physical disorders. From this viewpoint, Saha et al [37] developed a joint learning model, which was generated by multitask learning to simultaneously identify co-occurring social media communities related to mental health with consideration of the correlation between the communities. Based on 620,060 posts of 78,647 users in 247 online communities, 12 major mental health–related topics were employed in the categorization standards from “Live Journal” (eg, Abuse, Anorexia, Anxiety, Bipolar disorder, etc). Using these data, two features were extracted as inputs: language style (from the LIWC) and topics (from the results of LDA). In general, the proposed model outperformed single-task learning [39] and multitask learning [40] for 9 out of 12 and 8 out of 12 categories, respectively. Moreover, the model achieved an AUC of 0.94 with the community on eating disorders.

Cheng et al [34] utilized Weibo data to assess the levels of suicide risk and emotional distress such as depression, anxiety, and stress. For this purpose, the researchers completed an internet survey and gathered 974 respondents’ Weibo posts, the scores of mental health (ie, suicide probability, depression, anxiety, and stress) through psychological investigation tools, and Weibo Suicide Communication (WSC), which examined whether respondents had told others that they wanted to commit suicide through Weibo over the past 12 months. SVM was applied for a binary classification of five suicide risk factors (suicide probability, depression, anxiety, stress, and WSC), including 72 linguistic features of Simplified Chinese-LIWC from the respondents’ Weibo posts as independent variables. The model efficiently classified the respondents having a high suicide probability (AUC=0.61, P=.04) and severe anxiety (AUC=0.75, P<.001) among those who had WSC with leave-one-out cross-validation procedures.

Gkotsis et al [35] collected user-oriented data from the Reddit community to develop deep-learning models for classifying posts according to mental disorder topics. After an expert panel made a decision on whether a specific post contains mental health–related issues, they collected 10,146,60 posts and extracted 11 mental disorder themes, including a nonmental health conditions. To classify whether a specific post belongs to one of the mental health topics, they employed a CNN model with two parallel classification approaches: binary and multiclass classifications. The word vectors of each token extracted from post texts were used as input. The results of the model demonstrated that the CNN classifier showed 91.8% and 79.8% accuracy in binary and multiclass classification tasks, respectively.

Early estimation of a person’s suicide risk is also an important issue in our society. In accordance with this point, Coppersmith et al [36] employed social media data to predict the level of suicide risk using a long short-term memory (LSTM) model. Two different datasets were collected: one from donated data through OurDataHelps.org, which included social media data
of suicide victims (eg, Facebook, Instagram, Twitter), and the other from Harman Dredze [41], which provided Twitter data from users who mentioned their past suicide attempts in tweets. A total of 197,615 posts from 418 users were obtained. Based on the pretrained GloVe embeddings to feed sequences of word vectors into the bidirectional LSTM model, an AUC of 0.94 was achieved through 10-fold cross-validation procedures.

Discussion

This study involved a bibliometric analysis on the publications related to ML and mental health in social media from 2015 to 2020 with two citation databases, WoS and Scopus, as well as a trend review analysis. Although several prior studies have investigated mental illness, the majority of these studies employed both clinical and physical health care approaches. Along with these studies, social media is considered as one of the most important spaces for effectively and efficiently addressing individuals’ mental health issues [42]. Furthermore, with rapidly improved ML and big data techniques, both the significance and importance of employing social media and online communications are being consistently emphasized.

Rapidly and consistently increasing publication and citation numbers indicate that there is growing attention and interest in this research area. Among several publication venues, Lecture Notes in Computer Science (Scopus) and Journal of Medical Internet Research (WoS) were the most productive publication sources in this field. Moreover, Harvard University and Georgia Institute of Technology in the United States, and Tsinghua University and the Chinese Academy of Sciences in China were listed as the most vigorous institutes. For individual researchers, Professor Munmun De Choudhury from Georgia Institute of Technology emerged as the most productive and well-known researcher in this field, with 15 publications to her credit. Regarding publications, using social media data in predicting depression was Prof De Choudhury’s first step in this area [38], which allowed her affiliated nation (United States) to be the most productive country in this field. Computer science, medicine, and medical informatics were identified as the core research subjects, along with several other related subjects such as psychology, social science, and neuroscience. This suggests that this research area tends to require integrated or multidisciplinary approaches for gaining a better understanding of each research topic. In addition, the keyword co-occurrence network graph highlighted the representative ML techniques and social media for this multidisciplinary area.

Subsequently, we conducted a trend analysis review on highly cited articles, and notable research trends were identified. The highly cited articles tended to employ user-generated content in diverse forms, including text, images, and other metadata, for specific mental disorders. Because no ground truth labels exist for users who have mental disorders, the majority of studies adopted a crowdsourcing survey with a medical-oriented approach and consideration of the participants’ agreements in using their social media accounts [30-32,34]. Moreover, several scholars have employed user-oriented features, including users’ demographic profiles and activity logs, in social media (eg, comments, likes) to arrive at both academic and practical contributions [30,31].

Based on the employed approaches with several highly cited articles, three main implications for discussion can be derived.

First, the majority of the articles stated privacy and ethical issues as key considerations in using ML for specific mental illness in social media [23,30,32,36]. Although they met both research ethical guidelines and participants’ agreements in using their social media data, there were notable adverse reactions from several participants in sharing their social media information [32]. Moreover, compared to other issues in this area, both privacy and ethical issues are considered to be real issues requiring more academic and practical work [23]. Thus, researchers must make efforts to effectively consider these threats, which can negatively affect data providers and leave room for abusing ML techniques. Second, because there is potential for misclassified ground truth data, there should be more detailed and systematic examinations in building the early stage of datasets [28,29,34,36]. Third, because users’ expressions on social media can consistently change over time, time-oriented approaches with differing perspectives toward users’ activities and expressions should be considered in providing a better understanding in this area [32].

Considering these discussion points, a few limitations of this study remain. Although we employed WoS and Scopus as our subjects, which are both widely used academic databases globally, there can be other medical-oriented databases that may provide more significant academic and practical information. Moreover, considering more recent and applicable statistical or natural language processing techniques (such as exploratory factor analysis [23] or topic modeling [20,23]), future research should aim at obtaining deeper and comprehensive knowledge with more creative and significant approaches through various data sources of each article.

With the increase of AI applications in real-word health care settings [1], there have been numerous attempts to overcome the limitations of offline consultations such as wearable fitness trackers [43], mobile health apps [44], and conversational agents for patients’ mental health and wellness [1,45]. Moreover, since the use of social media has been widely adopted in health care [46], we believe that our analysis may trigger all stakeholders to further consider how to employ ML approaches toward mental health in social media. In addition, when applying social media data to clinical settings, there is a need to address different characteristics of social media platforms by utilizing the substantial research background.

Acknowledgments

This work was supported by an Institute of Information and Communications Technology Planning & Evaluation (IITP) grant funded by the Korean government (Ministry of Science and ICT; No. 2020-0-00990, Platform Development and Proof of High
Trust & Low Latency Processing for Heterogeneous Atypical Large Scaled Data in 5G-IoT Environment). This research was also supported by the National Research Foundation of Korea funded by the Korean Government (NRF-2020R1C1C004324).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Complete publication lists.
[XLSX File (Microsoft Excel File), 64 KB - jmir_v23i3e24870_app1.xlsx ]

References


Abbreviations

AI: artificial intelligence
AUC: area under the curve
CES-D: Center for Epidemiologic Studies Depression Scale
CNN: convolutional neural network
HCML: human-centered machine learning
LDA: latent Dirichlet allocation
LIWC: Linguistic Inquiry and Word Count
LSTM: long short-term memory
ML: machine learning
SNMD: social network mental disorders
SVM: support vector machine
WoS: Web of Science
WSC: Weibo Suicide Communication

©Jina Kim, Daeun Lee, Eunil Park. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 08.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
What Every Reader Should Know About Studies Using Electronic Health Record Data but May Be Afraid to Ask

Isaac S Kohane1, MD, PhD; Bruce J Aronow2, PhD; Paul Avillach1, MD, PhD; Brett K Beaulieu-Jones1, PhD; Riccardo Bellazzi3,4, PhD; Robert L Bradford5, BSc; Gabriel A Brat1, MD, MPH; Mario Cannataro6,7, MS; James J Cimino8, MD; Noelia García-Barrio9, MS; Nils Gehlenborg1, PhD; Marzyeh Ghassemi10, PhD; Alba Gutiérrez-Sacristán1, PhD; David A Hanauer11, MS, MD; John H Holmes12, PhD; Chuan Hong1, PhD; Jeffrey G Klann13,14, PhD; Ne Hooi Will Loh15, MBBS, FRCA, FFiCM, EDIC; Yuan Luo16, PhD; Kenneth D Mandl17, MPH, MD; Mohammad Dania18, MSIS; Jason H Moore19, PhD; Shawn N Murphy1,20, MD, PhD; Antoine Neuraz21,22, MD; Kee Yuan Ngiam15, MBBS, MRCS, MMed; Gilbert S Omenn23, MD, PhD; Nathan Palmer1, PhD; Lav P Patel24, MS; Miguel Pedraza-Jiménez9, MS; Piotr Sliż17, PhD; Andrew M South25, MS, MD; Amelia Li Min Tan1,26, BSc, PhD; Deanne M Taylor27,28, PhD; Bradley W Taylor29, MS; Carlo Torti7, MD; Andrew K Vallejos30, MS; Kayshwar B Wagholiak31,14, MBBS, PhD; The Consortium For Clinical Characterization Of COVID-19 By EHR (4CE)30; Griffin M Weber1*, MD, PhD; Tianxi Cai1*, SCD

1Department of Biomedical Informatics, Harvard Medical School, Boston, MA, United States
2Biomedical Informatics, Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH, United States
3Department of Electrical, Computer and Biomedical Engineering, University of Pavia, Pavia, Italy
4ICS Maugeri, Pavia, Italy
5North Carolina Translational and Clinical Sciences Institute, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States
6Data Analytics Research Center, University Magna Graecia of Catanzaro, Catanzaro, Italy
7Department of Medical and Surgical Sciences, University Magna Graecia of Catanzaro, Catanzaro, Italy
8Informatics Institute, University of Alabama at Birmingham, Birmingham, AL, United States
9Department of Informatics, 12 de Octubre University Hospital, Madrid, Spain
10Department of Computer Science and Medicine, University of Toronto, Toronto, ON, Canada
11Department of Learning Health Sciences, University of Michigan Medical School, Ann Arbor, MI, United States
12Department of Biostatistics, Epidemiology, and Informatics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States
13Department of Medicine, Harvard Medical School, Boston, MA, United States
14Laboratory of Computer Science, Massachusetts General Hospital, Boston, MA, United States
15National University Health Systems, Singapore, Singapore
16Department of Preventive Medicine, Northwestern University, Chicago, IL, United States
17Computational Health Informatics Program, Boston Children's Hospital, Boston, MA, United States
18Clinical Research Informatics, Boston Children's Hospital, Boston, MA, United States
19Institute for Biomedical Informatics, University of Pennsylvania, Philadelphia, PA, United States
20Department of Neurology, Massachusetts General Hospital, Boston, MA, United States
21Department of Biomedical Informatics, Necker-Enfant Malades Hospital, Assistance Publique - Hôpitaux de Paris, Paris, France
22Centre de Recherche des Cordeliers, INSERM UMR 1138 Team 22, Université de Paris, Paris, France
23Department of Computational Medicine & Bioinformatics, University of Michigan, Ann Arbor, MI, United States
24Department of Internal Medicine, Division of Medical Informatics, University of Kansas Medical Center, Kansas City, KS, United States
25Section of Nephrology, Department of Pediatrics, Brenner Children's Hospital, Wake Forest School of Medicine, Winston Salem, NC, United States
26Department of Biomedical Informatics, National University of Singapore, Singapore, Singapore
27Department of Biomedical and Health Informatics, The Children's Hospital of Philadelphia, Philadelphia, PA, United States
28Department of Pediatrics, Perelman School of Medicine, The University of Pennsylvania, Philadelphia, PA, United States
29Clinical and Translational Science Institute, Medical College of Wisconsin, Milwaukee, WI, United States
30See Acknowledgments

* these authors contributed equally

Corresponding Author:
Isaac S Kohane, MD, PhD

https://www.jmir.org/2021/3/e22219
Abstract

Coincident with the tsunami of COVID-19–related publications, there has been a surge of studies using real-world data, including those obtained from the electronic health record (EHR). Unfortunately, several of these high-profile publications were retracted because of concerns regarding the soundness and quality of the studies and the EHR data they purported to analyze. These retractions highlight that although a small community of EHR informatics experts can readily identify strengths and flaws in EHR-derived studies, many medical editorial teams and otherwise sophisticated medical readers lack the framework to fully critically appraise these studies. In addition, conventional statistical analyses cannot overcome the need for an understanding of the opportunities and limitations of EHR-derived studies. We distill here from the broader informatics literature six key considerations that are crucial for appraising studies utilizing EHR data: data completeness, data collection and handling (eg, transformation), data type (ie, codified, textual), robustness of methods against EHR variability (within and across institutions, countries, and time), transparency of data and analytic code, and the multidisciplinary approach. These considerations will inform researchers, clinicians, and other stakeholders as to the recommended best practices in reviewing manuscripts, grants, and other outputs from EHR-data derived studies, and thereby promote and foster rigor, quality, and reliability of this rapidly growing field.

Introduction

What should researchers and clinicians conclude about the recent high-profile retractions of COVID-19 studies based on electronic health record (EHR) data? It is impressive that two publications involving patients with COVID-19, one in The Lancet [1] and the other in the New England Journal of Medicine [2], were determined to be unsound and were retracted in less than 2 months from publication, as these journals’ review processes and quality checks are among the most rigorous in the world. Yet, upon closer inspection by those of us familiar with EHR-based research, there were many flaws to these studies involving data quality issues and a lack of transparency that should have been more readily identified during the peer and editorial review process. This is not to say that in-depth statistical analysis might not have eventually uncovered concerns but rather to point out incongruities and anomalies unique to EHR-based studies that should immediately raise concerns to experienced biomedical informaticians, much like an experienced contractor explaining to a homeowner why a competing bid is too good to be true.

In this viewpoint, we present six key questions that are necessary to consider when appraising EHR-based research, especially for research studies investigating the pandemic:

1. How complete are the data?
2. How were the data collected and handled?
3. What were the specific data types?
4. Did the analysis account for EHR variability?
5. Are the data and analytic code transparent?
6. Was the study appropriately multidisciplinary?

In particular, we focus on general aspects of these questions that are crucial to study and data quality and validity of and interpretability of the results and that are broadly applicable to many stakeholders, including researchers and clinicians, in order to optimize the review of submitted manuscripts, published studies, and grant applications containing preliminary data. These desiderata were compiled by the 96 members of the Consortium for Clinical Characterization of COVID-19 by EHR (4CE)—a self-assembled group of collaborating hospitals focused specifically on studying the clinical course of patients with COVID-19 using EHR-based data—most of whom are biomedical informaticians—across 7 countries. 4CE members were invited to contribute their specific key concerns to a shared checklist. This list was then pared down into a less technical list for a more general audience. We excluded those items that are generally considered to be good biostatistical practices (eg, manual review of sample data sets, detecting and understanding outliers [3,4]) to present EHR-specific concerns to a broad biomedical audience. We also excluded recommendations that are contained within the Reporting of Studies Conducted Using Observational Routinely Collected Health Data (RECORD) statement [5,6], which are not specific to EHR-derived data. Finally, we did not focus on the specific limitations of EHR-derived studies, which have been amply documented [7,8], or on the methods to minimize the impact of these limitations.
as this viewpoint is not focused on reviewing specific methodological options for investigators using EHR-derived data, which has been reviewed in detail previously [9-11]. We acknowledge that there are many other criteria that can inform evaluations of EHR-based studies, but we have purposefully limited this discussion to those issues that are most relevant to a general audience, centered on studies investigating the pandemic.

**Data Completeness**

There are several statistical tests to query data completeness and methods for incorporating missing data [12,13], but here we describe the reasonable expectations for such completeness with knowledge of current, state-of-the-art EHR usage. A publication that is specific about which data were obtained from the EHR (eg, specific laboratory tests or billing codes) is more credible than a study that simply claims it obtained 100% of the EHR data (as did the two recently retracted publications [1,2]). The range of data types from EHRs is extensive and highly varied; each data type requires its own specific quality control and transformations to standard terminologies. For example, laboratory measurements alone can have as many as hundreds of thousands of local codes at a large health care system such as the Veterans Health Administration. In many cases, these data require some level of manual record review to assure data quality and completeness.

Similarly, if a study reports a deidentification procedure, it must describe the details of said procedure. The goals of the deidentification process determine the nature of the deidentification process and the associated regulatory requirements. For example, US hospitals can meet HIPAA (Health Insurance Portability and Accountability Act) standards [14] if they require obfuscation of the counts of patients with rare clinical presentations below a specified prevalence threshold and if they employ date shifting. Knowledge of these methods is essential to analyzing and interpreting the derived data.

Some data types are represented theoretically in the EHR but in practice are only recorded occasionally. For example, standardized codes for smoking history or a family history of specific diseases exist but their underuse is well known. Thus, one cannot assume that the lack of smoking history codes equates to the patient being a nonsmoker. In such scenarios, one must provide an explicit description of the management of missing/null values. Many data elements, such as a complete pulmonary function test, exist in a fragmented form, scattered across different fields in the EHR, and are difficult to extract reliably. In addition, clinical notes allow clinicians greater qualitative expressivity on some of the above values, like smoking history, where they are documented more frequently but not consistently. The quality criteria for reporting narrative content from clinical notes are further addressed below.

Many clinical states are not represented explicitly in the EHR but can be inferred (often referred to as computational phenotypes). When a publication refers to hyperlipidemia, readers should ask themselves whether the hyperlipidemic phenotype is assessed from one or more lipid laboratory tests, billing diagnostic codes, prescription of lipid-lowering medication, or a combination of the above. It is important to document if only structured codes were used or if the phenotype was defined based on information extracted from clinical notes by using natural language processing (NLP) or manual chart review. Either a table describing these phenotypic methods or a reference to a public set of definitions (eg, Phenotype Knowledgebase, PhKB [15]) or a published algorithm with reported accuracy (as seen, for example, in Zhang et al [16] and Ananthakrishnan et al [17]) can provide transparency and precision to these EHR-driven computational phenotypes. The lack of this transparency should be a warning sign. If onset time or temporal trends of clinical events are used as outcomes, it is important to provide sufficient details on how the data were used to derive these outcomes, how granular time was incorporated (eg, by day, 24-hour period, or hour/minute), and to comment on their accuracy, since EHR data are particularly noisy with regards to capturing the timing of events [18,19].

If one uses EHR data to obtain population estimates (eg, prevalence of a complication per 100,000 patients), then additional information should be provided so that readers can determine which subset of patients from that population a given hospital’s EHR can capture. For example, if the EHR captures a patient’s hospitalization for heart failure, will the EHR also capture the preceding or subsequent outpatient clinic visits related to that hospitalization? With health maintenance organizations, such as Kaiser Permanente, that is much less of a concern, but many hospitals operate in a patchwork system where the patient’s data are spread across multiple heterogeneous EHRs that do not necessarily communicate. In our recent COVID-19 study [20], we found many instances in which patients with COVID-19 were transferred from another hospital; unless that other hospital was part of our consortium, it was impossible to have a complete record of their COVID-19 clinical course. It is also important to recognize that a given EHR may not fully capture the clinical course of certain patients, such as those infected with SAR-CoV-2 who have mild symptoms and are discharged home from the emergency room. In these instances, integration of EHR data with data from other sources (eg, primary care providers’ offices or nursing homes) may increase the reliability of analysis, although in practice this is rare and such integration methods have to be well documented. EHR systems may also fail to capture acute events that occur outside of the system, especially in the coded data. Leveraging NLP data from the clinical notes can potentially recover partial information if the patient has follow-up visits within that particular system.

**Data Collection and Handling**

Often the units of measurement and the codes used for data elements like laboratory tests, medications, and diagnoses are not the same across hospitals and may even differ within the same health care system or change over time. Single analytic concepts (eg, the troponin T test) can balloon into dozens of local codes at each hospital, since these tests may be performed at different diagnostic laboratories, each with its own distinct codes or with different technologies over time. Therefore, they have to be “harmonized,” or mapped, to agreed-upon standard terminologies and scales [21]. Even when they are the same,
their meaning can differ based on population or practice differences (eg, which sensitive troponin test is used or which reference range defines a test result being normal, or in children rather than in adults, whose normative values often change across the age range) [7]. In both instances, readers should expect that the specific procedures for harmonization or site-specific semantic alignment are described adequately in the Methods section (or via supplementary materials). A summary of this process can become increasingly complex within the usual confines of a Methods section for multisite and international studies where, by necessity, the site-by-site variability is high.

**Data Type**

There are large methodological divides and divergent ethical challenges between codified data (eg, discrete laboratory values such as serum glucose) and narrative text (eg, discharge summary) from which characterizations are obtained using NLP. While both data types have their own limitations, methods that incorporate both can greatly improve the sensitivity and/or specificity of the clinical characterizations and phenotyping of a group of patients. For example, signs and symptoms are often not codified discreetly or consistently (eg, not entered into the EHR’s Problem List) but are written in the clinical notes. Similarly, outpatient medication documentation in clinical notes does not necessarily represent accurately the medications that the patient is actually taking, but prescriptions entered into the EHR may. Combining both codified and NLP data can substantially improve sensitivity and/or specificity and ideally one should always use this complementarity [22-24]. For example, only about 10% of pregnant women with suicide ideation have related codes and vast majority of the cases are only documented in the notes [25]. However, the ability to extract NLP data and the accuracy of those data may be limited by each institution’s informatics infrastructure and expertise as well as local institutional review board (IRB) constraints. Furthermore, NLP application to clinical narrative text is relatively new and more prone to large variability in the quality of the obtained characterizations. Particularly in countries with different languages, the NLP techniques and their performance may vary widely. For this reason, readers should expect a reference to the specific NLP methods used and their performance characteristics on data of the sort that the study collected and analyzed. For example, if someone describes the use of an NLP approach on discharge summaries in intensive care units in Italy, but the provided citation was validated only for use in outpatient notes written in English, readers can be legitimately concerned about the accuracy and validity of the patient characterizations in that study. Furthermore, if a study claims very high accuracy, readers should expect a report (or citation of a report) that shows an expert review of the NLP method validated against a representative sample confirming the claimed performance.

**Robustness Against EHR Variability**

Beyond any variation in human biology across countries and continents, different styles of practice, and how different reimbursement schemes influence styles of practice and use of EHRs, have a very large impact on the nature of EHR data. Therefore, a multinational study should at least acknowledge these differences as a limitation or explicitly attempt to account for them in the analyses. For example, in COVID-19-related research, it has become increasingly apparent that there is an association between patient race/ethnicity and their risk for acquisition of and complications from COVID-19. However, this association is much less detectable in EHR data, as, for example, it is mostly invisible in data from Europe because several countries forbid collecting self-reported race in the EHR. Even in the United States, the coding of different ethnicities or multiracial identification is not standardized. In addition, some countries have far more comprehensive primary care EHR data sharing, whereas others (like the United States) cannot aggregate data systematically and consistently across major health care centers.

**Transparency**

In order to ensure patients’ rights to privacy, patient-level data can rarely be shared outside an institution. In many EHR-driven studies, the code to extract data from a source EHR can be protected by confidentiality agreements with the EHR vendor and is thus difficult to share. Nonetheless, the code or algorithm for creating the variables used for analyses should be provided even if the detailed data extraction procedures are not shared because of commercial restrictions. Running the code on synthetic data sets that follow a standard data model can demonstrate code functionality and facilitate code reuse [26]. The code used to conduct statistical analyses and create visualizations—after data extraction—should also be shared in public repositories to enable other researchers to follow each step of the analysis and provide further transparency. While there are significant challenges to sharing patient-level data, one can share intermediate results and aggregate distributions to increase transparency and understand between-institution differences [27]. One should archive the data used for analyses, along with the associated data extraction codes, at the local institution to ensure reproducibility. Authors should also make the deidentified data available—either publicly in a repository or by request. While only a small fraction of readers typically look at the code, whether referenced on a file server or shared as supplementary methods, the availability of the code provides reassurance and validation that the study utilized proper methodologies.

**Multidisciplinary Approach**

There may come a time when data can be aggregated automatically from multiple EHR environments to answer a particular question without relying on a human to understand the particular idiosyncrasies of each institution’s data and EHR system. Until that day, effective EHR data set analysis requires collaboration with clinicians and scientists who have knowledge of the diseases being studied and the practices of their particular health care systems; informaticians with experience in the underlying structures of biomedical record repositories at their own institutions and the characteristics of their data; data

https://www.jmir.org/2021/3/e22219

J Med Internet Res 2021 | vol. 23 | iss. 3 | e22219 | p.540

(page number not for citation purposes)
harmonization experts to help with data transformation, standardization, integration, and computability; statisticians and epidemiologists well versed in the limitations and opportunities of EHR data sets and related sources of potential bias; machine learning experts; and at least one expert in regulatory and ethical standards. Data provenance records should already exist to ensure compliance with privacy standards, so that authors can readily point to these processes and reference institutional officials who grant data access similarly to IRBs. In our experience, we often have an interdisciplinary team participate in the process of establishing the research question and study design, defining the data elements, and determining what analyses can be performed given the available data. It is also important that people with complementary skills work together to review and interpret the results [28]. Each of these steps is a major contribution deserving of authorship. Just as a population genetics study reporting across countries often has dozens of authors, so do we expect multihospital EHR-driven studies to acknowledge and name the individuals as authors and in doing so provide accountability for the dozens of procedures, checks, and balances necessary for the reliable extraction of EHR patient data. Consequently, contribution statements should list explicitly the responsibilities of each author with regard to study conceptualization and design, data extraction, data harmonization, data integration, data analysis, results interpretation, and regulatory and ethical oversight. Additionally, although reputation is sometimes overvalued, having no reputation or at least a track record of appropriate success should trigger greater attention to documenting the process to reach the same level of trust. Unlike a mathematical proof, simple inspection of the data may be insufficient and will become increasingly so in the era of data generated by machine learning algorithms purposefully built for the task of conditioning data to appear real. Trust and accountability become essential companions to transparency and clarity during the EHR analytic process.

Conclusion

Similar to publications from the early days of the genomic revolution, which initially included extensive sections on DNA sequencing validation, methods, reagents, and conditions that became progressively briefer as trust was built and the methods commoditized, comprehensively and transparently reported methods of EHR data extraction and transformation are at least as important as subsequent statistical analysis and interpretation. We need to be open and transparent about the inherent limitations of the data and the analyses. We should also acknowledge alternative interpretations of the results (eg, outlier prescribing practices in one country that confound the apparent effects of that drug in that country). Extra caution is also needed in how we draw causal inferences from EHR data, especially given the noisiness and incompleteness of the data in addition to several sources of bias, though application of a causal model framework and specific causal inference methods may help mitigate some of these concerns. The recommendations we have outlined here (see Table 1 for our 12-item checklist) do not substitute for a durable research infrastructure that would enable tracking EHR data provenance along explicit source, ownership, and data protocols, which would allow for rigorous and routine quality assurance in the use of EHR data [29].
Table 1. 12-item checklist to assess electronic health record (EHR) data–driven studies.

<table>
<thead>
<tr>
<th>Item</th>
<th>Reassuring</th>
<th>Concerning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defining study cohort/data extraction</td>
<td>Reporting the precise definition of the domains and/or subsets of EHR data extracted for the study cohort and the information system sources</td>
<td>100% of the EHR said to be extracted or no specification of which subsets of the EHR data were obtained</td>
</tr>
<tr>
<td>Deidentification</td>
<td>Specific deidentification algorithm documented with acknowledgment of analytic consequences/limitations</td>
<td>Only a statement that deidentification was performed</td>
</tr>
<tr>
<td>Defining clinical variables/data type–specific omissions/limitations</td>
<td>For data types represented poorly in EHR codified data, either NLP is deployed on the EHR clinical notes or additional data sources (eg, self-reported questionnaires) are used. Procedures to deal with missing values should also be made explicit</td>
<td>Referring data types like family/social history without explaining how they are obtained through NLP or exceptional codified data practice</td>
</tr>
<tr>
<td>Phenotypic transparency</td>
<td>Computational phenotypes that are more than just a specific native EHR variable (eg, hyperlipidemia vs a specific LDL measurement) are either defined in the study or a citation is given to algorithmic phenotype definitions</td>
<td>Clinical phenotypes are used in the study without specifying how they were derived from the EHR data</td>
</tr>
<tr>
<td>Generalizing EHR findings to the population/population denominator</td>
<td>Study heavily cautions on using prevalence/incidence estimates from the EHR data or refers to empirical estimates on how much of a patient’s entire health care is captured in that particular EHR</td>
<td>Direct estimates of prevalence or incidence from EHR frequencies without justifying that generalization</td>
</tr>
<tr>
<td>Data collection</td>
<td>Clinical forms or data models implemented in health care information systems are shared or clearly described. This includes the coding systems used</td>
<td>Mention structured data without specifying the clinical forms or data models. Mention coded data without mentioning coding systems</td>
</tr>
<tr>
<td>Data transformation/harmonization</td>
<td>Data transformation process shared or clear description of which methods were used to harmonize data to a standardized terminology, scale units, and account for different local usage</td>
<td>Mention of harmonization methods without specifying which ones and what problems were identified and addressed/overcome</td>
</tr>
<tr>
<td>Textual vs codified data</td>
<td>If textual data are used in the study, then specification of which clinical notes, in what language, with which NLP algorithm with either an explanation of or a citation to that algorithm’s validation, sensitivity, and specificity for comparable data</td>
<td>Harmonization efforts for codified and textual data treated as if they are the same process. Lack of specificity in describing the NLP algorithm and performance</td>
</tr>
<tr>
<td>Manual coding of data</td>
<td>Qualifications of coders described, formal coding criteria described or at least mentioned, intercoder reliability measured and reported</td>
<td>No description of process for turning text or nonstandard coded data into standard coded data; use of crowd-sourced coders (eg, graduate students or Mechanical Turk) without mention of quality assurance processes</td>
</tr>
<tr>
<td>Regional and global variation</td>
<td>A study describes how they adjust for (or exclude) differences that are due to variation in practice, regulation, and clinical documentation through the EHR from site to site</td>
<td>A study says they adjusted for regional or country differences in practice or EHR documentation but do not describe how they do it</td>
</tr>
<tr>
<td>Sharing analytic code</td>
<td>Analytic code is deposited in a public repository or study-specific public website</td>
<td>Code is not shared or only “shared on demand”</td>
</tr>
<tr>
<td>Acknowledge a multidisciplinary team</td>
<td>Authorships for all parts of the extraction-through-analysis pipeline with precision as to each contribution</td>
<td>Health care system sources not named or local health care system site collaborators not named</td>
</tr>
</tbody>
</table>

aNLP: natural language processing.
bLDL: low-density lipoprotein.

Finally, in crises such as the COVID-19 pandemic, we need to recognize that many studies can contribute to our understanding of what is happening to our patients and how our practices might affect patient outcomes. Overly generalized conclusions will likely strain the boundaries of what can be reasonably inferred from the kinds of data currently obtained through EHRs. Recommendations that flow from overly broad claims may irreversibly harm stakeholders, including patients and clinicians. Increased reader awareness of EHR-derived data quality indicators is crucial in critically appraising EHR-driven studies and to prevent harm from misleading studies, which will ensure sustainable quality in this rapidly growing field.

Acknowledgments

The members of the Consortium for Clinical Characterization of COVID-19 By EHR (4CE) are as follows: Adem Albayrak, Danilo F Amendola, Li LLJ Anthony, Bruce J Aronow, Andrew Atz, Paul Avillach, Brett K Beaulieu-Jones, Douglas S Bell,

Authors' Contributions

ISK led the 4CE international consortium, conceived and designed the study, and drafted the manuscript. TC led 4CE analytics strategies and made contributions to the study design and drafting of the manuscript. JIC contributed a validation strategy and made edits to the manuscript. NG-B was responsible for data extraction and transformation to 4CE format and quality control of the results and made internal contributions. NG led 4CE visualization strategies and made contributions/edits to the manuscript. JGK contributed to the 4CE validation strategy and data submission strategies and made edits to the manuscript. KDM made contributions to the text and framework and made edits to the manuscript. DM was involved in data extraction and transformation to 4CE format. SMN led 4CE data validation strategies and made contributions/edits to the manuscript. GSO made contributions to strategy and edits to the manuscript. NP contributed to 4CE data analysis, aggregation, and quality control. KBW contributed to validation strategies and made edits to the manuscript. BJA, PA, BKB-J, RB, RLB, GAB, MC, MG, AG-S, DAH, JHH, CH, NHW, YL, JHM, AN, KYN, LPP, MP-J, PS, AMS, ALMT, DMT, BMT, CT, AKV, and GMW made contributions/edits to the manuscript.

Conflicts of Interest

RB and AM are shareholders of Biomersis srl. GSO is affiliated with BoD, Galectin Therapeutics, Angion Biomedica, and Amesite, Inc. DMT consulted on a legal matter for AstraZeneca last year.

References


Abbreviations

4CE: Consortium for Clinical Characterization of COVID-19 by EHR
EHR: electronic health record
HIPAA: Health Insurance Portability and Accountability Act
RECORD: Reporting of Studies Conducted Using Observational Routinely Collected Health Data
NLP: natural language processing
IRB: institutional review board
PheKB: Phenotype Knowledgebase

Edited by R Kakaña; submitted 13.07.20; peer-reviewed by N Delvaux, M Adly, P Harris, A Adly, A Adly, J Li, L Genaro; comments to author 04.08.20; revised version received 14.09.20; accepted 10.01.21; published 02.03.21.

Please cite as:

What Every Reader Should Know About Studies Using Electronic Health Record Data but May Be Afraid to Ask
J Med Internet Res 2021;23(3):e22219
URL: https://www.jmir.org/2021/3/e22219
doi:10.2196/22219
PMID:33600347

©Isaac S Kohane, Bruce J Aronow, Paul Avillach, Brett K Beaulieu-Jones, Riccardo Bellazzi, Robert L Bradford, Gabriel A Brat, Mario Cannataro, James J Cimino, Noelia García-Barrio, Nils Gehlenborg, Marzyeh Ghassemi, Alba Gutiérrez-Sacristán, David A Hanauer, John H Holmes, Chuan Hong, Jeffrey G Klann, Ne Hooi Will Loh, Yuan Luo, Kenneth D Mandl, Mohammad Daniar, Jason H Moore, Shawn N Murphy, Antoine Neuraz, Kee Yuan Ngiam, Gilbert S Omenn, Nathan Palmer, Lav P Patel, Miguel Pedraja-Jiménez, Piotr Sliz, Andrew M South, Amelia Li Min Tan, Deanne M Taylor, Bradley W Taylor, Carlo Torti, Andrew K Vallejos, Kavishwar B Wagholikar, The Consortium For Clinical Characterization Of COVID-19 By EHR (4CE), Griffin M Weber, Tianxi Cai. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 02.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Practical Considerations and Successful Implementation of Vital Signs Monitoring. Comment on “Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial”

Caoimhe Walsh¹; David Zargaran²; Nikhil Patel³; Amelia White⁴; Foteini Stefania Koumpa⁵; Ravina Tanna⁶; Muhammad Arsalan Ashraf²

¹Epsom and St Helier University Hospitals NHS Trust, Surrey, United Kingdom
²Guy’s and St Thomas’ NHS Foundation Trust, London, United Kingdom
³Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom
⁴Royal Free London NHS Foundation Trust, London, United Kingdom
⁵London North West University Healthcare NHS Trust, London, United Kingdom
⁶Luton and Dunstable University Hospital NHS Foundation Trust, London, United Kingdom

Corresponding Author:
Caoimhe Walsh
Epsom and St Helier University Hospitals NHS Trust
Wrythe Lane, Carshalton
Surrey, SM5 1AA
United Kingdom
Phone: 44 7584061131
Email: caoimhenwalsh@gmail.com

Related Article:
Comment on: https://www.jmir.org/2018/12/e10802/ doi:10.2196/14042

KEYWORDS
general surgery; monitoring; observations; vital signs

We read with great interest the study by Downey et al [1], which examined the clinical utility and practicality of introducing a wearable, wireless patch device for continuous vital signs monitoring in surgical inpatients. As surgical trainees, we frequently rely on the recording of patients’ vital signs on observation charts and the use of early warning scores. These systems are in place as a safety mechanism to highlight acutely unwell patients and those at risk of clinical deterioration [2]. However, we are also all too familiar with the limitations posed by current methods of collecting and communicating this critical information, and there is a real need for further improvements in both of these areas [3].

Having a continuous monitoring device poses a number of potential benefits. First, by having many more data points clinicians can more accurately define long-term trends for each patient. Even more importantly, deterioration can be highlighted much sooner than currently permitted due to the 5-6–hour intervals between “observation rounds”—but will this result in information overload? It is easy to capture information, but this can be misleading, and overinterpretation of incidental or minor alterations in vital signs may lead to unnecessary additional investigations for a patient. Furthermore, although data are being collected continuously, nursing staff can only check this at discrete time points due to other jobs and ward responsibilities. Therefore, staff may nevertheless fail to recognize unwell patients at the earliest time point. This is evidenced by the fact that it still took an average of 626 minutes to initiate treatment for sepsis in the patient cohort with continuous monitoring, despite the UK national guidelines for the management of sepsis stating that antibiotics should be administered within 1 hour of the patient first being suspected to have sepsis [4].

We understand that the software initially overwhelmed nursing staff with false alerts, which highlights the important yet challenging balance to make between false alerts and detecting...
significant clinical changes. We would be interested to understand what parameters were used for the vital signs alerts, and whether these parameters were standardized across all patients or relative to the individual patient’s baseline vital signs. Furthermore, does the alert system indicate the severity of the trigger?

There is also the consideration of how practical it is for patients to wear such devices continuously around their chest. Anecdotally, we know that patients who are advised to wear TED (thromboembolism-deterrent) stockings as part of venous thromboembolism prophylaxis are often found to have removed them “temporarily” due to discomfort or to have a shower, with subsequent difficulty putting them back on. We can envisage similar factors affecting the wearing of these devices for vital signs monitoring; for example, they may be removed if they interfere with clinical examination of the chest, or again due to comfort or personal hygiene reasons. We already anticipate this happening as the study noted that 24% of patients did not wear the wireless patch for the whole length of their admission. This means that as well as providing training for nurses, doctors and indeed patients themselves would also need to be trained in how to position the devices on the chest to ensure they are placed back correctly if removed for whatever reason.

One solution to minimize the impact of wearing such devices would be to reserve them for use out of hours. Typically, this is when wards are minimally staffed and clinicians are individually responsible for a far larger number of patients, leading to a more significant need to highlight deteriorating patients [5]. During this time, patients are typically less active therefore there would be fewer false alarms, for example, from increased heart rate due to patients mobilizing, and with patients unlikely to be showering overnight, which would result in reduced chances for the need to remove or replace the device. Within normal working hours, nurses and doctors have a much greater presence in the ward; therefore, concerns regarding unwell patients are more likely to be raised in a timely manner. Thus, it may be that during the day, current methods of intermittently collecting vital signs data will continue to suffice; this would also reduce the interference of wearing the device with activities such as showering or being clinically examined.

We recommend that future studies control for the time of day when the clinical deterioration occurred. By analyzing separately the time to treat sepsis both in hours and out of hours for the continuously monitored and intermittently monitored groups, it would be possible to identify more objectively whether there is a particular time of day where continuous vital signs monitoring renders the greatest clinical benefit over intermittent monitoring.

This paper [1] has identified a sensible and considered solution to the issue of collecting and communicating vital signs data on surgical inpatients. Despite further work being required to streamline the implementation of this system into clinical use, we commend the authors on their innovative device. We hope this technology will soon help to improve clinical outcomes and look forward to seeing a study with a more significant population size, and thus greater power, to enable stronger conclusions to be drawn from the results.

Editorial Notice
The corresponding author of “Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial” did not indicate a desire to respond.

Conflicts of Interest
None declared.

References

Abbreviations
TED: thromboembolism-deterrent
Practical Considerations and Successful Implementation of Vital Signs Monitoring. Comment on “Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial”

J Med Internet Res 2021;23(3):e14042
URL: https://www.jmir.org/2021/3/e14042
doi:10.2196/14042
PMID:33704079

©Caoimhe Walsh, David Zargaran, Nikhil Patel, Amelia White, Foteini Stefania Koumpa, Ravina Tanna, Muhammad Arsalan Ashraf. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 11.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Corrigenda and Addenda

Correction: Using the Patient Portal Sexual Health Instrument in Surveys and Patient Questionnaires Among Sexual Minority Men in the United States: Cross-sectional Psychometric Validation Study

Kevon-Mark P Jackman¹, DrPH, MPH; Jeremy Kane², PhD, MPH; Hadi Kharrazi³, PhD, MD; Renee M Johnson¹, PhD, MPH; Carl Latkin⁴, MS, PhD

¹Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States
²Department of Epidemiology, Columbia University Mailman School of Public Health, NY, NY, United States
³Department of Health Policy and Management, Center for Population Health IT, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States
⁴Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

Corresponding Author:
Kevon-Mark P Jackman, DrPH, MPH
Department of Mental Health
Johns Hopkins Bloomberg School of Public Health
624 N Broadway
Hampton House 8th Floor
Baltimore, MD, 21205
United States
Phone: 1 410 955 3910
Email: kjackma2@jhmi.edu

Related Article:
Correction of: https://www.jmir.org/2021/2/e18750/
doi:10.2196/28358

(J Med Internet Res 2021;23(3):e28358)

In “Using the Patient Portal Sexual Health Instrument in Surveys and Patient Questionnaires Among Sexual Minority Men in the United States: Cross-sectional Psychometric Validation Study” (J Med Internet Res 2021;23(2):e18750) four errors were noted. The correction will appear in the online version of the paper on the JMIR Publications website on March 5, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

In the section “AMIS-PPSHI Scores,” the symbol was missing in the following sentence:

However, scores were marginally higher among participants with a Kessler 6-item psychological distress scale (K6) score≥13.

This has been corrected to:

However, scores were marginally higher among participants with a Kessler 6-item psychological distress scale (K6) score≥13.

The correction will appear in the online version of the paper on the JMIR Publications website on March 5, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.
Correction: Measurement of Digital Literacy Among Older Adults: Systematic Review

Sarah Soyeon Oh¹, PhD; Kyoung-A Kim², PhD; Minsu Kim³; Jaeuk Oh³; Sang Hui Chu¹, PhD; JiYeon Choi¹, PhD

¹Mo-Im Kim Nursing Research Institute, College of Nursing, Yonsei University, Seoul, Republic of Korea
²Department of Nursing, Yeoju Institute of Technology, Yeoju, Gyeonggi-do, Republic of Korea
³College of Nursing, Yonsei University, Seoul, Republic of Korea

Corresponding Author:
JiYeon Choi, PhD
Mo-Im Kim Nursing Research Institute, College of Nursing, Yonsei University
50 Yonsei-ro, Seodaemun-gu
Seoul, 03722
Republic of Korea
Phone: 82 2 2228 3301
Fax: 82 2 2227 8303
Email: jychoi610@yuhs.ac

Related Article:
Correction of: https://www.jmir.org/2021/2/e26145/
doi:10.2196/28211

In the originally published paper, the footnotes under Table 3 were incorrect.
The footnotes originally appeared as follows:

\[ b \] O: not included in the questionnaire
\[ c \] X: included in the questionnaire

These have now been corrected to the following:

\[ b \] O: included in the questionnaire
\[ c \] X: not included in the questionnaire

The correction will appear in the online version of the paper on the JMIR Publications website on March 03, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Submitted 24.02.21; this is a non–peer-reviewed article; accepted 25.02.21; published 03.03.21.

Please cite as:
Oh SS, Kim KA, Kim M, Oh J, Chu SH, Choi J
Correction: Measurement of Digital Literacy Among Older Adults: Systematic Review
J Med Internet Res 2021;23(3):e28211
URL: https://www.jmir.org/2021/3/e28211
doi:10.2196/28211
PMID:33657006

©Sarah Soyeon Oh, Kyoung-A Kim, Minsu Kim, Jaeuk Oh, Sang Hui Chu, JiYeon Choi. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 03.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Exploring Usage of COVID Coach, a Public Mental Health App Designed for the COVID-19 Pandemic: Evaluation of Analytics Data

Beth K Jaworski\(^1\), PhD; Katherine Taylor\(^1\)*, MPH, PsyD; Kelly M Ramsey\(^1\); Adrienne Heinz\(^1,2\)*, PhD; Sarah Steinmetz\(^1\), PhD; Ian Pagano\(^3\), PhD; Giovanni Moraja\(^4\); Jason E Owen\(^1\)*, MPH, PhD

\(^1\)National Center for PTSD, Dissemination & Training Division, US Department of Veterans Affairs, Menlo Park, CA, United States
\(^2\)School of Medicine, Stanford University, Stanford, CA, United States
\(^3\)University of Hawaii Cancer Center, Honolulu, HI, United States
\(^4\)Vertical Design, LLC, Berkeley, CA, United States

* all authors contributed equally

Corresponding Author:
Beth K Jaworski, PhD
National Center for PTSD, Dissemination & Training Division
US Department of Veterans Affairs
795 Willow Road
Menlo Park, CA, 94025
United States
Phone: 1 650 308 9437
Email: beth.jaworski@va.gov

Abstract

Background: The COVID-19 pandemic has significantly impacted mental health and well-being. Mobile mental health apps can be scalable and useful tools in large-scale disaster responses and are particularly promising for reaching vulnerable populations. COVID Coach is a free, evidence-informed mobile app designed specifically to provide tools and resources for addressing COVID-19–related stress.

Objective: The purpose of this study was to characterize the overall usage of COVID Coach, explore retention and return usage, and assess whether the app was reaching individuals who may benefit from mental health resources.

Methods: Anonymous usage data collected from COVID Coach between May 1, 2020, through October 31, 2020, were extracted and analyzed for this study. The sample included 49,287 unique user codes and 3,368,931 in-app events.

Results: Usage of interactive tools for coping and stress management comprised the majority of key app events (n=325,691, 70.4%), and the majority of app users tried a tool for managing stress (n=28,009, 58.8%). COVID Coach was utilized for \(\leq 3\) days by 80.9% (n=34,611) of the sample whose first day of app use occurred within the 6-month observation window. Usage of the key content in COVID Coach predicted returning to the app for a second day. Among those who tried at least one coping tool on their first day of app use, 57.2% (n=11,444) returned for a second visit; whereas only 46.3% (n=10,546) of those who did not try a tool returned (\(P<.001\)). Symptoms of anxiety, depression, and posttraumatic stress disorder (PTSD) were prevalent among app users. For example, among app users who completed an anxiety assessment on their first day of app use (n=4870, 11.4% of users), 55.1% (n=2680) reported levels of anxiety that were moderate to severe, and 29.9% (n=1455) of scores fell into the severe symptom range. On average, those with moderate levels of depression on their first day of app use returned to the app for a greater number of days (mean 3.72 days) than those with minimal symptoms (mean 3.08 days; \(t=3.01, P=.003\)). Individuals with significant PTSD symptoms on their first day of app use utilized the app for a significantly greater number of days (mean 3.79 days) than those with fewer symptoms (mean 3.13 days; \(t=2.29, P=.02\)).

Conclusions: As the mental health impacts of the pandemic continue to be widespread and increasing, digital health resources, such as apps like COVID Coach, are a scalable way to provide evidence-informed tools and resources. Future research is needed to better understand for whom and under what conditions the app is most helpful and how to increase and sustain engagement.

(J Med Internet Res 2021;23(3):e26559) doi:10.2196/26559
Impact of COVID-19 on Mental Health and Well-Being

In the United States, the COVID-19 pandemic has led to over 500,000 deaths, millions of job losses, and disruption of nearly every aspect of daily life. COVID-19 has also negatively impacted mental health and well-being globally [1-3]. One-third of American adults report a high level of psychological distress due to the pandemic [4].

Several studies now indicate that an unprecedented mental health crisis is underway. In a poll conducted by Harris [5] on behalf of the American Psychological Association, nearly 8 in 10 adults said the pandemic is a significant source of stress in their lives. The prevalence of depression symptoms among adults in the United States has risen from 8.5% of the population prior to the COVID-19 pandemic to 27.8% in the midst of the pandemic [6]. Researchers from the US Centers for Disease Control and Prevention found that 40% of respondents of a survey administered in June 2020 endorsed at least one adverse mental or behavioral health condition including symptoms of depression, anxiety, posttraumatic stress, or having started or increased substance use to cope with stress or emotions related to COVID-19. Over 10% of respondents reported seriously considering suicide in the previous 30 days [7]. Furthermore, there appears to be a bidirectional relationship between COVID-19 and psychiatric disorders, such that having a psychiatric disorder is associated with a greater likelihood of contracting COVID-19, and contracting COVID-19 is associated with an increased risk of receiving a psychiatric diagnosis [8].

Digital Mental Health as a Strategy for Addressing the Mental Health Impact of COVID-19

Digital mental health options are needed to help address the mental health effects of COVID-19 as well as the secondary impacts of the pandemic, such as fear of contracting the virus, financial stress related to job loss, loss of childcare, or the need to balance work with remote education. Mobile mental health apps are a promising strategy for addressing mental health impacts of the pandemic because of their potential scalability, reach, and utility, particularly during a time when in-person care may not be accessible due to social distancing and safety regulations. High-quality, accessible, and sustainable apps have been identified as part of an integrated “blueprint” for digital mental health services during the pandemic [9]. They may be a particularly useful tool for reaching a large number of individuals from highly impacted populations at risk for posttraumatic stress disorder (PTSD) or other mental health conditions, including those who have contracted COVID-19 and frontline health care workers [10].

Apps are a particularly appealing medium because of their potential reach. Individuals rarely turn off mobile devices [11], making apps available 24/7. Additionally, in the United States, 81% of adults own smartphones, with few differences among sociodemographic groups [12]. This reach is important because the pandemic has a disproportionate and complex impact on Black, Indigenous, people of color (BIPOC), people from low-income backgrounds, and women [13], and it is clear that vulnerable groups are at greater risk for behavioral and mental health consequences [6,7,14]. Systemic disadvantage with respect to social determinants of health, such as lack of internet access and reduced educational opportunities, has been associated with increased COVID-19 mortality rates [15]. Free, evidence-informed apps, such as COVID Coach, that are developed by government or not-for-profit entities and made specifically to address such systemic barriers, can contribute to a digital mental health safety net for vulnerable individuals. Beyond the ability to reach many people, apps have been shown to be useful adjunctive resources for a range of mental health concerns, including anxiety and depression [16] and PTSD [17].

Creation of the COVID Coach App

In response to the anticipated mental health impact of the COVID-19 pandemic, and as part of the Veterans Affairs’ (VA) “Fourth Mission” to help during times of national emergencies and support public health, the National Center for PTSD created COVID Coach (Multimedia Appendix 1). COVID Coach is a free, publicly available mental health app designed to help people cope with stress, find resources, and track mental health over time. It is intended to be simple to use, does not require an internet connection or data plan to access primary content, and all recommended activities and resources are low in cost or free to users. COVID Coach is one of only a few public mental health apps available for specifically addressing mental health concerns stemming from or exacerbated by COVID-19, and it is the newest in a suite of free mental health apps designed to support mental health [18,19].

COVID Coach is based upon the model of the empirically supported PTSD Coach app [20], which has been identified as a potential approach for the behavioral and mental health impact of COVID-19 [21]. COVID Coach provides app users with many of the features of PTSD Coach, including tools for coping with challenging situations and managing stress, psychoeducation, tracking of mental health symptoms, and quick access to support networks and crisis resources. COVID Coach also provides symptom management tools adapted for life during the pandemic (eg, sleep struggles; isolation; stress; sadness; and indoor, socially distanced activities), goal-setting, and over 50 unique psychoeducational topics about managing COVID-19–related concerns (ie, staying well, staying balanced, staying together, staying safe, and staying healthy). The app was released at the end of April 2020 and has been promoted as part of the VA’s response to the pandemic and highlighted as an important resource [22].

Evaluating COVID Coach in the Context of a Public Health Disaster

Mobile mental health apps can be useful tools in large-scale disaster responses [23], and their use has been indicated...
specifically within the context of the COVID-19 pandemic (eg, [24,25]). However, the utility of standalone apps “in the wild” can be limited by poor engagement and high attrition (eg, [26,27]). A host of challenges renders it difficult to conduct formal research and evaluation on disaster mental health interventions and resources [28]. Accordingly, there is often insufficient data on when, how, and why individuals utilize disaster mental health resources to help guide policy and budgetary allocation. Although COVID Coach has been well received in the general population, usage of the app, particularly the key content areas, and retention have not yet been formally evaluated.

Objective
This study utilized anonymous mobile analytics data to characterize the overall usage of an app designed specifically to provide tools and resources for addressing COVID-19–related stress, explore retention and return usage, and assess whether the app was reaching individuals that may benefit from mental health resources. Three key aims guided the study: (1) describe general usage trends between May 1, 2020, and October 31, 2020 (a key period of time during the pandemic), and identify how frequently specific types of key app content were used (ie, coping tools, psychoeducation, self-assessments, and accessing resources); (2) explore usage patterns, with a particular focus on understanding how usage of key content on the first day of use may be related to return use and retention; and (3) characterize baseline mental health and well-being among COVID Coach users.

Methods
COVID Coach Mobile App Description
COVID Coach, available for Android [29] and iOS [30], is an app designed specifically for the COVID-19 pandemic to provide users with interactive, evidence-informed tools for coping with stress and anxiety, information about how to stay well, stay connected, and navigate challenges, self-monitoring mental health symptoms and goals, and resources to discover and connect with various types of verified and vetted support. The app can be used independently or in conjunction with professional mental health care but is not a replacement for therapy. Users are not required to create an account or log in to access any of the content, and the app is fully compatible with assistive software technologies (eg, VoiceOver or TalkBack).

Mobile Analytics Data
COVID Coach collects anonymous information about app use for the purposes of quality improvement. Fully nonidentifying, anonymous, and encrypted event sequences were stored using JavaScript Object Notation (JSON) format on a remote GovCloud server that meets VA security and privacy requirements. Data are accessible from VA App Connect software, which has been approved for use under the VA’s Technical Reference Model [31]. Upon first launch of the app, a unique, randomly generated 32-character (256-bit) code is assigned to that particular app installation. Completely anonymous usage data, such as screens selected, button presses, and other nonidentifying patterns, are collected and associated with this install code. Install codes serve as a proxy for app users since the unique identity of each app user cannot be determined. Each in-app event contains a timestamp (in Coordinated Universal Time [UTC]) that corresponds to when the event actually occurred, but data are only transmitted to the server when the app is in use and connected to Wi-Fi or utilizing a data plan.

Procedures
For the purpose of this study, mobile analytics data with timestamps between May 1, 2020, and October 31, 2020, were extracted from the research server on November 4, 2020. Between May 1 and October 31, 3,368,931 in-app related events were captured (Android: n=847,260; iOS: n=2,521,612) across 49,297 unique install codes (Android: n=12,938; iOS: n=36,359).

Measures
App Use Metrics
Daily active users and monthly active users were measured by the total number of app users that used COVID Coach on a given day or at least once within a given month. Overall, frequencies for key content usage were computed for each of the four key sections in the app: Manage Stress (tried a tool), Learn (viewed a learn topic), Mood Check (created and rated a goal or completed an assessment), and Find Resources (viewed at least one specific subsection within Find Resources). These frequencies were computed for all key events and for all app users that had activity during the observation window (May 1, 2020, through October 31, 2020). Based on a rationale similar to Kwasny and colleagues [32], we decided a priori that frequency of use within the observation window would be measured in terms of unique days of use, rather than sessions or visits because of the variability in establishing the end of an app session, within and across platforms. Additionally, all app users were categorized according to whether their first day of app use occurred during the observation window (first-time users) or prior to the start of the observation window. Thus, all analyses related to distinct days of app use, return usage, and patterns of usage by day of use focused only on app events associated with first-time users. Among all first-time users, distinct days of app use within the observation window were calculated, as well as retention days (the number of days between the first day of use and the last day of use) and the number of days between the first day of use and the second day of use (for all individuals who used the app for at least 2 distinct days). For each first-time user, completion of tasks within each of the four key content areas were totaled, by each distinct day of use. First-time users who completed one or more assessments on their first day of app use were identified as “baseline” assessment completers.

In-App Assessments
Four assessments are available within the Mood Check section of COVID Coach. These assessments can be accessed and taken at any time by app users.

The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) [33] is a measure to assess the feelings and functional aspects
of positive mental health. COVID Coach contains the 14-item version of the scale, with each item measured on a Likert-type scale ranging from 1 (“none of the time”) to 5 (“all of the time”). For each item, respondents are asked to consider how they have been feeling over the past 2 weeks. Total score is obtained by summing all items. Scores of less than 42 are indicative of low well-being [34]. The scale was found to be a valid and reliable tool for measuring mental well-being in diverse populations and across project types, and has adequate internal reliability (α=.89) [35].

The Generalized Anxiety Disorder-7 (GAD-7) [36] is a measure to screen for GAD and assess severity of GAD symptoms. The scale consists of 7 items, each measured on a Likert-type scale ranging from 0 (“not at all”) to 3 (“nearly every day”), and total score is obtained by summing all items. For each item, respondents are asked to consider how they have been feeling over the past 2 weeks. Anxiety symptom severity is categorized as: minimal (total score=0-4), mild (total score=5-9), moderate (total score=10-14), and severe (total score=15 or higher). The scale has acceptable internal reliability and good psychometric properties, including among general population samples [37].

The Patient Health Questionnaire-9 (PHQ-9) [38] is a measure to assess the severity of depression symptoms. The scale consists of 9 items, each measured on a Likert-type scale ranging from 0 (“not at all”) to 3 (“nearly every day”), and total score is obtained by summing all items. For each item, respondents are asked to consider how they have been feeling over the past 2 weeks. Depression symptom severity is categorized as: minimal (total score=0-4), mild (total score=5-9), moderate (total score=10-14), moderately severe (total score=15-19), and severe (total score=20 or higher). The scale has acceptable internal reliability (α=.86-.89) and overall sound psychometric properties across settings [39].

The Posttraumatic Stress Disorder Checklist (PCL-5) [40] is a measure to assess symptoms of PTSD. The scale consists of 20 items, each measured on a Likert-type scale ranging from 0 (“not at all”) to 4 (“extremely”), and total score is obtained by summing all items. In COVID Coach, the PCL-5 is administered with only a brief introduction, followed by the assessment items. For each item, respondents are asked to consider how they have been feeling over the past month. Initial research suggests that total scores of 31 to 33 (or higher) are indicative of probable PTSD. For this study, we use 33 as the cut-off for significant PTSD symptoms. The PCL-5 was found to be reliable and valid in both veteran [41] and civilian populations [42].

Analyses

SQLPro Studio (Hankinsoft Development, Inc) was used for all data preprocessing and extraction. SAS University Edition (SAS Institute) software in conjunction with Oracle’s VirtualBox were used for all data analyses. We calculated descriptive statistics for key content usage, retention, and baseline levels of mental health symptom severity and levels of well-being. Chi-square analyses were conducted to understand differences in returning to the app for a second day of use based on key content usage on the first day of app use and baseline mental health symptoms. We ran separate chi-square analyses for each predictor. Independent samples t tests were conducted to examine differences in total unique days of app use and total manage stress tools utilized among app users who completed an assessment on their first day of app use compared to those who did not. An analysis of variance (ANOVA) was conducted with a Tukey test for post hoc analysis to examine differences in baseline WEMWBS scores, by month, among users who completed a well-being assessment on their first day of app use. Regression analyses were conducted to examine the relationship between baseline mental health symptoms and unique days of app usage.

Results

Reach and Reception

The app was released at the end of April 2020, and as of October 31, 2020, it has been downloaded 143,097 times. It is highly rated on both the Apple App Store (4.8 out 5 stars) and the Google Play Store (4.7 out of 5 stars). Users had the opportunity to provide written reviews along with star ratings. The majority of written reviews were overwhelmingly positive, with comments such as “Beautifully calming…,” “a necessity for our new normal,” “one of the best free apps I’ve found,” and “this is amazing… it has all you may need… mood trackers, resources, meditation-not too frilly, just important.” Notably, due to Google’s restrictions on mobile apps related to COVID-19 (including hiding certain results for apps among searches containing “COVID”), COVID Coach has been installed at a ratio of over 3:1 for iOS compared to Android mobile devices.

Daily and Monthly Active Users

The number of daily active users spiked in May 2020 (mean 1205.77, SD 615.70), shortly after the app’s release. The number of daily active users has leveled off but remained stable with average daily active users of 778.67 (SD 161.16), 752.03 (SD 128.60), respectively, during the months of June, July, August, September, and October 2020 (Figure 1). Although timestamp information is only captured in UTC, there appears to be a consistent, weekly pattern of usage such that the app is used more during the week than on weekends. The number of monthly active users followed a similar pattern as daily active users. The number of monthly active users peaked in May but remained steady through October 2020, at approximately 11,000 unique app users per month.
Key Content Usage

Within the observation window (May 1, 2020, through October 31, 2020), there were 49,297 unique app users and 462,651 app events associated with the four key content areas (Manage Stress, Learn, Mood Check, and Find Resources). Table 1 provides an overview.

Of the four key sections of the app, the Manage Stress section, which contains tools for coping with stress and anxiety, was the most utilized. Across the observation window, there were 325,691 total tool use events (70.4% of all key events), among 28,009 unique install codes (56.82% of all unique install codes).

Table 1. Overall key content usage among all COVID Coach users within the observation window (between May 1, 2020, and October 31, 2020).

<table>
<thead>
<tr>
<th>Key content area (specific in-app action)</th>
<th>Unique app users, n (%)a</th>
<th>Key events, n (%)b</th>
<th>Totals per app user, mean (SD); range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manage Stress (tried at least one tool)</td>
<td>28,009 (56.8)</td>
<td>325,691 (70.4)</td>
<td>11.63 (30.33); 1-2124</td>
</tr>
<tr>
<td>Learn (viewed at least one topic)</td>
<td>10,124 (20.5)</td>
<td>52,123 (11.3)</td>
<td>5.15 (8.09); 1-267</td>
</tr>
<tr>
<td>Mood Check (entered and rated at least one goal or completed at least one assessment)</td>
<td>13,510 (27.4)</td>
<td>47,821 (10.3)</td>
<td>3.54 (12.52); 1-1008</td>
</tr>
<tr>
<td>Find Resources (viewed at least one specific subsection)</td>
<td>9418 (19.1)</td>
<td>37,016 (8.0)</td>
<td>3.93 (7.82); 1-329</td>
</tr>
</tbody>
</table>

aTotal number of unique app users during the observation window=49,297. Percentage of total app users. Percentages in this column will not sum to 100% because app users could have completed actions across the four types of key content areas.
bTotal key app events during the observation window=462,651. Percentage of total key app events.

Within the Manage Stress section, app users can directly select individual tools from a list of all tools, or they can have a tool recommended to them by selecting from one of seven possible challenges related to the pandemic: (1) coping with stress, (2) feeling lonely, (3) creating space for myself, (4) feeling sad or hopeless, (5) handling anger and irritability, (6) navigating relationships, and (7) sleep struggles. Across all app users, 48.5% (n=23,885) selected at least one challenge. Among this group of app users, challenges related to coping with stress were the most commonly selected (n=12,696, 53.2%), followed by sleep struggles (n=9308, 39.0%) and feeling lonely (n=9153, 38.3%).

Overall, the psychoeducation content within the Learn section of the app was consumed less frequently and by fewer users than the Manage Stress tools. Within the observation sample, there were 52,123 unique learn topic views (11.3% of all key events), among 20.5% of all app users (10,124/49,297). Four out of the five most viewed topics appeared in the first subsection within Learn (Staying Well).

In total, core activities within the Mood Check section comprised 10.3% (47,821/462,651) of all key events. Across the observation window, 27.4% of all app users (13,510/49,297) submitted at least one goal success rating or completed at least one of the four available assessments in the Mood Check section. There were 10,253 submitted goal success ratings across 2285 app users (4.6% of the total sample), and 37,568 completed assessments across 13,223 unique app users (26.8% of all users).

Across the eleven subsections within Find Resources, 19.1% (9418/49,297) of all app users viewed the resource pages 37,016 times across the observation window, representing 8% of all key events. Notably, although not the most frequently viewed subsection, Crisis Resources (which includes direct links to
phone lines, text support, and online chat for services such as the National Suicide Prevention Lifeline, Crisis Text Line, and Substance Abuse and Mental Health Services Administration’s Helpline) was visited 3297 times (8.9% of all Find Resources visits) among 2131 unique users. Table 2 presents detailed information about key events within each of the four key sections.

Table 2. Detailed key content usage among all COVID Coach users within the observation window (between May 1, 2020, and October 31, 2020).

<table>
<thead>
<tr>
<th>Key content area</th>
<th>Unique app users, n (%)a</th>
<th>Key app events, n (%)b</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manage Stress: top 5 most frequently used tools</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambient Sounds (an audio-only tool with no narration)</td>
<td>7041 (14.3)</td>
<td>18,493 (4.0)</td>
</tr>
<tr>
<td>Deep Breathing (an audio-guided exercise)</td>
<td>7870 (16.0)</td>
<td>16,011 (3.5)</td>
</tr>
<tr>
<td>Change Your Perspective (a tool with tips for how to replace negative thoughts with more helpful ones)</td>
<td>6721 (13.6)</td>
<td>12,480 (2.7)</td>
</tr>
<tr>
<td>Muscle Relaxation (an audio-guided exercise focused on relaxing distinct core body parts)</td>
<td>6037 (12.2)</td>
<td>11,599 (2.5)</td>
</tr>
<tr>
<td>Grounding (a tool with tips on how to stay connected to the present moment and surroundings)</td>
<td>5718 (11.6)</td>
<td>9767 (2.1)</td>
</tr>
<tr>
<td><strong>Learn: top 5 most frequently viewed topics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prioritizing Yourself, Right Now</td>
<td>2131 (4.3)</td>
<td>2811 (0.6)</td>
</tr>
<tr>
<td>Managing Irritability</td>
<td>1856 (3.8)</td>
<td>2281 (0.5)</td>
</tr>
<tr>
<td>Finding Humor</td>
<td>1506 (3.1)</td>
<td>1817 (0.4)</td>
</tr>
<tr>
<td>Finding Calm</td>
<td>1442 (2.9)</td>
<td>1813 (0.4)</td>
</tr>
<tr>
<td>Sleep</td>
<td>1184 (2.4)</td>
<td>1511 (0.3)</td>
</tr>
<tr>
<td><strong>Find Resources: top 3 most frequently viewed sections</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finding Local Resources (for locating state-specific COVID-19 guidelines and information)</td>
<td>2927 (5.9)</td>
<td>6451 (1.4)</td>
</tr>
<tr>
<td>Meeting Your Needs (for basic needs support)</td>
<td>3176 (6.4)</td>
<td>6223 (1.3)</td>
</tr>
<tr>
<td>Mobile Apps to Support Mental Health (information about other free apps to support mental health)</td>
<td>2461 (5.0)</td>
<td>3748 (0.8)</td>
</tr>
<tr>
<td><strong>Mood Check: completion of assessments, by type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Track Mood (PHQ-9)</td>
<td>7698 (15.6)</td>
<td>11,732 (2.5)</td>
</tr>
<tr>
<td>Track Anxiety (GAD-7)</td>
<td>8115 (16.5)</td>
<td>11,649 (2.5)</td>
</tr>
<tr>
<td>Track Well-Being (WEMWBS)</td>
<td>6151 (12.5)</td>
<td>8860 (1.9)</td>
</tr>
<tr>
<td>Track PTSD Symptoms (PCL-5)</td>
<td>3568 (7.2)</td>
<td>5327 (1.2)</td>
</tr>
</tbody>
</table>

aTotal number of unique app users during the observation window=49,297. Percentage of total app users.
bTotal key app events during the observation window=462,651. Percentage of total key app events.
cPHQ-9: Patient Health Questionnaire-9.
dGAD-7: Generalized Anxiety Disorder-7.
eWEMWBS: Warwick-Edinburgh Mental Well-Being Scale.
fPTSD: posttraumatic stress disorder.
gPCL-5: Posttraumatic Stress Disorder Checklist-5.

Return Usage and Retention

Among the 49,297 app user install codes present in the observation window, 86.8% (n=42,783) of COVID Coach users had their first day of app use occur within the observation window. Thus, for the analyses presented in this section, usage patterns will be restricted to only the app users and events associated with those whose first day of app use occurred during the observation window.

Nearly half of COVID Coach users used the app for a single day (n=20,793, 48.6%), and an additional 32.3% (n=13,818) used the app for 2 or 3 days in total. Less than 2% of the sample (n=709) used the app for 15 or more distinct days (Table 3). On average, across all app users with ≥2 distinct days of app use (n=21,990), the number of days retained was 42.44 (SD 44.40, median 25, range 1-179). On average, the number of days between the first day of app use and the second day of app use was 14.65 (SD 24.52, median 4, range 1-176). Although the majority of app users who returned to the app for at least a second day returned within 14 days, there was variability, including users whose second day of use occurred over 90 days after the first (see Table 4 for a detailed analysis among users.
whose first month of use occurred in May, June, or July so that returns within a 90-day or longer window could be examined).

### Table 3. Total number of distinct days of COVID Coach use, by month of first app use.

<table>
<thead>
<tr>
<th>Month of first app use</th>
<th>Frequency of users per distinct day, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 day only</td>
</tr>
<tr>
<td>May</td>
<td>6573 (42.67)</td>
</tr>
<tr>
<td>June</td>
<td>2533 (44.26)</td>
</tr>
<tr>
<td>July</td>
<td>2939 (48.79)</td>
</tr>
<tr>
<td>August</td>
<td>3165 (51.31)</td>
</tr>
<tr>
<td>September</td>
<td>2783 (53.66)</td>
</tr>
<tr>
<td>October</td>
<td>2800 (65.25)</td>
</tr>
<tr>
<td>All</td>
<td>20,793 (48.6)</td>
</tr>
</tbody>
</table>

### Table 4. Analysis of days between first and second app use among COVID Coach users with at least 2 distinct days of app use, by month of first use.

<table>
<thead>
<tr>
<th>First return after more than 90 days, n (%)</th>
<th>First return within 61-90 days, n (%)</th>
<th>First return within 31-60 days, n (%)</th>
<th>First return within 15-30 days, n (%)</th>
<th>First return within 8-14 days, n (%)</th>
<th>First return within 7 days, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>May</td>
<td>436 (4.94)</td>
<td>391 (4.43)</td>
<td>870 (9.85)</td>
<td>1107 (12.54)</td>
<td>391 (4.43)</td>
</tr>
<tr>
<td>June</td>
<td>50 (1.62)</td>
<td>130 (4.21)</td>
<td>298 (9.38)</td>
<td>457 (14.38)</td>
<td>118 (3.71)</td>
</tr>
<tr>
<td>July</td>
<td>709 (1.66)</td>
<td>2345 (5.48)</td>
<td>5118 (11.96)</td>
<td>4726 (11.05)</td>
<td>3177 (9.38)</td>
</tr>
</tbody>
</table>

### Differential Day 2 Return Rates Based on Day 1 Key Content Usage

On both the first and second days of app use (see Table 5 for an overview of usage), many app users tried at least one tool within the Manage Stress section (46.80% [n=20,222] on the first day, 41.85% [n=9202] among individuals who returned to the app for a second day). Usage of the key content in COVID Coach predicted returning to the app for a second day.

Of those who tried at least one Manage Stress tool on their first day of app use, 57.2% (n=11,444) returned for a second visit; whereas only 46.3% (n=10,546) of those who did not try a tool returned (P<.001). Among those who viewed at least one Learn topic on their first day of app use, 58.8% (n=3292) returned for a second day of use; whereas only 50.3% (n=18,698) who did not view a learn topic returned (P<.001). With respect to the Mood Check section, 57.2% (n=4892) of app users that completed at least one goal rating or one assessment activity returned for a second day of use, compared to 50.0% (n=17,098) of users who did not complete any Mood Check activities (P<.001). Lastly, among app users who viewed at least one specific Find Resources subsection, 57.4% (n=3014) returned for a second day of app use, compared to only 50.6% (n=18,976) of users who did not view any resources returned (P<.001).

Additionally, usage patterns among individuals who completed an assessment on the first day of app use were significantly different than those who did not complete an assessment on their first day. On average, individuals who completed at least one assessment on their first day of app use utilized COVID Coach for more unique days within the observation window (mean 3.29 days, SD 5.44) compared to individuals who did not complete an assessment on the first day (mean 2.66 days, SD 4.37; P<.001). Similarly, individuals who completed at least one assessment on their first day of app use utilized, on average, significantly more Manage Stress tools within the observation window (mean 9.2 tools, SD 24.6) compared to individuals who did not complete an assessment on the first day (mean 5.8 tools, SD 19.3; P<.001).
Table 5. Comparison of key content area usage, by first and second day of app use.

<table>
<thead>
<tr>
<th>Number of key content areas accessed</th>
<th>App users</th>
<th>First day of app use (n=42,783), n (%)</th>
<th>Second day of app use (n=21,990), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All four key areas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed at least one action within all four key content areas</td>
<td>650 (1.5)</td>
<td>192 (0.9)</td>
<td></td>
</tr>
<tr>
<td>Two to three key areas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage Stress (with one or two other key areas; tried at least one tool and completed another action within one or two other key areas)</td>
<td>7953 (18.6)</td>
<td>3143 (14.3)</td>
<td></td>
</tr>
<tr>
<td>Two or three key areas (excluding Manage Stress; completed at least one action within two or more of the Learn, Mood Check, or Find Resources sections)</td>
<td>1129 (2.6)</td>
<td>405 (1.8)</td>
<td></td>
</tr>
<tr>
<td>One key area</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manage Stress only (only tried at least one tool)</td>
<td>11,419 (26.7)</td>
<td>5867 (26.7)</td>
<td></td>
</tr>
<tr>
<td>Mood Check only (only completed at least one goal rating or assessment)</td>
<td>2677 (6.3)</td>
<td>1355 (6.2)</td>
<td></td>
</tr>
<tr>
<td>Find Resources only (only viewed at least one resource subsection)</td>
<td>1196 (2.8)</td>
<td>660 (3.0)</td>
<td></td>
</tr>
<tr>
<td>Learn only (only viewed at least one learn topic)</td>
<td>805 (1.9)</td>
<td>485 (2.2)</td>
<td></td>
</tr>
<tr>
<td>No key area actions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not complete an action within any of the four key areas</td>
<td>16,954 (39.6)</td>
<td>9883 (44.9)</td>
<td></td>
</tr>
</tbody>
</table>

Characterizing Baseline Mental Health Among COVID Coach Users

Baseline well-being among individuals using COVID Coach appeared to be relatively low and decreased over time. Among app users who completed a WEMWBS assessment on their first day of app use (n=3558, 8.32% of all users whose first day of app use occurred during the observation window), average well-being scores, by month, were all less than 42, which has been used as a cut-off to identify low well-being [34]. These average baseline scores decreased over time, with app users who completed their first WEMWBS on their first day of app use in September 2020 (n=416; mean 38.7, SD 0.04) or October 2020 (n=341; mean 38.1, SD 9.50) demonstrating significantly lower average well-being scores than app users who completed their first WEMWBS on their first day of using the app in May 2020 (n=1361; mean 41.2, SD 9.65).

Symptoms of anxiety, depression, and PTSD were prevalent among app users. For all app users who completed a GAD-7 assessment on their first day of app use (n=4870; 11.4% of users), 12.8% (n=625) had scores suggesting minimal anxiety (total score=0-4), 32.1% (n=1565) endorsed mild levels of anxiety (total score=5-9), 25.2% (n=1225) indicated moderate levels of anxiety (total score=10-14), and 29.9% (n=1455) of scores fell into the severe symptom range (total score=15 or higher).

Unlike the GAD-7 and the PHQ-9, the PCL-5 does not have symptom severity categorizations. However, among app users who completed a PCL-5 on their first day of app use (n=2064, 4.8% of users), the majority of individuals who completed the assessment (n=1234, 59.8%) had a total score ≥33, which is consistent with significant PTSD symptoms.

Baseline Mental Health Characteristics and Return Usage

Baseline PTSD symptoms predicted returning to the app for a second day. Among individuals with a baseline PCL-5 score of 33 or greater, 62.5% returned to the app for a second day of use, compared to only 56.4% of individuals with scores below 33 (P=.006). Neither symptom severity for anxiety or depression nor levels of well-being were predictive of return usage.

We conducted regression analyses to examine the relationship between baseline mental health symptoms and unique days of app usage. Depression and PTSD symptoms were predictive of the total number of unique days of app use. With respect to depression symptoms, we utilized the group with minimal symptoms as the reference group in comparison to those with mild, moderate, moderately severe, and severe symptoms. On average, those with moderate levels of depression on their first day of app use returned to the app for a greater number of days (mean 3.72 days) than those with minimal symptoms of depression (mean 3.08 days; t1=3.01, P=.003). Individuals with mild, moderately severe, and severe depression did not significantly differ from the reference group. Although the
difference in usage between moderately severe and minimal symptom severity categories was not statistically significant, it was trending in the predicted direction. With respect to PTSD symptoms, individuals with baseline PCL-5 scores indicating significant PTSD symptoms utilized the app for a significantly greater number of days (mean 3.79 days) than those with subthreshold symptom levels (mean 3.13 days; \(t_1=2.29, P=.02\)).

**Discussion**

**Principal Findings**

This exploration of COVID Coach usage among the general population suggests that mobile apps may have the reach and accessibility necessary to be a useful medium for disseminating mental health information and resources to individuals experiencing stress related to the COVID-19 pandemic.

Between May 1, 2020, and October 31, 2020, the app was used by nearly 50,000 individuals, and daily active usage has remained steady over time. In addition to the total number of individuals reached, the key content within the app was utilized in over 450,000 instances. The stress management tools were most frequently used with over 28,000 users utilizing individual tools over 300,000 times. Further, each of the other three key content areas in the app were accessed tens of thousands of times by tens of thousands of users. This reach and scalability of COVID Coach across the general population is an example of how digital mental health tools can become successfully integrated into disaster response strategies. From a public mental health perspective (eg, [43]), being able to rapidly deploy evidence-informed tools and reliable health information via a free, accessible, and secure app is a way for the federal government to contribute to a digital mental health safety net and reduce barriers to accessing mental health resources.

Importantly, COVID Coach appears to be reaching individuals in need of mental health resources. On average, among app users who completed assessments during their first day of use, well-being was low, and the majority of individuals were indicating greater than minimal symptoms of anxiety, depression, and PTSD. Additionally, among app users who identified challenges they are facing, the majority reported difficulties with managing stress, troubles with sleep, and feelings of loneliness. We cannot determine if individuals utilizing COVID Coach are representative of the general population, but elevated levels of anxiety, depression, and posttraumatic stress are consistent with other research conducted during the pandemic [6,7,44]. Individuals with significant PTSD symptoms at baseline were more likely to return to the app for a second day of app use. On average, individuals with significant PTSD symptoms used the app for a greater number of days than those with subthreshold symptoms, and individuals with moderate depression used the app for more days than those with minimal symptoms. Greater usage among individuals with moderate depression symptoms is consistent with previous research [45].

Although overall app utilization data suggested considerable reach, engagement proved to be less consistent. Our analyses revealed that the majority of COVID Coach users (80.9%) utilized the app on \(\leq 3\) days. This finding is consistent with research indicating that self-management apps for mental health are often not used over extended periods of time [26,27,46]. However, as noted by Ng and colleagues [47], there is a need for more standardized reporting of measures related to user engagement and retention. The average number of retention days, as well as the number of days between days of use, suggest that the app may not be something that individuals use on a daily basis, but rather during moments of distress or need. This type of usage is consistent with the overall design of COVID Coach as a self-management tool, which does not provide any guidance on how often or when to use the app.

This research also provides some guidance on how engagement might be encouraged in future app versions. In general, app users that completed actions within the key content areas on the first day of app use were more likely to return for a second day of app use. More specifically, users that completed an assessment on the first day of app use were significantly more likely to use the app for a greater number of days and to use a greater number of stress management tools than app users who did not complete an assessment on the first day of app use. These findings suggest that finding ways to motivate users to complete actions within key areas on their first day of app use, particularly tools and assessments, may be one way to enhance engagement and retention. For example, having recommendations for a tool or assessment to try, easily accessible from the app home screen, may encourage users to try a specific in-app activity. Additionally, the onboarding sequence could include a few brief questions to help tailor in-app recommendations to the user’s intentions and preferences, and guide them through the process of setting customized goals for using the features within the app most relevant to them. Lastly, finding ways to regularly disseminate and highlight new app content (eg, managing stress around prolonged distance learning, vaccine information) may encourage users to return to the app more frequently.

**Limitations**

Because COVID Coach does not collect any identifying information, we cannot say anything about the populations that we have reached, other than what we can characterize based upon in-app actions. Future research that permits collection of identifying information is needed, particularly given the disproportionate impact the pandemic has had on vulnerable groups of people. A Spanish version of COVID Coach has recently been released, and plans for data collection on app usage within Spanish-speaking populations are underway.

Additionally, we utilize the unique install codes as a proxy for an individual user. We assume that most individuals do not delete and reinstall the app multiple times. However, if an individual were to download COVID Coach on more than one mobile device, or delete it and reinstall, each of those installations would be assigned a unique install code, and would appear as a new user.

Although the app includes assessments for individuals to self-monitor well-being and symptoms of anxiety, depression, and PTSD, it is difficult to reliably measure change in these constructs via the app, due to the naturalistic nature of this study.
and the changing landscape of the pandemic over time. It is important to highlight that even though a score of 33 or higher on the PCL-5 is suggestive of PTSD, the assessment questions in the app do not ask app users to respond to the questions while focusing on a particular traumatic incident, so caution in interpreting the meaning of these scores is warranted. Because the PCL-5 refers to “the stressful experience” in each item, in the context of COVID Coach, the PCL-5 may be capturing overall levels of distress. While desirable, we also did not have a way to measure other potential proxy variables of interest such as coping self-efficacy, perceived helpfulness of the app, improved opinions about mental health care, or reduction in stress related to enhanced support access, as these cannot be determined solely by in-app usage data.

Future research is needed to better understand who is interested in public mental health apps like COVID Coach, what their primary goals are for using the app, which outcomes are most useful in understanding engagement patterns, and how successful usage is defined. For example, someone may use the app only once, find the exact resource they need, and not use the app again, whereas someone else may be experiencing significant stress, use tools in moments of distress, and track mental health symptoms on a weekly basis. Findings from this type of research could be used to advance the science of mobile mental health and also be directly applied to a suite of publicly available apps that have been downloaded over 4 million times and are in widespread use across the VA, the largest health care organization in the United States.

Conclusions
As the mental health impacts of the pandemic continue to be widespread and increasing, digital health resources, such as apps like COVID Coach, are a scalable way to provide evidence-informed tools and resources. We believe that this is the first evaluation of a mobile mental health app designed specifically for use during the COVID-19 pandemic. This work shows that tens of thousands of people are accessing the app, with a particular focus on the tools for stress and coping. Such rapid uptake of a public mobile mental health app is unprecedented and signals perceived value. Specially, the findings from this evaluation suggest that apps may play a helpful role in providing mental health resources in the context of a public health disaster.

Future research should attempt to elucidate for whom and under what conditions the app is most helpful, and how to increase and sustain engagement. Additional areas of focus should include how to optimize the app for populations impacted by disparities related to mental health literacy, digital literacy, and stigma around mental health care. As noted by many mHealth (mobile health) scholars [48-50], there is no reason to believe that digital mental health care and blended options will disappear after the pandemic, so it is important to find strategies for increasing reach and optimizing for engagement within self-management tools. These strategies must also attend to issues of health inequities [48,49,51]. Due to the scale of the crisis, the pandemic may have opened the door to conversations about mental health, and apps may be a helpful first step in providing tools, accurate information, and connecting people with reliable resources. Those in government and nonprofit organizations may be able to provide these kinds of tools as a way to contribute to a digital mental health safety net and help alleviate mental health disparities.

Acknowledgments
This paper was not sponsored by any funder. The views expressed in this work are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

Authors’ Contributions
All authors contributed to the conceptualization, writing, and editing of the paper.

Conflicts of Interest
None declared.

Multimedia Appendix 1
COVID Coach screenshots.
[PDF File (Adobe PDF File), 2624 KB - jmir_v23i3e26559_app1.pdf ]

References


Abbreviations

ANOVA: analysis of variance
BIPOC: Black, Indigenous, people of color
GAD-7: Generalized Anxiety Disorder-7
JSON: JavaScript Object Notation
mHealth: mobile health
PCL-5: Posttraumatic Stress Disorder Checklist-5
PHQ-9: Patient Health Questionnaire-9
PTSD: posttraumatic stress disorder
UTC: Coordinated Universal Time
VA: Veterans Affairs
WEMWBS: Warwick-Edinburgh Mental Well-Being Scale

©Beth K Jaworski, Katherine Taylor, Kelly M Ramsey, Adrienne Heinz, Sarah Steinmetz, Ian Pagano, Giovanni Moraja, Jason E Owen. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 01.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Barriers to the Large-Scale Adoption of a COVID-19 Contact Tracing App in Germany: Survey Study

Annelies G Blom¹²*, PhD; Alexander Wenz¹²*, PhD; Carina Cornesse¹, PhD; Tobias Rettig¹, MA; Marina Fikel¹, MA; Sabine Friedel¹, MA; Katja Möhring¹², PhD; Elias Naumann¹, PhD; Maximiliane Reifenscheid¹, MA; Ulrich Krieger¹, PhD

¹Collaborative Research Center 884 “Political Economy of Reforms”, University of Mannheim, Mannheim, Germany
²School of Social Sciences, University of Mannheim, Mannheim, Germany
*these authors contributed equally

Corresponding Author:
Alexander Wenz, PhD
School of Social Sciences
University of Mannheim
A5, 6
Mannheim, 68131
Germany
Phone: 49 621 181 2298
Email: a.wenz@uni-mannheim.de

Abstract

Background: During the COVID-19 pandemic, one way to reduce further transmissions of SARS-CoV-2 is the widespread use of contact tracing apps. Such apps keep track of proximity contacts and warn contacts of persons who tested positive for an infection.

Objective: In this study, we analyzed potential barriers to the large-scale adoption of the official contact tracing app that was introduced in Germany on June 16, 2020.

Methods: Survey data were collected from 3276 adults during the week the app was introduced using an offline-recruited, probability-based online panel of the general adult population in Germany.

Results: We estimate that 81% of the population aged 18 to 77 years possess the devices and ability to install the official app and that 35% are also willing to install and use it. Potential spreaders show high access to devices required to install the app (92%) and high ability to install the app (91%) but low willingness (31%) to correctly adopt the app, whereas for vulnerable groups, the main barrier is access (62%).

Conclusions: The findings suggest a pessimistic view on the effectiveness of app-based contact tracing to contain the COVID-19 pandemic. We recommend targeting information campaigns at groups with a high potential to spread the virus but who are unwilling to install and correctly use the app, in particular men and those aged between 30 and 59 years. In addition, vulnerable groups, in particular older individuals and those in lower-income households, may be provided with equipment and support to overcome their barriers to app adoption.

(J Med Internet Res 2021;23(3):e23362) doi:10.2196/23362

KEYWORDS
digital health; mobile health; smartphone; mobile phone; app; digital technology; contact tracing; coronavirus; COVID-19; survey

Introduction

Since the outbreak of COVID-19, millions of people worldwide have been infected with SARS-CoV-2 [1]. In the absence of an effective vaccine or cure, societies across the globe are testing various combinations of measures to contain the spread of the virus [2]. Many countries have introduced lockdowns to reduce the number of new infections to a level that allows national health systems to treat all patients effectively despite the additional influx of seriously ill people [3].

While lockdowns have proven effective at reducing the spread of the virus, they have a major impact on the economy and
social life [4,5]. A less economically damaging measure is contact tracing, where persons who have been in close proximity of someone known to be infected are quarantined until they can be confirmed not infected (ie, tested negative) or, if confirmed infected (ie, tested positive), until they are not contagious anymore. In Germany, this task has been performed by officials in local public health departments, who through personal conversations with infected persons, have been collecting proximity contacts to inform them of their potential infection and to implement quarantines [6].

To grant some relief to this labor-intensive system and to account for regionally strewn sudden new outbreaks, scientists have been discussing app-based contact tracing as a supplementary measure [7]. Once installed on a smartphone, a contact tracing app warns users when they have been in close contact with an infected person and may advise them to go into quarantine and get tested for infection. Thus, if adopted widely, apps may allow for a more efficient tracing of infection chains.

On June 16, 2020, 141 days after the first diagnosis of COVID-19 in Germany [8], the federal government and the Robert Koch Institute (RKI) (ie, the German center for disease control and prevention) launched their official COVID-19 contact tracing app [9,10]. Simulations estimate that for the app to contain the epidemic, at least 56% of a country’s population needs to use the app and comply with the app’s recommendations [11], although lower uptake rates are also effective in reducing the number of infections [12]. This paper examines to what extent this goal is likely to be achieved in Germany by providing answers to the following research question: What proportions of the general population aged 18 to 77 years in Germany (1) have access to the devices required to install the official contact tracing app, (2) are able to install it, and (3) are willing to install the app, use it, and act according to its recommendations?

Our predictions show that the adoption rate of 56% needed to contain the epidemic will be missed by a considerable margin. However, contact tracing apps may still be effective if specific subgroups adopted them at a higher rate. In particular, if a high proportion of persons who are frequently in contact with persons outside their household (ie, potential spreaders) adopted the app, its spread may be significantly curbed. In a similar vein, if a high proportion of persons who are likely to get severely ill from the disease (ie, vulnerable groups) adopted the app, health workers may be able to treat them early on and, thus, decrease the impact of COVID-19. Therefore, we investigate adoption rates among these two population subgroups by asking the following research questions:

1. What proportions of potential spreaders (1) have access to the devices required to install the official contact tracing app, (2) are able to install it, and (3) are willing to install the app, use it, and act according to its recommendations?
2. What proportions of persons with high vulnerability to a serious infection (1) have access to the devices required to install the official contact tracing app, (2) are able to install it, and (3) are willing to install the app, use it, and act according to its recommendations?

The official COVID-19 contact tracing app in Germany, the Corona-Warn-App, can be downloaded from the Apple App Store or Google Play free of charge and installed on iPhones, with iOS version 13.5 or higher, and Android smartphones, with Android version 6.0 or higher [9,10]. The app can be installed by the same person on multiple devices. Once installed, the app detects other app users in proximity by exchanging encrypted ID numbers between devices using Bluetooth Low Energy technology. The ID numbers change constantly and are stored locally on the device, relying on a decentralized approach for data storage. The user’s geolocation is not tracked. The app automatically informs users when they have been in contact with someone confirmed infected with SARS-CoV-2 and provides behavioral recommendations, including domestic quarantine and tests for SARS-CoV-2. The identity of the person using the app remains anonymous. An app user with a positive test result can enter this result into the Corona-Warn-App. By doing so, all proximity contacts are automatically notified of their own potential infection. Users can deactivates and reactivate the COVID-19 exposure notifications at any time or can completely uninstall the app. Using the Corona-Warn-App is voluntary and meets the European Union General Data Protection Regulation [13,14].

There are several potential barriers that may prevent people from using an app [15,16]. An initial barrier is access to a smartphone capable of installing the desired app and access to the internet [17,18]. In the case of the Corona-Warn-App, persons additionally need a smartphone with an iOS or Android operating system [9,10]. Among smartphone users with compatible devices, a second barrier is their ability to carry out the tasks required to operate the app [19]. The Corona-Warn-App requires the user to have the ability to download and install the app and to handle Bluetooth [9,10]. A final potential barrier is a person’s willingness to use the contact tracing app. A key correlate of this barrier in Germany seems to be privacy concerns regarding the sharing of personal data and distrust in unfamiliar technology and processes running in the background [20,21].

The effectiveness of contact tracing apps not only hinges on access, ability, and willingness to use such an app, but also on how individuals use the app. People need to carry their smartphone with them throughout the day, regularly recharge the smartphone batteries, keep their smartphone turned on, and keep the contact tracing feature activated so that the app can detect proximity contacts at all times. For some activities, however, people usually do not take their phone with them; for example, while exercising. As a result, the contacts during these periods are not being tracked. In addition, app-based contact tracing is subject to technical limitations, such as Bluetooth-based measurement errors, which may cause errors in the contacts detected [22].

COVID-19 exposure apps have been developed in many countries [23-25]. The MIT Technology Review’s Covid Tracing Tracker currently lists 47 countries with available or soon-to-be available contact tracing apps [23], yet installation rates across countries are low. For example, there were only 22.4 million app downloads in Germany as of November 12, 2020, around 5 months after its introduction, compared to a
population of 83.2 million [10], even though an early Oxford-led study suggested high support for contact tracing apps of 74.8% across five countries: France, Germany, Italy, the United Kingdom, and the United States [26]. However, the Oxford study comes with a major caveat: the predictions were based on nonprobability online samples, which are known to be self-selective and severely overrepresent technologically interested persons; thus, they do not accurately represent likely behaviors in those countries’ populations [27]. The selective nature of the data may, therefore, explain the discrepancy between the high support for the apps in the Oxford study and observed installation rates.

Methods

Data
To allow for timely and accurate population predictions of the adoption of the Corona-Warn-App, we based our analyses on data collected close to the launch of the app and on a probability sample of the general population aged 18 to 77 years. In this section, we describe key aspects of our data collection according to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [28].

The data were collected in the Mannheim Corona Study (MCS) [29]. The MCS was implemented within the German Internet Panel (GIP), a long-standing, offline-recruited, probability-based online panel of the general adult population in Germany. GIP sample members were recruited in 2012, 2014, and 2018. The 2012 and 2014 recruitments were based on area probability samples with full address listings and face-to-face recruitment interviews [30]. Persons in households without internet and/or computer access were provided with user-friendly devices, internet connections, and/or information technology support to enable their participation in the panel [31]. The 2018 recruitment was based on a probability sample drawn from municipal population registers and initial postal invitations. Sample members were informed about the scope of the study, the investigator, as well as how their data would be stored, and they consented to their participation and data storage.

A subsample of the GIP was invited to participate in the MCS that was conducted for 16 weeks from March 20 to July 10, 2020. The MCS was fielded with a rotating daily panel design. Each week the same MCS sample members were invited via email to participate in the study on the same day of the week and were re-interviewed on a variety of social, psychological, and economic topics [29]. They were sent a personalized link to the survey or were able to log in to the study website using their username and password to access the survey. Upon survey completion, respondents received an incentive of €2 (US $2.40).

Our study on the Corona-Warn-App, which was launched on June 16, 2020, was implemented within the MCS in week 13 (ie, June 12 to 19, 2020). The questionnaire from that week contained 44 pages, with one item per page. Respondents were able to change their answers using a back button on most pages. Prior to fielding the study, the usability and technical functionality of the questionnaire was tested. A total of 5427 persons, aged 18 to 77 years, were invited to participate in our study, of which 3276 responded (60.4%). To correct for a potential overrepresentation of persons with higher digital affinity [32], all predictions were weighted with a two-stage weighting procedure. Our weighting accounted for potential coverage, sampling, and nonresponse biases of the online data collection [33,34]. At the first stage, we estimated a response propensity weight, which projected the characteristics of the MCS respondents to the GIP recruitment samples. The weighting characteristics for the 2012 and 2014 samples included computer and internet access within the household; weighting characteristics for the 2018 sample included frequency of internet use, intensity of internet use, computer use, smartphone use, tablet use, and importance of up-to-date technology. At the second stage, we estimated a raking weight, which extrapolated the characteristics of the MCS respondents to the general population according to the Mikrozensus, that is, official statistics provided by the German Federal Statistical Office [35]. The weighting characteristics included age, gender, marital status, highest level of education, household size, and federal state. Missing values on the weighting variables were imputed with a chained-equations algorithm [36]. The final weight was trimmed for values greater than 4 and values less than 0.25. Despite the weighting procedure, our analyses were still likely to overestimate the app adoption rate in the general population, which we further address in the Discussion section.

Measures
Access, Ability, and Willingness
We measured adoption rates and potential barriers to adoption in sequential sets of survey questions and estimated (1) the population’s access to and use of compatible smartphones, (2) their ability to install and correctly use the app, and (3) their willingness to adopt the app and act according to its instructions.

Through three questions, we estimated people’s access: “Do you personally use a smartphone?”; if yes, “Which of the following types best describes your smartphone?” and “How often do you carry your smartphone with you when you leave the house?” (see Multimedia Appendix 1). We defined persons as having access to the app if they own an iPhone or Android phone and carry it with them at least most of the time when they leave the house. We did not differentiate between operating system versions and were, thus, likely to overestimate access to the app. However, research about the distribution of operating system versions installed on smartphones in Germany suggests that the large majority of Android smartphones and iPhones have the version installed that is required for the Corona-Warn-App to work [37,38].

People’s ability to use the app was measured through four questions: “Do you know how to install an app, i.e. an additional program, on your smartphone?”; if no or not sure, “Do you know anyone who could help you with installing the Corona-Warn-App on your smartphone, e.g. family, friends, or neighbors?”; “Do you know how to activate Bluetooth on your smartphone?”; and if no or not sure, “Do you know anyone who could help you with the activation of Bluetooth on your smartphone, e.g. family, friends, or neighbors?” (see Multimedia Appendix 1). A limitation of the two questions about the potential help of family, friends, or neighbors is that they do not differentiate between the usual situation before the
COVID-19 lockdown measures came into effect and the present situation: while some individuals may generally know plenty of people who can assist them with technology-related issues, they may not be able to meet these people due to the lockdown measures. However, since infection rates fell in June 2020 and the lockdown measures were gradually lifted, this limitation likely ceased to affect adoption rates during the summer. We defined persons as able to use the app if they know how to install an app or have someone who can help them with it, and if they know how to activate Bluetooth on their smartphone or have someone who can help them with it. Since access is a necessary condition for being able to install the Corona-Warn-App on a smartphone, persons who were defined as not having access were also defined as not being able to use the app.

Finally, we measured people’s willingness to correctly use the app through four questions: “Would you install the official Corona-Warn-App on your smartphone when it is available?”; if at least probably not install, “Would you follow the request of the Corona-Warn-App and go into domestic quarantine as a precaution?”; “Would you comply with the request of the Corona-Warn-App and get tested for the virus?”; and “Would you enter the test result into the Corona-Warn-App if you were tested positive for the virus?” (see Multimedia Appendix 1).

We defined persons as willing to correctly use the app if they are probably or definitely willing to install the app, if they are probably or definitely willing to quarantine if requested, if they are probably or definitely willing to get tested if requested, and if they are probably or definitely willing to enter their own test result into the app if they were tested positive. Since access and ability are necessary conditions for being willing to install the Corona-Warn-App on their smartphone, persons who were defined as not having access or not being able to use the app were also defined as not being willing to correctly use the app.

### Potential to Spread SARS-CoV-2 and Potential to Be at Risk of COVID-19

Two variables from the MCS and GIP data collection classified persons according to their potential for spreading the virus: number of social contacts within the past 7 days and employment situation, both collected from the MCS in week 13 (see Multimedia Appendix 1). The resulting variable has the following categories:

1. Met socially with other persons several times in the past 7 days and worked full time outside the home.
2. Met socially with other persons several times in the past 7 days but did not work full time or did not work outside the home.
3. Met socially with other persons once or less often in the past 7 days but worked full time outside the home.
4. Met socially with other persons once or less often in the past 7 days and did not work full time or did not work outside the home.

In addition, two variables from the MCS and GIP data collection classified persons according to their potential for being vulnerable to a serious infection: being aged 60 to 77 years, collected from the GIP, and having any health condition that, according to the RKI, may be correlated with an increased risk, collected from the MCS in week 13 (see Multimedia Appendix 1). The resulting variable has the following categories:

1. Aged 60 to 77 years and with at-risk health conditions.
2. Aged 60 to 77 years but without at-risk health conditions.
3. Aged 18 to 59 years but with at-risk health conditions.
4. Aged 18 to 59 years and without at-risk health conditions.

Although participants were not required to respond to all questions in the MCS survey, the amount of missing data was low for frequency of social contacts (8 missing values), work outside home (1 missing value), and health condition (5 missing values).

### Analytical Strategy

First, we reported overall rates of Corona-Warn-App adoption, distinguishing the three levels of potential barriers: access, ability, and willingness. Subsequently, we estimated separate adoption rates by the potential to spread SARS-CoV-2 and the potential to be vulnerable to COVID-19. All estimations were weighted as described above to enable reliable population predictions. Adoption rates across subgroups were reported by means of the predicted probabilities of a logistic regression, not including any covariates. Using the margins command in Stata 16.0 (StataCorp LLC), predicted probabilities were computed to conduct chi-square tests of differences in adoption rates across subgroups. Finally, we examined whether the introduction of the Corona-Warn-App during our data collection period influenced people’s willingness to install and use the app. For this purpose, we estimated a logistic regression for willingness on a dummy variable identifying whether our data were collected before or after the publication of the Corona-Warn-App, controlling for key sociodemographic characteristics (see Multimedia Appendix 1).

### Results

For the overall rate of adoption of the Corona-Warn-App, we estimated that 37.9% of the population in Germany aged 18 to 77 years have access to, are able to, and are willing to install the app (see Figure 1 and Multimedia Appendix 2). Asked whether they would be willing to go into domestic quarantine and get tested when requested to do so by the app, these rates reduce to 34.9% and 37.3%, respectively. If tested positive, 37.6% of the population aged 18 to 77 years would be willing to enter the test result into the app.

Whereas a lack of willingness is the foremost barrier to app adoption, access also plays a considerable role. Only 91.8% of the population aged 18 to 77 years uses a smartphone, 88.5% uses one with a compatible operating system, and 85.0% carries it with them most or all of the time outside the house. An inability to install apps and handle Bluetooth further reduces potential adoption rates to 81.3% and 81.8%, respectively.

Next, we examined whether higher adoption rates were achieved among the relevant subgroups of potential spreaders (see Figure 2 and Multimedia Appendix 3) and the potentially vulnerable (see Figure 3 and Multimedia Appendix 4).
**Figure 1.** Predicted adoption rates by access, ability, and willingness (N=3276). Error bars represent 95% CI.

**Figure 2.** Predicted adoption rates by potential to spread SARS-CoV-2 (access: N=3267; ability: N=3267; willingness: N=3266). Error bars represent 95% CI.
Persons with a high potential to spread the virus (ie, met socially several times last week and worked full time outside the home: 91.8%) are significantly more likely to have access than those with a medium potential to spread the virus (ie, met socially several times last week and did not work full time outside the home: 83.0%; and met socially once or less often last week and worked full time outside the home: 85.9%). Persons with a medium potential to spread the virus are, in turn, significantly more likely to have access than persons with a low potential to spread the virus (ie, met socially once or less often last week and did not work full time outside the home: 77.4%). The same pattern of significant group differences was found for ability (90.7% vs 81.9% and 84.4% vs 75.2%). However, in predicting the overall adoption rates (ie, access + ability + willingness), we did not find any significant group differences (ie, met socially several times last week and worked full time outside the home: 31.0%; met socially several times last week and did not work full time outside the home: 37.0%; met socially once or less last week and worked full time outside the home: 32.6%; and met socially once or less last week and did not work full time outside the home: 35.2%). In fact, the pattern does not deliver support for the hope that the contact tracing app may be more effective in the subgroup with a high potential to spread the virus, with similarly low overall adoption rates for those with a high potential to spread SARS-CoV-2 compared to those with a medium or low potential.

When examining the characteristics of those with a high potential to spread SARS-CoV-2 but unwilling to install and correctly use the Corona-Warn-App, we found that the large majority (68%) are between the ages of 30 and 59 years, with an additional 22% between 18 and 29 years and 10% between 60 and 77 years. Furthermore, most of these individuals are male (67%), with an intermediate (42%) or higher education (40%) as opposed to a lower education (18%). Only 10% feel personally threatened by COVID-19, while a majority (65%) think that the economic damage of the measures taken by governments to fight the pandemic is greater than their benefit for society. Interestingly, privacy concerns do not seem to be the driving factors that influence their decision to not adopt the app, since only 13% indicated they are very concerned about their privacy.

Regarding potential vulnerability, we observed an age effect on access and ability (see Figure 3 and Multimedia Appendix 4). The older age groups (ie, aged 60-77 years, with at-risk health conditions; and aged 60-77 years, without at-risk health conditions) are significantly less likely than younger age groups (ie, aged 18-59 years, with at-risk health conditions; and aged 18-59 years, without at-risk health conditions) to use a compatible smartphone (62.4% and 63.2% vs 87.1% and 91.8%) and to be able to install and use the app (60.6% and 59.7% vs 85.8% and 90.6%), with very large differences independent of at-risk health conditions. In predicting the overall adoption rates (ie, access + ability + willingness), we did not find any consistent significant differences across vulnerability groups (ie, aged 60-77 years, with at-risk health conditions: 35.9%; aged 60-77 years, without at-risk health conditions: 34.7%; aged 18-59 years, with at-risk health conditions: 41.3%; and aged 18-59 years, without at-risk health conditions: 30.6%).

Figure 3. Predicted adoption rates by potential vulnerability to COVID-19 (access: N=3270; ability: N=3270; willingness: N=3269). Error bars represent 95% CI.
When examining the characteristics of those with a high vulnerability to COVID-19 who do not have access and are unable to use the app, we found that the majority (43%) are older than 70 years, with an additional 28% between 60 and 64 years and 29% between 65 and 69 years. Most of these individuals are living in lower-income households, with a monthly net income between €0 (US $0) and €1999 (US $2414) (41%) or between €2000 (US $2415) and €2999 (US $3623) (39%), as opposed to those living in higher-income households (ie, between €3000 [US $3624] and €3999 [US $4830]: 11%; and €4000+ [US $4831+]: 10%).

Finally, when examining whether persons who were interviewed before the introduction of the Corona-Warn-App showed different adoption rates than persons interviewed after the app launch, we found no significant differences (see Multimedia Appendix 5).

Discussion

The official contact tracing app by the German federal government and the center for disease control and prevention, RKI, was introduced on June 16, 2020. The Corona-Warn-App was heavily advertised by government officials and health representatives as an effective way to contain the spread of SARS-CoV-2. According to epidemiological models, however, 56% of the population needs to adopt the app for it to contain the epidemic [11].

Our study shows that the 56% target mark will likely be missed by a considerable margin. For the population aged 18 to 77 years, our estimations predict an overall adoption rate of 34.7%. The largest barrier is people’s willingness to install and correctly use the app; however, access to a compatible smartphone and the ability to install the app also play roles. Given the age groups covered in our study, we consider this an optimistic estimate. For cohorts aged 78 years and over and children, the adoption rates are likely considerably lower.

Persons with the highest potential to spread the virus (ie, with frequent social and work contacts) are more likely to have access and the ability to use the app (90.7%) than the average in the population aged 18 to 77 years (81.0%). Overall, persons with a high potential to spread the virus are no more likely to adopt the app than persons with fewer social and work interactions.

Persons at risk to fall seriously ill or die from an infection (ie, those aged 60 to 77 years with at-risk health conditions) have significantly reduced access and ability to use the app (60.6%) compared to the average in the population aged 18 to 77 years (81.0%). Those who can use the app, however, are overwhelmingly willing to do so. As a consequence, persons with high vulnerability to COVID-19 are equally likely to adopt the app as are less vulnerable groups.

Overall, the findings imply a pessimistic view on the effectiveness of app-based contact tracing to contain the COVID-19 pandemic in Germany, with low adoption rates in the general population and issues of selectivity across subgroups as noted by Klingwort and Schnell [22]. In addition to low uptake in the general population, vulnerable groups who would benefit from an efficient contact tracing approach have limited smartphone coverage and limited ability to use the app. Furthermore, those with a high potential to spread SARS-CoV-2 who would have the necessary devices and abilities to install the app are predominantly unwilling to do so. Even though, as Hinch et al [11] pointed out, uptake rates of contact tracing apps lower than the 56% target may still contribute to a reduction in the number of infections, Germany will miss the 56% target by a huge margin and would do well investing in additional routes of tracing potentially infected individuals.

Our study was conducted during the week the Corona-Warn-App was introduced in Germany. This enabled us to implement a questionnaire that considers all technological and data privacy specifications of the actual app. The findings also allow us to formulate actionable policy recommendations. First, we recommend targeting information campaigns at groups with a high potential to spread the virus but who are unwilling to install and correctly use the Corona-Warn-App, in particular men and those aged between 30 and 59 years, to encourage them to adopt the app. Our second recommendation is to invest further resources to provide vulnerable groups of the population, in particular older individuals and those in lower-income households, with the necessary devices and assistance to overcome their specific barriers to app adoption.

This study is not free from limitations. First, the data were collected from an online panel. Although individuals without computer or internet access were provided with the necessary equipment and support, and weights were used in all analyses to correct for coverage and nonresponse biases, we cannot rule out that the data still overrepresent individuals with an interest in technology. When invited to the MCS, panel members had already completed online surveys over the course of at least 2 years. They are, thus, more likely to be interested in digital technologies, such as the Corona-Warn-App, than their counterparts who dropped out of the online panel.

Second, we can expect panel members who agreed to participate in the MCS and be interviewed every week on topics related to the COVID-19 pandemic to be more interested in contributing to a better understanding of the social impacts of the pandemic and possibly be more concerned than the average citizen. Such traits may also affect their willingness to install a contact tracing app.

Third, our analyses are limited to individuals aged between 18 and 77 years. We are, thus, missing sizable population groups: those aged 0 to 10 years make up 10% of the general population in Germany, those aged 11 to 17 years constitute 6%, and those aged 78 years or older make up 9% [39]. The youngest age group might be disregarded in an estimation of the effectiveness of the Corona-Warn-App since they predominantly move within small, defined social circles and are unlikely to carry smartphones with them at all times. The age group of 11 to 17 years is likely to have a high potential to spread SARS-CoV-2 but possibly low interest in adopting the Corona-Warn-App, whereas the oldest age group is highly vulnerable to COVID-19 and is also likely to have low app adoption rates because of limited smartphone access. As a result of all of these limitations, our predicted adoption rates are an optimistic view of the
situation. True values in the general population are likely to paint an even more pessimistic reality.

Fourth, our study is based on reported hypothetical behavior rather than actual behavior. Although hypothetical measures of willingness to install an app are subjective and may be subject to various response errors, such as social desirability or recall errors [40], these measures were shown to be correlated with actual behavior in previous studies [15,16,20,41]. In weeks 14 to 16 of the MCS, fielded between June 19 and July 10, 2020, we also collected data about whether people installed the Corona-Warn-App on their smartphone. The results suggest that the actual installation rate is very similar to the app adoption rate estimated in this paper: by July 10, 2020, almost 1 month after the app was introduced, 36% (95% CI 34%-38%) of the population between 18 and 77 years had installed the app, 55% (95% CI 53%-58%) had not installed the app, 1% (95% CI 1%-2%) had installed the app but had uninstalled it since then, and 7% (95% CI 6%-8%) did not use a smartphone. We also compared the responses about hypothetical and actual willingness to install the app among 2877 survey respondents who completed the questions both in week 13 and week 16 of the MCS survey, combining the categories app not installed; app installed, but uninstalled since then; and don’t use a smartphone. The results show a correlation of \( r=0.6 \) (\( P<.001 \)), which gives us confidence that the hypothetical measures used in this paper are rather accurate.

A potential avenue of future research would be to study whether the use of such a contact tracing app changes people’s behavior. After the installation, individuals’ behavior may become riskier (eg, less compliant toward social distancing measures), since the app may give them a feeling of security. If such a behavior is prevalent in the population, this may further reduce the effectiveness of app-based contact tracing.

Regarding data availability, the GIP data used in the analyses of this article are freely available as part of the GIP Scientific Use Files. They can be requested from the GESIS Data Archive for the Social Sciences (GESIS-DAS) [42]. The MCS data are envisioned to be published as Scientific Use Files by the end of 2021 at the latest. Until then, these data can be accessed at the Onsite Data Access facilities of the GIP Secure Data Center located at the Collaborative Research Center Political Economy of Reforms (SFB 884), University of Mannheim, B6 30-32, Mannheim, Germany. Researchers wishing to make use of the Onsite Data Access facilities may contact secretary@reforms.uni-mannheim.de. Researchers wishing to get access to the analysis code may contact the corresponding author.

Acknowledgments
We thank Elena Madiai, Lisa Wellinghoff, Katja Sonntag, and Sabrina Seidl for excellent research assistance. The GIP and the MCS are funded by the German Research Foundation (Deutsche Forschungsgemeinschaft, DFG) through the Collaborative Research Center Political Economy of Reforms (SFB 884; project ID: 139943784). The data collection for the MCS is also funded by the German Federal Ministry for Work and Social Affairs (BMAS; project ID: FIS.00.00185.20).

Authors' Contributions
AB was responsible for the study conceptualization and methodology, funding acquisition, study investigation, supervision, obtaining resources, writing the original draft, and reviewing and editing subsequent drafts. AW was responsible for the study conceptualization and methodology, data analysis, study investigation, data visualization, writing the original draft, and reviewing and editing subsequent drafts. CC was responsible for the study investigation and methodology. TR was responsible for data curation, study investigation, and project administration. MF was responsible for study investigation and project administration. SF was responsible for data curation and study investigation. KM, EN, and MR were responsible for study investigation. UK was responsible for study investigation and methodology as well as supervision.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Study questionnaire.

Multimedia Appendix 2
Predicted adoption rates of the COVID-19 contact tracing app in Germany by access, ability, and willingness.

Multimedia Appendix 3
Predicted adoption rates of the COVID-19 contact tracing app in Germany by potential to spread SARS-CoV-2.
Multimedia Appendix 4
Predicted adoption rates of the COVID-19 contact tracing app in Germany by potential vulnerability to COVID-19.

[PDF File (Adobe PDF File), 79 KB - jmir_v23i3e23362_app4.pdf ]

Multimedia Appendix 5
Results of a logistic regression of willingness to use the COVID-19 contact tracing app.

[PDF File (Adobe PDF File), 142 KB - jmir_v23i3e23362_app5.pdf ]

References


42. GN0109: German Internet Panel. GESIS Leibniz Institute for the Social Sciences. URL: https://dbk.gesis.org/dbksearch/GDesc2.asp?no=0109&tab=&kll=10&notabs=1&db=E [accessed 2021-02-18]

Abbreviations

- **CHERRIES**: Checklist for Reporting Results of Internet E-Surveys
- **GESIS-DAS**: GESIS Data Archive for the Social Sciences
- **GIP**: German Internet Panel
- **MCS**: Mannheim Corona Study
- **RKI**: Robert Koch Institute
Minimizing the Impact of the COVID-19 Epidemic on Oncology Clinical Trials: Retrospective Study of Beijing Cancer Hospital

Zhiying Fu1*, MPH; Min Jiang1*, M.Pharm; Kun Wang1, MD; Jian Li1, MD

Beijing Institute for Cancer Research, Beijing Cancer Hospital, Beijing, China
*these authors contributed equally

Corresponding Author:
Jian Li, MD
Beijing Institute for Cancer Research
Beijing Cancer Hospital
No 52 Fucheng Road
Haidian District
Beijing
China
Phone: 86 1088196949
Email: LIJIAN8409@126.com

Abstract

Background: In view of repeated COVID-19 outbreaks in most countries, clinical trials will continue to be conducted under outbreak prevention and control measures for the next few years. It is very significant to explore an optimal clinical trial management model during the outbreak period to provide reference and insight for other clinical trial centers worldwide.

Objective: The aim of this study was to explore the management strategies used to minimize the impact of the COVID-19 epidemic on oncology clinical trials.

Methods: We implemented a remote management model to maintain clinical trials conducted at Beijing Cancer Hospital, which realized remote project approval, remote initiation, remote visits, remote administration and remote monitoring to get through two COVID-19 outbreaks in the capital city from February to April and June to July 2020. The effectiveness of measures was evaluated as differences in rates of protocol compliance, participants lost to follow-up, participant withdrawal, disease progression, participant mortality, and detection of monitoring problems.

Results: During the late of the first outbreak, modifications were made in trial processing, participant management and quality control, which allowed the hospital to ensure the smooth conduct of 572 trials, with a protocol compliance rate of 85.24% for 3718 participants across both outbreaks. No COVID-19 infections were recorded among participants or trial staff, and no major procedural errors occurred between February and July 2020. These measures led to significantly higher rates of protocol compliance and significantly lower rates of loss to follow-up or withdrawal after the second outbreak than after the first, without affecting rates of disease progression or mortality. The hospital provided trial sponsors with a remote monitoring system in a timely manner, and 3820 trial issues were identified.

Conclusions: When public health emergencies occur, an optimal clinical trial model combining on-site and remote management could guarantee the health care and treatment needs of clinical trial participants, in which remote management plays a key role.

(J Med Internet Res 2021;23(3):e26799) doi:10.2196/26799

KEYWORDS
COVID-19; clinical trials; management strategy; information technology

Introduction

COVID-19 was recognized as a global pandemic on March 11, 2020 [1,2]. Efforts to stem the spread of SARS-CoV-2 led to isolation measures and travel restrictions that have severely hindered the smooth conduct of clinical trials [3]. Participants may no longer be able to visit the hospital to receive treatment [4], resulting in protocol deviations. The regular monitoring and auditing of trials may also be affected [5], leading trials to be postponed or terminated; this in turn can delay marketing of drugs and even lead to the scrapping of development plans for new drugs. Several studies from several countries have reported obvious decreases in the numbers of participants newly enrolled...
in trials, and many oncology clinical trials were suspended in April 2020 in several countries [6-8].

It seems likely that as COVID-19 outbreaks repeatedly occur in many countries, clinical trials will continue to be conducted under public health emergency conditions for some time to come. The conduct of oncology clinical trials will be particularly challenging, given that such trials usually require many follow-up visits and sophisticated monitoring of complex disease courses [9,10]. Therefore, insights into how to optimize oncology clinical trial management during public health emergencies are urgently needed.

This study examined the experiences of Beijing Cancer Hospital in its efforts to conduct anticancer drug trials through two COVID-19 outbreaks in 2020. During the first outbreak from February to April 2020, the hospital implemented a series of modifications in participant management and monitoring, including remote drug administration, remote visits, and remote trial monitoring. Relying on data processing and application platform (DPAP) technology, remote trial monitoring enables clinical research associates and inspectors to monitor trial data at any time and in any place, regardless of geographical and time constraints. At present, remote trial monitoring is rare in China and other countries. Here, we analyzed how the COVID-19 epidemic affected ongoing clinical trials and whether the hospital’s modifications to trial management during the epidemic helped ensure the smooth conduct of these trials through the second outbreak from June to July 2020. Our experiences may be relevant to other countries as they seek to ensure the functioning of clinical trials during the COVID-19 epidemic and other public health emergencies.

**Methods**

This study was approved by the Ethics Committee of Beijing Cancer Hospital, which waived the requirement for informed consent for the participants because those individuals had already provided written informed consent for their medical data to be analyzed and published in an anonymized format for medical research purposes.

**Study Assumption**

During public health emergencies, combining on-site and remote clinical trial management models could guarantee the health and treatment needs of clinical trial participants.

**Study Design**

During the COVID-19 epidemic, the ultimate goal of the management measures was to ensure the treatment of the participants and the implementation of the trials while avoiding the spread of the disease. In this case, remote management was the determinant of strategy effectiveness. Therefore, in addition to the COVID-19 infection rate of the participants, we selected the indicators that were important to the trials and the participants: protocol compliance rate, rate of loss to follow-up, rate of participant withdrawal, rates of disease progression and mortality, and detection rate of monitoring problems.

Clinical trials that were ongoing at the hospital from February 1, 2020, were eligible to be enrolled in the study. The following data were collected through July 31, 2020: numbers of outpatient and inpatient visits, numbers of enrolled participants, visits that were not performed according to protocol, participants who were not administered according to protocol, losses to follow-up, withdrawals, cases of disease progression, and deaths. These data allowed us to assess the clinical trials during the first COVID-19 outbreak from February to April 2020 and during the second outbreak from June to July 2020. The corresponding data during the periods from February to April 2019 and June to July 2019 were also collected. Data were extracted from the hospital information system (HIS) and clinical trial management system (CTMS). We also collected data regarding the use of the remote monitoring system from February 01, 2020, to July 31, 2020, including the frequency of use, number of trials checked, and number of participants checked.

**Statistical Methods**

To assess the impact of the COVID-19 epidemic on the conduct of clinical trials at our hospital, we compared the trial data from February to April 2020 and June to July 2020 with data from February to April 2019 and June to July 2019, respectively. To assess the effects of our hospital’s modifications to the clinical trials after the first COVID-19 outbreak, we compared the trial data obtained during February and July in 2020. All statistical analyses were performed using SPSS, version 22.0 (IBM Corporation). Categorical data were reported as frequencies or percentages, and differences were assessed for significance using the chi-square test.

**Results**

**Impact of the COVID-19 Outbreak on Clinical Trials at Beijing Cancer Hospital**

On July 31, 2020, 572 trials of investigational drugs were being conducted at Beijing Cancer Hospital. More than 50% of all trials (303/572, 53.0%) were affected by the COVID-19 outbreak, including 65 international trials and 238 domestic trials. Of the 303 affected trials, 91 were phase 1 trials, accounting for 55.3% (91160) of ongoing phase 1 trials. Only 28 new patients were enrolled each month through the two outbreaks, which was 6 times fewer than the monthly enrollment in 2019, and the numbers of various types of protocol deviations were higher than for the same period in 2019. The most frequent deviations were “dosing out of window” and “visit out of window.” Due to the outbreak, 42 participants withdrew from trials and 39 were lost to follow-up. The impact of the COVID-19 outbreak on the clinical trials at our hospital is summarized in Figure 1.
Figure 1. The impact of the COVID-19 outbreak on clinical trials at our hospital. (A) Distribution of product phases affected by the outbreak. (B) Protocol violations from February to April 2020 compared to February to April 2019. (C) Protocol violations from June to July 2020 compared to June to July 2019.

Modifications to Clinical Trial Management During the First COVID-19 Outbreak

Remote Trial Approval and Initiation

Starting in February 2020, the hospital implemented information-communication technology to reduce human interactions during clinical trials. The hospital connected its CTMS to an external network so that staff could conduct numerous trial-related activities on the web, including trial review, application for ethics approval, review of collaboration agreements to conduct trials, quality control, and other filings. Trial sponsors and contract research organizations were able to review trials using the same system. Software was also
Remote Trial Monitoring

A remote monitoring system, relying on DPAP technology, integrating various business systems of the hospital, such as the HIS, electronic medical record, laboratory information system, picture archiving and communication system, and radiology information system, was implemented to allow monitors to conduct virtual “site visits” under a virtual private network (VPN). Monitors could check all the medical treatment data of the participants in hospital as authorized and receive a panoramic data view of the participants under the dimensions of medical treatment, examination, medical records, and medical orders. Figure 2 shows the remote monitoring technology roadmap, and Figure 3 shows a screenshot of a panoramic view of a participant’s data in the remote monitoring system.

Remote Visits and Treatment of Participants

Trial participants who were able to return to hospital upon the resumption of trials were tested for SARS-CoV-2 infection based on nucleic acid detection. Hospitalized participants were examined for COVID-19 symptoms by chest computerized tomography. Beds were placed with sufficient distancing.

Trial participants who could not return to hospital were “visited remotely”: the principal investigator of the trial was located an
appropriate hospital that was relatively close to the participant’s residence. Priority was given to hospitals that were also participating in the trial, followed by hospitals that had been certified by the National Medical Products Administration to be following good clinical practice [11]. Trial investigators remotely reviewed examination results through email or fax, and they generated the corresponding medical records, which were stored on a cloud-based platform from July 2020.

Trial medications for oral use were sent to these participants if the trial investigator judged that the drug treatment could continue based on the participant’s examination results. Medications were sent by mail using the hospital’s standard operating procedures for mailing of investigational products during major public health emergencies. The participants sent back relevant data by mail.

**Figure 4.** Schedule of the panoramic view of a clinical trial participant’s visits and treatments according to modified clinical trial management procedures implemented from February 01, 2020.

Comparison of Clinical Trial Data Between the First and Second COVID-19 Outbreaks

During the first outbreak from February 1 to April 30, 2020, 18 new trials were remotely initiated, and 45 participants were newly enrolled. Moreover, during the second outbreak from June 1 to July 31, 2020, 56 new trials were remotely initiated and 103 participants were newly enrolled, which are nearly double the numbers of trials and enrollments in the first outbreak. By July 31, 572 trials for investigational drugs involving 3718 participants were ongoing at Beijing Cancer Hospital. Between February and July 2020, no infections were recorded among participants or trial staff, and no major procedural errors occurred.

Analysis of the numbers of visits by inpatients and outpatients to Beijing Cancer Hospital for participation in clinical trials showed that both types of visits decreased in February, coinciding with the first COVID-19 outbreak (Table 1). Thereafter, both types of visits continuously increased and had nearly returned to pre-epidemic levels by July (Figure 5).
Table 1. Data on participant visits within clinical trials during the two COVID-19 outbreaks in 2020.

<table>
<thead>
<tr>
<th>Category</th>
<th>Monthly average for the indicated period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First outbreak (February to April)</td>
</tr>
<tr>
<td></td>
<td>Second outbreak (June to July)</td>
</tr>
<tr>
<td>Return visits to hospital for outpatient examination or treatment</td>
<td>1212</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>509</td>
</tr>
<tr>
<td>Remote visits</td>
<td>340</td>
</tr>
<tr>
<td>Drug shipments to participants</td>
<td>281</td>
</tr>
<tr>
<td>Participants changed from intravenous to oral administration</td>
<td>10</td>
</tr>
<tr>
<td>Participants transferred to another hospital (times)</td>
<td>16</td>
</tr>
<tr>
<td>Internet-based diagnostic visits and treatments</td>
<td>0</td>
</tr>
<tr>
<td>Completed visit/medication (times)</td>
<td>2368</td>
</tr>
<tr>
<td>Total required visits/medication (times)</td>
<td>3097</td>
</tr>
</tbody>
</table>

Figure 5. Outpatient and inpatient status of clinical trials at Beijing Cancer Hospital during the COVID-19 epidemic, January 2020 to July 2020.

During the latter part of the first outbreak, 1941/9291 visits with participants (20.89%) were conducted remotely, oral medications were mailed directly to participants, or the participants were treated intravenously at carefully selected local hospitals. The protocol compliance rate was 76.46%. During the second outbreak (June to July), the protocol compliance rate was significantly higher at 90.85% (2879/3169, \( P < .001 \)) (Table 2). Loss to follow-up was significantly smaller during the second outbreak than during the first (7/3718, 0.19% vs 32/3570, 0.89%, \( P < .001 \)), as was participant withdrawal (6/3718, 0.16%, vs 36/3570, 1.00%, \( P < .001 \)). In contrast, the rates of disease progression and mortality did not differ statistically between the two outbreaks (Table 2). Thus, the clinical trials at our hospital remained stable across both COVID-19 outbreaks, and the rate of compliance for the entire period was 85.24% (16007/18778).

During the whole outbreak period, the infection rate of SARS-CoV-2 among personnel involved in clinical trials was 0, and the error rate in the clinical trials was 0.
Table 2. Clinical trial outcomes.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Value, n/total (%)</th>
<th>First outbreak</th>
<th>Second outbreak</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol compliance</td>
<td>2368/3097 (76.46)</td>
<td>2879/3169 (90.85)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Loss to follow-up</td>
<td>32/3570 (0.89)</td>
<td>7/3718 (0.19)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Withdrawals</td>
<td>36/3570 (1.00)</td>
<td>6/3718 (0.16)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Disease progression</td>
<td>88/3570 (2.34)</td>
<td>88/3718 (2.37)</td>
<td>.86</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>48/3570 (1.33)</td>
<td>68/3718 (1.83)</td>
<td>.08</td>
<td></td>
</tr>
</tbody>
</table>

Effects of the Measures on Trial Quality During the COVID-19 Epidemic

By July 31, 2020, 176 clinical research associates from 76 sponsors or clinical research organizations had used the remote monitoring system to monitor 1318 participants in 228 trials conducted in 16 departments of Beijing Cancer Hospital. The total number of log-ins to the system was 10,470, and the median number of monitoring visits was 23 (range 1-729). The total number of issues logged in the remote monitoring system was 3820, corresponding to an average of 16.75 per trial and 2.90 per participant. The most frequent findings were errors or omissions on case report forms (950/3820, 24.87% of all issues), lack of compliance with planned trial visits (849/3820, 22.23% of all issues), and lack of compliance with protocol administration (713/3820, 18.66% of all issues). The rate of findings with remote monitoring between original records, informed consent, adverse events, and investigational drugs in 2020 were significantly lower than the rate during the same period in 2019 ($P$<.001), but the two monitoring approaches were similar in terms of case report forms, concomitant medication, and biological samples ($P$>.05) (Table 3).

Table 3. Clinical trial–related events detected during on-site monitoring in 2019 and remote monitoring in 2020.$^a$

<table>
<thead>
<tr>
<th>Error or omission in a trial event</th>
<th>Value per capita, n (%)</th>
<th>Remote monitoring in 2020 (n=1318)$^b$</th>
<th>On-site monitoring in 2019 (n=1120)$^c$</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case report forms</td>
<td>950 (72.08)</td>
<td>805 (71.88)</td>
<td>.91</td>
<td></td>
</tr>
<tr>
<td>Visits not conducted per protocol</td>
<td>849 (64.42)</td>
<td>579 (51.69)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Drug not dosed per protocol</td>
<td>713 (54.10)</td>
<td>279 (24.91)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td>513 (38.92)</td>
<td>643 (57.41)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Concomitant medications</td>
<td>435 (33.00)</td>
<td>401 (35.80)</td>
<td>.15</td>
<td></td>
</tr>
<tr>
<td>Original record</td>
<td>154 (11.68)</td>
<td>874 (78.04)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Biological samples</td>
<td>146 (11.08)</td>
<td>159 (14.20)</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Other drug problems</td>
<td>33 (2.50)</td>
<td>119 (10.63)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Informed consent</td>
<td>27 (2.05)</td>
<td>119 (10.63)</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

$^a$Data were compared for the same trials for the period of February to July in 2019 or 2020.

$^b$Total errors/emissions=3820; 289.83% cumulative for all events.

$^c$Total errors/emissions=3978; 355.18% cumulative for all events.

Discussion

The COVID-19 outbreak is a major global public health emergency, and at its beginning, authorities were taken by surprise [12]. Our analysis of clinical trials at Beijing Cancer Hospital from the beginning of the COVID-19 epidemic showed that 53.0% of investigational drug trials were affected, particularly phase I clinical trials, which involve more extensive interventions. During the first outbreak (February to April 2020), the rate of “dosing out of window” was 6 times higher than the rate during the same period in 2019, while the rate of “visits out of window” was 3 times higher than in 2019. This is especially true of clinical trials of anticancer drugs, which usually require drug administration every 1-2 weeks, and most trials require regular sample collection and patient examinations. These protocol deviations could severely compromise the quality of the trial data as well as the safety and interests of participants [13].

While regulatory authorities in the United States, European Union, and China as well as other associations have guidelines for clinical trial conduct and management during the COVID-19 epidemic [14-17], implementing them in hospitals is not always straightforward. At Beijing Cancer Hospital, discussions were conducted among trial participants, trial investigators, members of the hospital’s Ethics Committee, and trial sponsors to develop modifications to the standard management of the clinical trials and participant visits to protect the health and safety of participants as well as the integrity of the trial. These discussions and the ensuing measures were documented in real time and...
archived at the hospital and in the records of the Ethics Committee.

Starting from the middle of the first COVID-19 outbreak, our hospital resumed clinical trials with a series of measures to reduce virus transmission: diagnostic visits and treatment were conducted by appointment only or via the internet; participants were visited remotely; drugs were mailed to participants, including replacement of intravenous treatments with oral treatments that could be mailed; and participants were sent to local hospitals, protecting them from infection during travel to the clinical trial center. To encourage participants to return to the hospital for treatment during the second outbreak, we subjected them to nucleic acid tests and provided beds with adequate separation. Only 50% of beds in each ward were available to patients. These measures may help to explain why more participants returned to the hospital during the second outbreak than during the first. All these measures led to higher protocol compliance rates during the second COVID-19 outbreak than during the first, as well as lower rates of loss to follow-up and withdrawal.

Internet diagnostics and treatment are a new direction in the medical industry, and our experience suggests that this approach can be effective for conducting clinical trials during public health emergencies. Quality control standards are needed to ensure high-quality treatment comparable to that with in-person medicine. To that end, China and other countries have issued regulations and policies to standardize internet diagnostics and treatment [18-20].

Just as internet-based approaches can bring trial clinicians and participants together safely, remote monitoring can allow trial auditors and sponsors to perform necessary reviews. Already in 2019, the US Food Drug and Administration had encouraged sponsors to use remote monitoring for early detection of problems in clinical trials [21], and several national and other agencies have since encouraged remote monitoring in response to the COVID-19 pandemic [14-17]. At Beijing Cancer Hospital, approximately 40% of clinical trials were remotely monitored from February to July 2020, and these activities identified 16.75 issues per trial. Our experience supports the expanding reliance on remote trial monitoring to safeguard patients and trial quality.

Clinical trials in China and abroad face challenges due to the COVID-19 pandemic [22]. Our experience supports the idea that appropriate software and network infrastructure can allow medical facilities to conduct clinical trials effectively [23-25], while properly archiving, managing, and sharing the large amount of data generated [26]. It may even be possible to bypass some aspects of participant follow-up by using smartphones or other wearable devices that can automatically transmit participant data [27]. Conducting a remote clinical trial depends on having a complete information management system, infrastructure for fast and safe delivery of medicines, and a safe, seamless system for managing and transferring trial data.

Remote trial management at Beijing Cancer Hospital can still be improved. For example, we were unable to use the remote informed mode due to technical limitations. Insufficient personnel and delays in data transmission during the epidemic in 2020 contributed to data errors or omissions on case report forms, which accounted for 24.87% of all issues. The system of remote monitoring and automatic collection of clinical trial data should be improved, particularly the extraction of data from paper records.

This study was necessarily retrospective, which increases the risk of selection and information bias. As the pandemic continues, it may be advisable to launch relevant prospective studies to assess the efficacy and efficiency of measures to ensure the smooth conduct of clinical trials during a public health emergency.

**Conclusion**

Clinical trials have been greatly impacted during the current public health emergency of the COVID-19 pandemic. By using information technology, Beijing Capital Hospital was able to ensure the smooth conduct of hundreds of oncology clinical trials. This success was due to a clinical trial management model combining on-site and remote trial approval, initiation, visits, administration, and monitoring. Our experience provides a reference for clinical trial management under the current pandemic and in future public health emergencies.

**Authors’ Contributions**

ZF and MJ performed data collection and analysis, reviewed the literature, and contributed to drafting the manuscript. KW coordinated and reviewed the manuscript. JL conceptualized and designed the study; supervised, coordinated, and were responsible for the integrity of the data and the accuracy of its analysis; critically reviewed the interpretation of the results; and assisted in the final preparation of the manuscript. All authors read the final manuscript and approved it.

**Conflicts of Interest**

None declared.

**References**


Abbreviations

CTMS: clinical trial management system
DPAP: data processing and application platform
HIS: hospital information system
VPN: virtual private network

©Zhiying Fu, Min Jiang, Kun Wang, Jian Li. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 02.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Adoption of COVID-19 Contact Tracing Apps: A Balance Between Privacy and Effectiveness

Emily Seto1,2,3, PhD, PEng; Priyanka Challa1, MHI; Patrick Ware2, MPH, PhD

1Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada
2Centre for Global eHealth Innovation, University Health Network, Toronto, ON, Canada
3Techna Institute, University Health Network, Toronto, ON, Canada

Corresponding Author:
Emily Seto, PhD, PEng
Institute of Health Policy, Management and Evaluation
Dalla Lana School of Public Health
University of Toronto
155 College Street, Suite 425
Toronto, ON, M5T 3M6
Canada
Phone: 1 416 669 9295
Email: emily.seto@utoronto.ca

Abstract

With the relative ubiquity of smartphones, contact tracing and exposure notification apps have been looked to as novel methods to help reduce the transmission of COVID-19. Many countries have created apps that lie across a spectrum from privacy-first approaches to those that have very few privacy measures. The level of privacy incorporated into an app is largely based on the societal norms and values of a particular country. Digital health technologies can be highly effective and preserve privacy at the same time, but in the case of contact tracing and exposure notification apps, there is a trade-off between increased privacy measures and the effectiveness of the app. In this article, examples from various countries are used to highlight how characteristics of contract tracing and exposure notification apps contribute to the perceived levels of privacy awarded to citizens and how this impacts an app’s effectiveness. We conclude that finding the right balance between privacy and effectiveness, while critical, is challenging because it is highly context-specific.

Introduction

Many countries around the world have released contact tracing and exposure notification apps in an attempt to help combat the spread of COVID-19 [1,2]. However, the technologies used, adoption rates, and potential impact of the apps have been extremely varied across countries. Moreover, each country has developed contact tracing apps that meet the level of privacy required for their citizens. Often, increased privacy has been deemed a fair trade-off for a decrease in the potential effectiveness of the app.

Privacy-Related Characteristics of COVID-19 Apps

Although privacy laws provide a foundation that can inform the design and implementation of exposure notification and true contact tracing apps [3], it is the types of technologies used (eg, quick response [QR] codes, GPS, Bluetooth Low Energy) and the way they are applied within those legal frameworks that determine the level of privacy afforded to citizens. The important distinction between contact tracing apps and exposure notification apps is that the former collects tracking data so that public health authorities can determine who individuals have been in contact with, as well as the location and time of the contact. On the other hand, exposure notification apps collect only the data required to determine if an individual may have transmitted the virus to others.
been in close contact with someone who has been identified as being positive for COVID-19, which provides significantly more privacy. Table 1 expands upon research by Liu and Guo [4], which was published in the initial months of the pandemic. Specifically, it presents privacy-related characteristics of COVID-19 apps in various countries. The examples have been selected to demonstrate a spectrum of privacy-related features in countries where information about their apps is publicly available, as well as to demonstrate that the optimal balance between privacy and effectiveness may be culturally dependent.

Table 1. Privacy characteristics of COVID-19 contact tracing and exposure notification apps.

<table>
<thead>
<tr>
<th>Country</th>
<th>App name (month of launch)</th>
<th>Voluntary or mandatory</th>
<th>Technology</th>
<th>App data bound by privacy laws</th>
<th>Consent for data sharing required</th>
<th>Centralized or decentralized data storage</th>
<th>Approximate adoption rate, % (month of reporting)</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>HealthCode (February 2020)</td>
<td>Voluntary (required to move around cities)</td>
<td>May use GPS or records of individual’s location</td>
<td>Yes</td>
<td>No</td>
<td>Information not found</td>
<td>~64 (April 2020)³ [8]</td>
</tr>
<tr>
<td>Canada</td>
<td>COVID Alert (July 2020)</td>
<td>Voluntary</td>
<td>Bluetooth</td>
<td>Yes</td>
<td>Yes</td>
<td>Decentralized</td>
<td>~15 (December 2020)³ [10]</td>
</tr>
<tr>
<td>Germany</td>
<td>Corona-Warn-App (June 2020)</td>
<td>Voluntary</td>
<td>Bluetooth</td>
<td>Yes</td>
<td>Yes</td>
<td>Centralized (pseudonymized contact identifiers)</td>
<td>1.4 (July 2020) [6]</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>StayHomeSafe (April 2020)</td>
<td>Mandatory for 14-day home quarantine</td>
<td>Bluetooth and geofencing technology using wristbands</td>
<td>Yes</td>
<td>Yes</td>
<td>Decentralized</td>
<td>Information not found</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>LeaveHomeSafe (November 2020)</td>
<td>Voluntary</td>
<td>QR codes</td>
<td>Yes</td>
<td>Yes</td>
<td>Decentralized</td>
<td>Information not found</td>
</tr>
<tr>
<td>New Zealand</td>
<td>NZ COVID Tracer App (May 2020)</td>
<td>Voluntary</td>
<td>Bluetooth, QR codes, location alert through push notifications</td>
<td>Yes</td>
<td>Yes</td>
<td>Decentralized</td>
<td>10.7 (July 2020) [6]</td>
</tr>
<tr>
<td>Russia</td>
<td>Social Monitoring (April 2020)</td>
<td>Mandatory for individuals with COVID-19; voluntary for others</td>
<td>App seeks consent to access Bluetooth, GPS, and camera</td>
<td>Yes</td>
<td>Yes</td>
<td>Centralized</td>
<td>Information not found</td>
</tr>
<tr>
<td>Singapore</td>
<td>TraceTogether (March 2020)</td>
<td>Voluntary (required to move around the city)</td>
<td>Bluetooth</td>
<td>Yes</td>
<td>Not for infected persons</td>
<td>Centralized</td>
<td>70 (December 2020) [16]</td>
</tr>
<tr>
<td>South Korea</td>
<td>Self-Quarantine Safety Protection (March 2020)</td>
<td>Required for new arrivals for 2 weeks (telephone calls are alternative option)</td>
<td>Bluetooth, GPS, credit card transactions, surveillance cameras, and others</td>
<td>Yes</td>
<td>Yes</td>
<td>Centralized</td>
<td>Information not found</td>
</tr>
<tr>
<td>South Korea</td>
<td>Corona 100m (February 2020)</td>
<td>Voluntary</td>
<td>GPS, uses data from public government sources</td>
<td>Yes</td>
<td>No</td>
<td>Decentralized</td>
<td>~2 (end of February 2020, 3 weeks after rollout)³ [18]</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>Tawakkalna (May 2020)</td>
<td>Voluntary</td>
<td>GPS</td>
<td>Information not found</td>
<td>Information not found</td>
<td>Centralized</td>
<td>4.9 (July 2020) [6]</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>NHS COVID-19 (September 2020)</td>
<td>Voluntary</td>
<td>Bluetooth 4.0 or higher</td>
<td>Yes</td>
<td>Yes</td>
<td>Centralized (nonidentifiable information)</td>
<td>40 (October 2020) [21]</td>
</tr>
</tbody>
</table>

ᵃEstimated adoption rate based on number of downloads divided by the country’s entire population.
ᵇIn Canada, the app was rolled out in Ontario first; as of December 2020, only 9 of the 13 provinces and territories had adopted the app.
ᶜQR: quick response.
Privacy Measures Related to Adoption

Beyond the inherent value of privacy as a human right and as a protection against bias and stigma, the intent of increasing an app’s privacy measures is to broaden its adoption. This has been confirmed by studies conducted since the start of the pandemic, which have demonstrated the important role of trust and perceived privacy in influencing the adoption and use of COVID-19 apps [22-24]. The perception of privacy is not only determined by a user’s interpretation of existing safeguards (eg, the underlying technology, whether the app is voluntary, and the degree of data centralization), but also requires those details be effectively communicated to citizens, which is not always the case. For example, an analysis of COVID-19 app privacy policies concluded that improvements to the readability of privacy policies could lead to increased usage [25].

Modelling by a research group at Oxford has indicated that the pandemic can be stopped if about 60% of the population uses the app. Lower adoption rates of 15% would still reduce infection and deaths by about 8% and 6%, respectively [26]. At the time of writing, Singapore and China have been able to reach the 60% threshold, while many other countries have reported adoption rates greater than 15%, including Ireland, Canada (ie, Ontario, where the app was first launched), Germany, and Iceland (the first country in Europe to launch their app) [27].

While adoption rates are affected by numerous nuanced factors, they are likely highly influenced by three broad categories of privacy-related factors highlighted in Table 1. First, apps that are mandatory would presumably result in higher adoption rates than voluntary apps. For example, although use of the apps in Singapore and China is technically voluntary, the apps are required for citizens to move around freely in cities, which may have resulted in the high adoption rates of those apps. Specifically, citizens in China are unable to move freely within cities and enter establishments without showing their color-coded individual QR codes at checkpoints. A color code (green, yellow, or red) is assigned depending on the user’s travel history and health status, with green allowing unrestricted movement, and yellow and red indicating different quarantine requirements [28].

Second, the technology employed in the apps will largely dictate how intrusive the apps are to an individual’s privacy. Public transparency about the technology used may also increase confidence in the use of the app. To increase adoption, some countries—including Canada, Germany, and the United Kingdom—have opted to use the well-documented and highly vetted Google and Apple Exposure Notification application programming interface (API), which enables the swapping of anonymous identifier beacons (ie, random strings of numbers that are frequently changed) between phones in close proximity via Bluetooth Low Energy [29]. This provides a very high level of privacy because no identifiable data is transmitted. Other countries, such as China, have opted for technology that tracks the location of individuals (eg, GPS), which may be a deterrent to their use. Local Chinese governments have developed their own apps with algorithms that assign the color code, but little information has been made available on the details of how the algorithms work [28]. As another example, in South Korea, all people coming into the country are required to quarantine for two weeks and to download the “Self-Quarantine Safety Protection” app, which tracks a person’s movement via GPS to monitor compliance with isolation procedures (telephone calls are an option if someone does not have a smartphone) [30]. After the two-week quarantine period, the app tells the user that they are able to delete the app from their phones. In addition, Corona 100m is a voluntary app in South Korea that was built by a private developer after the government made certain data about patients with COVID-19 freely available [31]. The Corona 100m app shows the location of people infected with the virus, the date the infection was confirmed, and the nationality, sex, and age of the infected person. Alerts are sent to users when they are within 100 meters of the latest tracked location visited by someone positive for COVID-19. Data used by the app comes from smartphone location logs, credit and debit card transactions, and an extensive network of surveillance cameras [32].

Third, data governance in terms of privacy laws related to the app data, user consent for data sharing, and centralization of data storage are also important factors that can impact citizens’ comfort level with using the apps. Countries with data governance laws and policies that protect privacy, such as the United Kingdom and Canada, appear to have relatively good adoption rates. On the other hand, a lower adoption rate was reported in Saudi Arabia, where it is not clear if the apps are bound by privacy laws and whether consent for data sharing is required. Some countries have centralized the storage of data into a database controlled by a public health authority, while others have decentralized data storage (ie, data is stored only on an individual’s smartphone). While a centralized data storage system could provide added value through the ability to analyze the data for trends and adoption information, decentralized systems may invoke more trust in the app, which could drive up adoption. Germany’s exposure notification app was initially developed to support a centralized approach, but was met with much criticism, leading to a change to a decentralized model [33].

The Privacy Versus Effectiveness Trade-Off

The trade-off between privacy and effectiveness is apparent at both the individual and system level. For example, apps leveraging the Google and Apple Exposure Notification API, which was designed with a privacy-first approach, do not provide users with the identity of the person with COVID-19 that they were in close proximity to, or information about the location or time of the potential exposure beyond the fact that it was within the past 14 days. Therefore, the user is provided with little context to determine the actual risk (eg, whether personal protective equipment was used) and how long they should be exercising extra precaution to reduce the risk of transmission of the virus.

The limited collection of data and decentralized systems that are used to protect privacy also hinder the ability of governments...
to analyze aggregate data, including demographics, time stamps, and geolocalization, which could inform the design and implementation of more targeted public health strategies. Specifically, COVID-19 apps that prioritize effectiveness over privacy could aggregate reliable demographic information about potentially exposed users that is grounded in a specific place and time. In its absence, governments and public health officials must largely rely on information gathered when patients positive for COVID-19 interact with the health system (which is almost always temporally dissociated from the time of infection) or human-driven contact tracing, which relies on citizens’ recall and willingness to report accurate information. While useful, these data may be less reliable and comprehensive compared to data collected via a COVID-19 app, thus limiting the data’s ability to inform the types of targeted interventions that could simultaneously decrease the spread of COVID-19 and avoid the negative societal consequences of more generalized lockdowns.

Furthermore, the lack of detailed and centralized data limits evaluations of the effectiveness of these apps. For instance, many exposure notification systems will only be able to determine the number of downloads and the number of users who have chosen to identify themselves as positive for COVID-19 through the app. It is not known whether the user has since deleted the app or has chosen to turn off Bluetooth. Other unknowns include how many people have been notified of a potential exposure, how many people chose to be tested because of an alert, and how many people tested positive for COVID-19 earlier than they would have otherwise due to an alert. In these situations, there is mainly anecdotal effectiveness evidence of users getting alerted about an exposure, getting tested, and then modifying their behavior to reduce the transmission of the virus. Evidence of the effectiveness of the app can help drive adoption of the app, as well as inform future implementations of and improvements to the app. Furthermore, the perception that the app is effective may incentivize individuals to download and use the app, which in itself would presumably increase its effectiveness.

**Other Factors Impacting the Adoption of COVID-19 Apps**

In addition to privacy concerns, a barrier to adoption is the inability for some to download the app. While the proportion of people who own smartphones is high and increasing (upwards of 80% in some countries), there is still a considerable number of people who do not own smartphones [34]. In addition, a criticism of using the Google and Apple Exposure Notification API is that it works only on phones that were released in the past five years or so, which could have the effect of excluding lower-income communities that may have particularly high rates of COVID-19 transmission [35]. Singapore’s innovative solution to help reach citizens that are unable to download the TraceTogether app was to distribute a device called the TraceTogether token, which works by swapping identifier beacons via Bluetooth, similar to the app [36].

There are other methods that have been used to try to increase adoption of voluntary exposure notification apps. One is to incorporate features in the app to increase its perceived value [37]. For example, some exposure notification apps can provide COVID-19 test results. In the United Kingdom, the NHS COVID-19 app has features such as ordering COVID-19 tests, receiving test results, regional risk score alerts, symptom recorders, and a self-isolation countdown and advice [38]. A second way to increase adoption of these apps is through social influence and media campaigns. In Canada, influential brands and high-profile individuals like athletes have partnered to promote the use of the COVID Alert app [39]. New Zealand has used humor and creativity in their efforts to inform citizens about the NZ COVID Tracer app, and the pandemic more generally, through comedic skits with well-known television personalities and a call for filmmakers to submit short videos [40]. Opportunities to communicate the privacy safeguards as well as personal and societal benefits should also be explored in these campaigns.

Finally, reducing user effort by making the app easier to download and use may also increase adoption. For example, during the launch of the COVID Alert app in Ontario, Canada, a government alert was sent to smartphones regarding the app, with information on how to download the app, which runs in the background after setup without further user interaction.

**Conclusion**

With increased privacy, there are inherent trade-offs in the effectiveness of COVID-19 contact tracing and exposure notification apps. The effectiveness of the apps might be impossible to evaluate fully due to the lack of collected data, especially for apps with privacy-first approaches, as well as confounding factors like community lockdowns. However, given the assumption that higher adoption translates into increased effectiveness, broadening adoption of voluntary apps is a goal of many countries, which can be achieved through several techniques. These include investing in a promotional campaign that may involve hiring a professional marketing firm, partnering with high-profile personalities to endorse the app, and increasing ease of app download via smartphone alerts by the government that link to the app. While the level of privacy required for a COVID-19 contact tracing and exposure notification app will depend on factors including whether it is voluntary, the underlying technology, and degree of data centralization, translation of those important safeguards into a user’s perception of privacy will occur within the context of the norms and values of their country. Therefore, striking the right balance between privacy and effectiveness requires careful consideration, especially as the urgency to reduce transmission of the virus evolves based on fluctuating case numbers and vaccination efforts.
Conflicts of Interest
None declared.

References


Abbreviations

API: application programming interface
QR: quick response
Understanding Concerns, Sentiments, and Disparities Among Population Groups During the COVID-19 Pandemic Via Twitter Data Mining: Large-scale Cross-sectional Study

Chunyan Zhang1*, MS; Songhua Xu1*, PhD; Zongfang Li1*, PhD; Shunxu Hu2, BS

1Institute of Medical Artificial Intelligence, The Second Affiliate Hospital of Xi’an Jiaotong University, Xi’an, China
2School of Mathematics and Statistics, Xi’an Jiaotong University, Xi’an, China
* these authors contributed equally

Corresponding Author:
Songhua Xu, PhD
Institute of Medical Artificial Intelligence
The Second Affiliate Hospital of Xi’an Jiaotong University
No.157 Xiwu Road
Xi’an
China
Phone: 86 18710823698
Email: songhua_xu1@163.com

Abstract

Background: Since the beginning of the COVID-19 pandemic in late 2019, its far-reaching impacts have been witnessed globally across all aspects of human life, such as health, economy, politics, and education. Such widely penetrating impacts cast significant and profound burdens on all population groups, incurring varied concerns and sentiments among them.

Objective: This study aims to identify the concerns, sentiments, and disparities of various population groups during the COVID-19 pandemic through a cross-sectional study conducted via large-scale Twitter data mining infoveillance.

Methods: This study consisted of three steps: first, tweets posted during the pandemic were collected and preprocessed on a large scale; second, the key population attributes, concerns, sentiments, and emotions were extracted via a collection of natural language processing procedures; third, multiple analyses were conducted to reveal concerns, sentiments, and disparities among population groups during the pandemic. Overall, this study implemented a quick, effective, and economical approach for analyzing population-level disparities during a public health event. The source code developed in this study was released for free public use at GitHub.

Results: A total of 1,015,655 original English tweets posted from August 7 to 12, 2020, were acquired and analyzed to obtain the following results. Organizations were significantly more concerned about COVID-19 (odds ratio [OR] 3.48, 95% CI 3.39-3.58) and expressed more fear and depression emotions than individuals. Females were less concerned about COVID-19 (OR 0.73, 95% CI 0.71-0.75) and expressed less fear and depression emotions than males. Among all age groups (ie, ≤18, 19-29, 30-39, and ≥40 years of age), the attention ORs of COVID-19 fear and depression increased significantly with age. It is worth noting that not all females paid less attention to COVID-19 than males. In the age group of 40 years or older, females were more concerned than males, especially regarding the economic and education topics. In addition, males 40 years or older and 18 years or younger were the least positive. Lastly, in all sentiment analyses, the sentiment polarities regarding political topics were always the lowest among the five topics of concern across all population groups.

Conclusions: Through large-scale Twitter data mining, this study revealed that meaningful differences regarding concerns and sentiments about COVID-19-related topics existed among population groups during the study period. Therefore, specialized and varied attention and support are needed for different population groups. In addition, the efficient analysis method implemented by our publicly released code can be utilized to dynamically track the evolution of each population group during the pandemic or any other major event for better informed public health research and interventions.

(J Med Internet Res 2021;23(3):e26482) doi:10.2196/26482
KEYWORDS
COVID-19; Twitter mining; infodemiology; infoveillance; pandemic; concerns; sentiments; population groups; disparities

Introduction

Background
Since December 2019, COVID-19 has rapidly spread all over the world and caused millions of deaths [1,2]. Although many countries have implemented various countermeasures [3,4], an end to the pandemic is still not in sight. So far, COVID-19 has already exerted tremendous impacts across various aspects of human life, such as health, economy, politics, and education [5-8], whose influences may last for an unknown period. Such widely penetrating and long-lasting impacts are likely to cause disproportionate burdens on different population groups, incurring varied concerns and sentiments among them. Therefore, it is of great importance to understand the disparities in the responses of these population groups to COVID-19 for better informed public health research and intervention.

Literature Reviews
So far, two classes of methods have been utilized to study the impacts of COVID-19 on public and personal life, including large-scale social media mining approaches and cross-sectional analyses through online and offline questionnaires, which are briefly reviewed in the following text.

The first class of methods provides a fast and economical way to analyze the population impacts of COVID-19 through mining social media data generated during the pandemic. Currently, such methods have been employed in a number of studies. For example, Lwin et al [9] studied Twitter data to explore global trends of four emotions—fear, anger, sadness, and joy—as well as their relative salience. After studying the topics obtained by latent Dirichlet allocation topic modeling on Twitter text data, Abd-Alrazaq et al [10] identified the sentiments of four major topics and 12 subtopics, and showed that all topics were positive except for two (ie, death and racial discrimination). Similarly, Hung et al [11] adopted the Valence Aware Dictionary and Emotional Reasoner (VADER) model to analyze the sentiments expressed in user tweets and found that positive, neutral, and negative emotions accounted for 48.2%, 20.7%, and 31.1% of the tweets, respectively.

Despite the informative understanding regarding people’s sentiments provided by these prior studies, it is noted that these existing methods tend to treat their study population as a whole in the analysis, ignoring likely disparities among population groups. Case reports from many countries and epidemiological research on COVID-19 state that the morbidity and mortality of COVID-19 are related to age and gender [12-14], calling for a more fine-grained analysis regarding the concerns and sentiments of each population group during the pandemic.

The second class of methods has been popularly leveraged to understand the health statuses of population groups, uncover health-related factors, and carry out disease epidemiology research. Table 1 [15-20] lists some representative cross-sectional surveys on COVID-19. Compared with the first class of data mining methods, cross-sectional studies can provide richer and more fine-grained information through well-controlled questionnaires, which is of great use for analyzing the detailed disparities of population groups.

Table 1. Representative cross-sectional studies on COVID-19.

<table>
<thead>
<tr>
<th>Author and reference</th>
<th>Study target area</th>
<th>Study period (all in 2020)</th>
<th>No. of participants (online or offline)</th>
<th>Highlights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nelson et al [17]</td>
<td>Parts of the United States</td>
<td>March 14-16</td>
<td>9009 (online)</td>
<td>Age differences exist in concerns about COVID-19: people aged 40-54 years and 55-75 years are very worried and extremely worried population groups, respectively.</td>
</tr>
<tr>
<td>Ahmad and Murad [20]</td>
<td>Iraqi Kurdistan</td>
<td>Not stated</td>
<td>516 (online)</td>
<td>Age differences exist in mental health during COVID-19: young people aged 18-35 years are facing psychological anxiety.</td>
</tr>
</tbody>
</table>

Table 1. Representative cross-sectional studies on COVID-19.

However, the shortcomings of both online and offline cross-sectional studies are also commonly acknowledged. In particular, launching offline questionnaires during the COVID-19 pandemic may pose eminent public health hazards because of the risk of virus transmission through personal contacts. Online questionnaires also have their own challenges, mainly difficulties in finding an adequate number of willing participants to complete the online questionnaires honestly and...
at a high quality. The operational obstacle of online questionnaires is further elevated if repeated surveys are intended to track the dynamic evolution of population groups regarding their thoughts and needs [21].

Recognizing the limitations of the two classes of existing study methods, in this work, we conducted a new cross-sectional study via large-scale Twitter data mining. Through this method, we aimed to identify the concerns, sentiments, and disparities of various population groups during the COVID-19 pandemic in fine granularity without administrating any online or offline questionnaires. The advantage of our approach lies in its economic and efficient way of gathering multifaceted awareness information from population groups and their disparities. With such an understanding of the concerns and sentiments of population groups regarding COVID-19, specialized attention and customized programs can be developed to assist each population group. It is noted that the method implemented through our social media data mining approach can be easily repurposed to study the evolution of different population groups during any major public health event for better informed public health research and interventions. The source code developed in this study has been released for free public use at GitHub [22].

**Methods**

As shown in Figure 1, the cross-sectional method proposed in this study consists of three steps. The implementation details of each step are described in the following sections.

![Figure 1. The structure of our cross-sectional method. API: application programming interface; POMS: Profile of Mood States.](https://www.jmir.org/2021/3/e26482)

**Step 1: Data Collection and Preprocessing**

Data Collection and Preprocessing

The Twitter data used in this study were collected by sampled stream application programming interface v1 [23] and v2 [24] from Twitter Developer Labs, which can stream about 1% of publicly available tweets in real time. Meanwhile, detailed author data from all the tweets were collected to extract population characteristics. Unlike those in other research studies on Twitter [9-11], the data captured in this study are a random sampling of all Twitter data without using any filter, which can...
better reflect the common opinions in people’s daily lives. As of November 2020, we have collected, in total, more than 600 million tweets (ie, over 2 Terabytes) during the COVID-19 pandemic.

In the data preprocessing step, an original English filter and a COVID-19 filter were used to generate the original and COVID-19 tweet data sets based on all the captured tweets. Since original tweets can better reflect the authors’ dynamic thoughts and sentiments, and English tweets comprise over half of all tweets (see Figure 2), we only focused on original English tweets, which can be filtered by the attributes of the tweet object. In order to obtain COVID-19 tweets, we made a filter pattern that is composed of 590 COVID-19 keywords and hashtags provided by Twitter COVID-19 filter rules [25].

Figure 2. The language distribution of tweets. ar: Arabic; en: English; es: Spanish; hi: Hindi; others: other languages; pt: Portuguese.

### Data Mining

Data mining is the key step in emulating cross-sectional questionnaires based on the two tweet data sets. This step contained four intelligent modules: demographic characteristic extractor, concern classifier, sentiment analyzer, and emotion detector.

#### Demographic Characteristic Extractor

This module was used to extract three demographic characteristics—user type, gender, and age—through profile images, screen names, names, and biographies. It was implemented by an open source package of the M3 (multimodal, multilingual, and multi-attribute) model [26], which is a multimodal deep neural system trained on a massive data set, composed of Twitter, IMDB, and Wikipedia data [27], for demographic inference. In this M3 model, user type (ie, person or organization) and gender (ie, male or female) were modeled as binary classification tasks, while age was modeled as a 4-class classification task with the following age groups: ≤18, 19-29, 30-39, and ≥40 years of age. As shown in Figure 3, the structure of the M3 model consisted of two separate pipelines—image pipeline and text pipeline—and a shared pipeline. The image pipeline was employed to process profile images using the dense convolutional network (DenseNet) [28], and the text pipeline was used for processing three text sources of screen names, names, and biographies by adopting three character-based neural networks. The shared pipeline combined the outputs of the two separate pipelines and then mainly applied two fully connected dense layers to predict the user type, gender, and age state of each Twitter user. All of these pipelines were fine-tuned to capture accurate demographic features. For more detailed information, readers can refer to the original literature [26].
We tested the M3 model on a subset of our original English tweets that carried ground-truth labels of user type, gender, and age explicitly or implicitly; the detection procedure is explained in detail in Multimedia Appendix 1. The benchmark performance of the M3 model on this subset is as follows: for user type, gender, and age, the accuracy scores are 99.07%, 95.88%, and 77.65%, respectively, and the macro–F1 scores are 0.9860, 0.9572, and 0.7311, respectively.

**Concern Classifier**

This module was used to classify the tweets into five categories of human life—economics, politics, health, education, and entertainment—which was based on our self-designed matching patterns. First, five specialized vocabulary dictionaries were collected and constructed from Oxford Reference and other sources, including an economic vocabulary (ie, A Dictionary of Economics [29] and The Economist [30]) and a political vocabulary (ie, A Concise Oxford Dictionary of Politics and International Relations [31]). Then, the vocabulary dictionaries were imported into the matching patterns in a regular expression format, with which we labeled all the tweets.

**Sentiment Analyzer**

This module calculated the sentiment polarities of the tweets based on the VADER [32] model. The VADER model is a sentiment analysis tool based on lexicons of sentiment-related words, which can automatically classify each word in the lexicon as positive, neutral, or negative. The range of the sentiment polarity is –1 to 1, which is divided into three subranges: negative (–1 to –0.05), neutral (–0.05 to 0.05), and positive (0.05 to 1).

**Emotion Detector**

This module is based on an emotion recognition model on Twitter [33], which utilizes a character-based trained recurrent neural network algorithm. It employs three emotion models to recognize different human emotions, including Ekman’s six basic emotions model [34]; Plutchik’s eight primary emotions model, also known as the emotion wheel [35]; and the Profile of Mood States (POMS) model [36], which measures six mood states. Based on the above-mentioned modules, the template of the emulated cross-sectional questionnaire is shown in Table 2.
Table 2. The template of the cross-sectional questionnaire.

<table>
<thead>
<tr>
<th>Question category</th>
<th>Response categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population characteristic</strong></td>
<td></td>
</tr>
<tr>
<td>User type</td>
<td>Person</td>
</tr>
<tr>
<td></td>
<td>Organization</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
</tr>
<tr>
<td>Age (years)</td>
<td>≤18</td>
</tr>
<tr>
<td></td>
<td>19-29</td>
</tr>
<tr>
<td></td>
<td>30-39</td>
</tr>
<tr>
<td></td>
<td>≥40</td>
</tr>
<tr>
<td><strong>Concern</strong></td>
<td></td>
</tr>
<tr>
<td>Economics</td>
<td>Concerned</td>
</tr>
<tr>
<td></td>
<td>Unconcerned</td>
</tr>
<tr>
<td>Health</td>
<td>Concerned</td>
</tr>
<tr>
<td></td>
<td>Unconcerned</td>
</tr>
<tr>
<td>Politics</td>
<td>Concerned</td>
</tr>
<tr>
<td></td>
<td>Unconcerned</td>
</tr>
<tr>
<td>Education</td>
<td>Concerned</td>
</tr>
<tr>
<td></td>
<td>Unconcerned</td>
</tr>
<tr>
<td>Entertainment</td>
<td>Concerned</td>
</tr>
<tr>
<td></td>
<td>Unconcerned</td>
</tr>
<tr>
<td><strong>Sentiment polarity</strong></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>–1 to –0.05</td>
</tr>
<tr>
<td>Neutral</td>
<td>–0.05 to 0.05</td>
</tr>
<tr>
<td>Positive</td>
<td>0.05 to 1</td>
</tr>
<tr>
<td><strong>Emotions</strong></td>
<td></td>
</tr>
<tr>
<td>Ekman’s six emotions: anger, disgust, fear, joy, sadness, and surprise</td>
<td>0 to 1 for each emotion</td>
</tr>
<tr>
<td>Plutchik’s eight emotions: anger, disgust, fear, joy, sadness, surprise, trust, and anticipation</td>
<td>0 to 1 for each emotion</td>
</tr>
<tr>
<td>POMS® six emotions: anger, depression, fatigue, vigor, tension, and confusion</td>
<td>0 to 1 for each emotion</td>
</tr>
</tbody>
</table>

*POMS: Profile of Mood States.

**Cross-sectional Analysis**

The purpose of this step was to analyze the concerns and sentiments of different population groups in response to COVID-19 based on the Twitter data mining outcomes of the emulated questionnaire. It includes two parts: the COVID-19 concern and sentiment polarity analysis and the COVID-19 emotion analysis. The odds ratio (OR) was employed in these two parts to compare the relative ratios of population groups under multiple variable conditions. Meanwhile, we used the chi-square test to measure the significance level of difference (ie, \(P\) value) under each condition.

**Results**

**Overall Analysis**

During the COVID-19 pandemic, various emotions were expressed by the general public. To study the disparities between different population groups during this period, we conducted a cross-sectional analysis on the daily Twitter data collected from August 7 to 12, 2020. In total, 7,590,844 unfiltered tweets were captured during the research period, of which 1,015,655 were original English tweets; these are referred to as the original data set. From this original data set, 27,216 tweets were related to COVID-19; these are referred to as the original data set. The statistical distributions and \(P\) values, by chi-square test, of the two data sets are shown in Table 3.

We can see from Table 3 that the population groups under each variable all showed significant differences (\(P<.001\)) in response...
to COVID-19. As shown in Table 3, 89.94% of the total participants were persons and 10.06% were organizations. As a comparison, 73.00% and 27.00% of COVID-19-related participants were persons and organizations, respectively. The total proportion of male participants on social media was slightly higher than that of females (52.74% vs 47.26%), while this gap was further widened to 60.38% versus 39.62% under COVID-19, respectively. The total proportions of the four age groups—≤18, 19-29, 30-39, and ≥40 years of age—were 37.93%, 38.42%, 11.41%, and 12.24%, respectively; from this, it can be inferred that people below 30 years of age are more active on social media. Under COVID-19, the proportions increased in the age groups above 30 years and decreased in the age groups below 30 years; thus, the proportions of the four age groups changed to 17.83%, 29.18%, 18.32%, and 34.67%, respectively. The total proportions of the five topics—economics, health, politics, education, and entertainment—were 13.99%, 13.90%, 7.27%, 6.38%, and 7.79%, respectively; under COVID-19, their proportions changed to 34.30%, 22.60%, 19.97%, 15.74%, and 6.38%, respectively. The total proportions of positive, neutral, and negative sentiments were 42.46%, 31.38%, and 26.16%, respectively; the mean sentiment polarity was 0.1067 (SD 0.4647). Under COVID-19, the proportions of positive, neutral, and negative sentiments were 43.15%, 24.37%, and 32.48%, respectively; the mean sentiment polarity fell to 0.0659 (SD 0.4941).

Table 3. Statistical distributions of the emulated questionnaire answers.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total tweets, n (%)</th>
<th>COVID-19-related tweets, n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>1,015,655 (100)</td>
<td>27,216 (100)</td>
<td>N/A</td>
</tr>
<tr>
<td>User type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person</td>
<td>913,480 (89.94)</td>
<td>19,869 (73.00)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Organization</td>
<td>102,175 (10.06)</td>
<td>7347 (27.00)</td>
<td>N/A</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>481,770 (52.74)</td>
<td>11,997 (60.38)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Female</td>
<td>431,710 (47.26)</td>
<td>7872 (39.62)</td>
<td>N/A</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤18</td>
<td>346,483 (37.93)</td>
<td>3542 (17.83)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>19-29</td>
<td>350,959 (38.42)</td>
<td>5798 (29.18)</td>
<td>N/A</td>
</tr>
<tr>
<td>30-39</td>
<td>104,228 (11.41)</td>
<td>3640 (18.32)</td>
<td>N/A</td>
</tr>
<tr>
<td>≥40</td>
<td>111,810 (12.24)</td>
<td>6889 (34.67)</td>
<td>N/A</td>
</tr>
<tr>
<td>Concern</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Economics</td>
<td>142,090 (13.39)</td>
<td>9334 (34.30)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Health</td>
<td>141,176 (13.90)</td>
<td>6152 (22.60)</td>
<td>N/A</td>
</tr>
<tr>
<td>Politics</td>
<td>73,838 (7.27)</td>
<td>5434 (19.97)</td>
<td>N/A</td>
</tr>
<tr>
<td>Education</td>
<td>64,799 (6.38)</td>
<td>4284 (15.74)</td>
<td>N/A</td>
</tr>
<tr>
<td>Entertainment</td>
<td>79,119 (7.79)</td>
<td>1736 (6.38)</td>
<td>N/A</td>
</tr>
<tr>
<td>Sentiment polarity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall (–1 to 1), mean (SD)</td>
<td>0.1067 (0.4647)</td>
<td>0.0659 (0.4941)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Positive (–1 to 0.05)</td>
<td>431,247 (42.46)</td>
<td>11,744 (43.15)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Neutral (–0.05 to 0.05)</td>
<td>318,713 (31.38)</td>
<td>6632 (24.37)</td>
<td>N/A</td>
</tr>
<tr>
<td>Negative (0.05 to 1)</td>
<td>265,695 (26.16)</td>
<td>8840 (32.48)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

All values are expressed as n (%), except for overall sentiment polarity, which is expressed as mean (SD).
P values were calculated for the main variables and not for individual responses.

The above analysis cannot provide fine-grained differences between population groups under multivariate conditions. To understand these differences more clearly, we adopted a cross-sectional analysis based on the emulated questionnaire outcomes, which consists of two parts: one is COVID-19 concern and sentiment polarity analysis, including univariate, bivariate, and trivariate analysis, and the other one is COVID-19 emotion analysis, including three emotion models. The analysis process and results are presented in the following sections.

COVID-19 Concern and Sentiment Polarity Analysis

Univariate Analysis

The population characteristics in this study included four variables—user type, gender, age, and concern—on which we
first performed a univariate statistical analysis of COVID-19 concerns and sentiment polarities. The results are shown in Figure 4.

**Figure 4.** Univariate analysis of COVID-19 concerns and sentiment polarities among different population groups. OR: odds ratio.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Attention Ratio (%)</th>
<th>Attention OR Forest Plot</th>
<th>OR (95% CI)</th>
<th>Sentiment Polarity Forest Plot</th>
<th>Sentiment Polarity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>User type</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person</td>
<td>2.18</td>
<td></td>
<td>1 (ref)</td>
<td></td>
<td>0.0483</td>
</tr>
<tr>
<td>Organization</td>
<td>7.19</td>
<td></td>
<td>3.48 (3.39-3.58)</td>
<td></td>
<td>0.1135</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2.49</td>
<td></td>
<td>1 (ref)</td>
<td></td>
<td>0.0386</td>
</tr>
<tr>
<td>Female</td>
<td>1.82</td>
<td></td>
<td>0.73 (0.71-0.75)</td>
<td></td>
<td>0.0630</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18</td>
<td>1.02</td>
<td></td>
<td>1 (ref)</td>
<td></td>
<td>0.0406</td>
</tr>
<tr>
<td>19-29</td>
<td>1.65</td>
<td></td>
<td>1.63 (1.56-1.70)</td>
<td></td>
<td>0.0479</td>
</tr>
<tr>
<td>30-39</td>
<td>3.49</td>
<td></td>
<td>3.50 (3.34-3.67)</td>
<td></td>
<td>0.0784</td>
</tr>
<tr>
<td>≥40</td>
<td>6.16</td>
<td></td>
<td>6.36 (6.10-6.62)</td>
<td></td>
<td>0.0366</td>
</tr>
<tr>
<td><strong>Concern</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Economics</td>
<td>6.57</td>
<td></td>
<td>1 (ref)</td>
<td></td>
<td>0.1001</td>
</tr>
<tr>
<td>Health</td>
<td>4.36</td>
<td></td>
<td>0.65 (0.63-0.67)</td>
<td></td>
<td>0.1110</td>
</tr>
<tr>
<td>Politics</td>
<td>7.36</td>
<td></td>
<td>1.13 (1.09-1.17)</td>
<td></td>
<td>0.0291</td>
</tr>
<tr>
<td>Education</td>
<td>6.61</td>
<td></td>
<td>1.01 (0.97-1.05)</td>
<td></td>
<td>0.1184</td>
</tr>
<tr>
<td>Entertainment</td>
<td>2.19</td>
<td></td>
<td>0.32 (0.30-0.34)</td>
<td></td>
<td>0.1503</td>
</tr>
</tbody>
</table>

It can be seen that the organizations’ attention ratio (7.19%) to COVID-19 was significantly higher than that of individuals (2.18%), and the attention OR of organizations was 3.48 (95% CI 3.39-3.58) compared with individuals. Moreover, organizations’ sentiment polarity (0.1135) was more positive than that of individuals (0.0483). The COVID-19 attention ratio of females (1.82%) was a bit lower than that of males (2.49%), with an attention OR of 0.73 (95% CI 0.71-0.75). Meanwhile, females were more positive than males, and the sentiment polarities were 0.0630 and 0.0386 for females and males, respectively. In addition, COVID-19 attention increased significantly with age. Among the four age groups, the attention ORs of the groups that were 19 to 29 years, 30 to 39 years, and 40 years or older were 1.63 (95% CI 1.56-1.70), 3.50 (95% CI 3.34-3.67) and 6.36 (95% CI 6.10-6.62), respectively, in comparison with the group that was 18 years or less, which implies that older people are more concerned about COVID-19. The group that was 40 years or older was less positive than other age groups, with a sentiment polarity of 0.0366. For the concern variable, the COVID-19 attention ratios for politics (7.36%), education (6.61%), and economics (6.57%) were relatively high, followed by health (4.36%) and entertainment (2.19%). The sentiment polarity of political topics (0.0291) was the lowest among these topics, followed by economic (0.1001), health (0.1110), education (0.1184), and entertainment (0.1503) topics.

In general, these data indicate that organizations, as compared to individuals; males, as compared to females; and older people, as compared to young people, are more concerned about the pandemic. In addition, these data indicate that people are more concerned about politics, education, and economics under COVID-19.

**Bivariate Analysis**

Furthermore, we performed a bivariate analysis on COVID-19 attention and sentiment polarity by crossing any two population characteristic variables, as shown in Figure 5.
It can be seen that many results are consistent with the univariate analysis in the previous section. For example, under the combination of age and gender variables, the attention ratios grew with age, both for males and females. Moreover, females were more positive than males in all age groups. Under the combination of user type and concern variables, the order of concerns for individuals is politics, education, economics, health, and entertainment, which is similar to the univariate results.

However, there are still some noteworthy differences. First, not all females of different ages paid less attention to COVID-19 than males, but as individuals got older, females became more concerned than males, with the highest attention ratio of 7.45% and OR of 6.94 (95% CI 6.49-7.42) in females 40 years or older. Second, males 40 years or older (0.0249) and 18 years or younger (0.0268) were the least positive among all population groups. Third, different from the univariate concern analysis, the order of concerns for groups 30 to 39 years and 40 years or older...
older changed to economics, politics, education, health, and entertainment.

From the bivariate results, we can see that not all the population groups obeyed the same rules, but some of them presented worthy differences under multivariable conditions. We further conducted a deeper exploration in the following trivariate analysis.

**Trivariate Analysis**

In this part of the study, we crossed the three variables—gender, age, and concern—of population characteristics to study the COVID-19 responses, and a total of 40 combinations were produced, as shown in Figure 6. Since gender and age attributes did not exist in the organization group, this trivariate analysis only concentrated on individuals.

Figure 6. Trivariate analysis of COVID-19 concerns and sentiment polarities among different population groups. OR: odds ratio.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Attention Ratio (%)</th>
<th>Attention OR Forest Plot</th>
<th>OR (95% CI)</th>
<th>Sentiment Polarity Forest Plot</th>
<th>Sentiment Polarity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Age</td>
<td>Concern</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male ≤18</td>
<td>Economics 2.65</td>
<td>1 (ref)</td>
<td></td>
<td></td>
<td>0.0361</td>
</tr>
<tr>
<td>Male ≤18</td>
<td>Health 1.75</td>
<td>0.66 (0.57-0.76)</td>
<td></td>
<td></td>
<td>0.0629</td>
</tr>
<tr>
<td>Male ≤18</td>
<td>Politics 3.38</td>
<td>1.29 (1.10-1.30)</td>
<td></td>
<td></td>
<td>-0.0008</td>
</tr>
<tr>
<td>Male ≤18</td>
<td>Education 3.17</td>
<td>1.20 (1.03-1.41)</td>
<td></td>
<td></td>
<td>0.0444</td>
</tr>
<tr>
<td>Male ≤18</td>
<td>Entertainment 1.06</td>
<td>0.39 (0.32-0.48)</td>
<td></td>
<td></td>
<td>0.0991</td>
</tr>
<tr>
<td>Male 19-29</td>
<td>Economics 4.12</td>
<td>1.58 (1.41-1.77)</td>
<td></td>
<td></td>
<td>0.0292</td>
</tr>
<tr>
<td>Male 19-29</td>
<td>Health 2.73</td>
<td>1.03 (0.91-1.17)</td>
<td></td>
<td></td>
<td>0.0613</td>
</tr>
<tr>
<td>Male 19-29</td>
<td>Politics 4.83</td>
<td>1.87 (1.64-2.13)</td>
<td></td>
<td></td>
<td>-0.0757</td>
</tr>
<tr>
<td>Male 19-29</td>
<td>Education 4.13</td>
<td>1.58 (1.38-1.82)</td>
<td></td>
<td></td>
<td>0.0402</td>
</tr>
<tr>
<td>Male 19-29</td>
<td>Entertainment 1.36</td>
<td>0.51 (0.43-0.60)</td>
<td></td>
<td></td>
<td>0.0334</td>
</tr>
<tr>
<td>Male 30-39</td>
<td>Economics 6.96</td>
<td>2.73 (2.45-3.09)</td>
<td></td>
<td></td>
<td>0.1194</td>
</tr>
<tr>
<td>Male 30-39</td>
<td>Health 5.40</td>
<td>2.10 (1.84-2.39)</td>
<td></td>
<td></td>
<td>0.1381</td>
</tr>
<tr>
<td>Male 30-39</td>
<td>Politics 6.61</td>
<td>2.60 (2.28-2.97)</td>
<td></td>
<td></td>
<td>0.0777</td>
</tr>
<tr>
<td>Male 30-39</td>
<td>Education 6.25</td>
<td>2.45 (2.12-2.83)</td>
<td></td>
<td></td>
<td>0.1368</td>
</tr>
<tr>
<td>Male 30-39</td>
<td>Entertainment 1.84</td>
<td>0.69 (0.57-0.83)</td>
<td></td>
<td></td>
<td>0.2053</td>
</tr>
<tr>
<td>Male ≥40</td>
<td>Economics 10.97</td>
<td>4.53 (4.08-5.03)</td>
<td></td>
<td></td>
<td>0.0653</td>
</tr>
<tr>
<td>Male ≥40</td>
<td>Health 8.54</td>
<td>3.43 (3.08-3.83)</td>
<td></td>
<td></td>
<td>0.0815</td>
</tr>
<tr>
<td>Male ≥40</td>
<td>Politics 11.02</td>
<td>4.83 (4.33-5.39)</td>
<td></td>
<td></td>
<td>-0.0982</td>
</tr>
<tr>
<td>Male ≥40</td>
<td>Education 10.18</td>
<td>4.16 (3.71-4.68)</td>
<td></td>
<td></td>
<td>0.1175</td>
</tr>
<tr>
<td>Male ≥40</td>
<td>Entertainment 3.54</td>
<td>1.33 (1.16-1.56)</td>
<td></td>
<td></td>
<td>0.1368</td>
</tr>
<tr>
<td>Female ≤18</td>
<td>Economics 2.66</td>
<td>0.93 (0.81-1.07)</td>
<td></td>
<td></td>
<td>0.0518</td>
</tr>
<tr>
<td>Female ≤18</td>
<td>Health 1.32</td>
<td>0.49 (0.43-0.57)</td>
<td></td>
<td></td>
<td>0.0443</td>
</tr>
<tr>
<td>Female ≤18</td>
<td>Politics 2.78</td>
<td>1.05 (0.89-1.25)</td>
<td></td>
<td></td>
<td>-0.0456</td>
</tr>
<tr>
<td>Female ≤18</td>
<td>Education 2.38</td>
<td>0.90 (0.75-1.07)</td>
<td></td>
<td></td>
<td>0.0840</td>
</tr>
<tr>
<td>Female ≤18</td>
<td>Entertainment 1.04</td>
<td>0.39 (0.31-0.47)</td>
<td></td>
<td></td>
<td>0.1315</td>
</tr>
<tr>
<td>Female 19-29</td>
<td>Economics 3.71</td>
<td>1.42 (1.26-1.59)</td>
<td></td>
<td></td>
<td>0.0712</td>
</tr>
<tr>
<td>Female 19-29</td>
<td>Health 2.40</td>
<td>0.96 (0.80-1.02)</td>
<td></td>
<td></td>
<td>0.0567</td>
</tr>
<tr>
<td>Female 19-29</td>
<td>Politics 4.47</td>
<td>1.72 (1.50-1.97)</td>
<td></td>
<td></td>
<td>0.0501</td>
</tr>
<tr>
<td>Female 19-29</td>
<td>Education 4.31</td>
<td>1.65 (1.44-1.90)</td>
<td></td>
<td></td>
<td>0.0785</td>
</tr>
<tr>
<td>Female 19-29</td>
<td>Entertainment 1.56</td>
<td>0.58 (0.49-0.70)</td>
<td></td>
<td></td>
<td>0.1675</td>
</tr>
<tr>
<td>Female 30-39</td>
<td>Economics 8.28</td>
<td>3.32 (2.92-3.78)</td>
<td></td>
<td></td>
<td>0.1289</td>
</tr>
<tr>
<td>Female 30-39</td>
<td>Health 5.70</td>
<td>2.22 (1.94-2.55)</td>
<td></td>
<td></td>
<td>0.1351</td>
</tr>
<tr>
<td>Female 30-39</td>
<td>Politics 9.12</td>
<td>3.69 (3.17-4.29)</td>
<td></td>
<td></td>
<td>-0.0031</td>
</tr>
<tr>
<td>Female 30-39</td>
<td>Education 8.52</td>
<td>3.42 (2.91-4.02)</td>
<td></td>
<td></td>
<td>0.1084</td>
</tr>
<tr>
<td>Female 30-39</td>
<td>Entertainment 4.27</td>
<td>1.64 (1.34-2.01)</td>
<td></td>
<td></td>
<td>0.0799</td>
</tr>
<tr>
<td>Female ≥40</td>
<td>Economics 13.56</td>
<td>5.67 (5.02-6.41)</td>
<td></td>
<td></td>
<td>0.0823</td>
</tr>
<tr>
<td>Female ≥40</td>
<td>Health 10.70</td>
<td>4.40 (3.86-5.02)</td>
<td></td>
<td></td>
<td>0.0915</td>
</tr>
<tr>
<td>Female ≥40</td>
<td>Politics 10.82</td>
<td>4.46 (3.90-5.10)</td>
<td></td>
<td></td>
<td>-0.0029</td>
</tr>
<tr>
<td>Female ≥40</td>
<td>Education 12.54</td>
<td>5.27 (4.54-6.12)</td>
<td></td>
<td></td>
<td>0.1001</td>
</tr>
<tr>
<td>Female ≥40</td>
<td>Entertainment 4.80</td>
<td>1.85 (1.49-2.30)</td>
<td></td>
<td></td>
<td>0.1876</td>
</tr>
</tbody>
</table>

Like in the bivariate analysis, there were some consistent results in the trivariate analysis. For example, the COVID-19 attention ratios increased with age, both for males and females in each topic of concern. Meanwhile, many detailed population differences were also clearly shown in these trivariate results. First, we can see that all of the groups presented different amounts of attention on the five topics of concern. In particular, females 40 years or older paid the greatest amount of attention to economic topics (OR 5.67, 95% CI 5.02-6.41), followed by education topics (OR 5.27, 95% CI 4.54-6.12). As a comparison, males in the same age group (ie, ≥40 years) had the highest concerns regarding political topics (OR 4.83, 95% CI 4.33-5.39), followed by economic (OR 4.53, 95% CI 4.08-5.03) and education (OR 4.16, 95% CI 3.71-4.68) topics. Second, the sentiment polarities of political topics were the lowest in all population groups, of which six had negative values. Lastly, the sentiment polarities of entertainment topics were always the highest among the five topics of concern across all population groups.

**COVID-19 Emotion Analysis**

We applied three different emotion models—Ekman’s six basic emotions, Plutchik’s eight primary emotions, and POMS six mood states—to perform emotion detection, both on the original...
tweets and the COVID-19 tweets. The comparison results are shown in Figures 7 and 8. Figure 7 presents the mean intensity scores of the three emotion models, and Figure 8 shows the population distribution for each emotion from the models based on both original and COVID-19 tweets. As Ekman’s six basic emotions (ie, anger, disgust, fear, joy, sadness, and surprise) are included in Plutchik’s eight emotions, and these six common emotions had the same proportion rank in our experimental results, we only then analyzed Plutchik’s and POMS emotions.

**Figure 7.** The mean intensity scores for the three emotion models. Scores range from 0 to 1 for each emotion. POMS: Profile of Mood States.

![Figure 7](image)

In general, when Plutchik’s emotion model was applied to the original tweets, trust, joy, and surprise were the highest emotions. When the model was applied to COVID-19 tweets, fear increased significantly, then joy, trust, and fear became the highest emotions. Meanwhile, when the POMS emotion model was applied to original tweets, depression was the most prominent emotion, and when applied to COVID-19 tweets, depression became even more prominent.

Afterward, we studied the differences in emotions considering the population characteristic attributes under COVID-19 by performing a chi-square test on each population attribute for each emotion. The results are shown in Multimedia Appendix 2. Figures 9 and 10 illustrate the emotion analysis by applying Plutchik’s and POMS models to each population characteristic. We observed differences in emotions with respect to population variables, but among all the dominant emotions after applying Plutchik’s and POMS models, fear and depression had significantly different scores and proportions in different populations. A further detailed statistical analysis was conducted on these two emotions (see Figure 11). We can see that organizations expressed more fear and depression than individuals, and females expressed less fear and depression than males. With increasing age, fear and depression increased significantly; in addition, people expressed more fear regarding political and health topics, and more depression regarding entertainment, economic, and political topics.
Figure 9. Plutchik emotion analysis on four population characteristics. Scores range from 0 to 1 for each emotion.

Figure 10. Profile of Mood States (POMS) emotion analysis on four population characteristics. Scores range from 0 to 1 for each emotion.
In summary regarding the emotion analysis, it can be concluded that the emotions differed between original tweets and COVID-19 tweets, and they further differed among different population groups during the COVID-19 pandemic.

**Discussion**

**Principal Findings**

In this study, we analyzed a large amount of Twitter data collected from August 7 to 12, 2020, during the COVID-19 pandemic. In the overall analysis, the average sentiment polarity of COVID-19-related tweets posted by participants was less positive than that of the original tweets. In addition, the population groups under each variable (ie, user type, gender, age, and concern) all showed significant differences ($P < .001$) in response to COVID-19. In univariate analysis, organizations, as compared to individuals; males, as compared to females; and older people, as compared to young people were more concerned about the pandemic and had greater proportions of fear and depression emotions. In addition, the COVID-19 attention ratios of politics, education, and economics were relatively high, followed by health and entertainment, while the sentiment polarity of politics was the lowest, followed by economics, health, education, and entertainment.

Furthermore, the multivariate analyses showed more fine-grained and meaningful results. Among the findings, it is worth noting that not all female groups paid less attention to COVID-19 than male groups in the same age range, and not all groups’ top concerns were the same. As age increased to above 30 years, females were gradually more concerned about COVID-19 than males. Moreover, females above 40 years of age were the group most concerned about COVID-19, and they were most concerned about economics and education. As a comparison, males in the same age group were most concerned about politics and economics. Males above 40 years of age and below 18 years of age were the least positive in sentiment. Among all the five topics of concern, the sentiment polarities of politics were the lowest in all population groups. These findings demonstrate that there exist population-level disparities in concerns and sentiments about COVID-19 in response to the pandemic during our research period.

We speculate that there are two reasons for the population-level differences. First, they are related to the concrete needs of specific age groups. For example, people older than 30 years of age may pay more attention to COVID-19 impacts on economics, while young people may concentrate more on education. Second, they are also related to the features of this novel coronavirus. Epidemiological studies have shown that the older population is more susceptible to COVID-19 and mortalities among this age group are higher than in other populations [13].

**Limitations**

The algorithm of demographic characteristic extraction used in this study is only capable of extracting three basic attributes: user type, gender, and age. Therefore, it is difficult for us to conduct a more detailed multivariable analysis compared with traditional questionnaire methods. In addition, the age range divisions were not fine-grained enough for COVID-19, especially for the group that was 40 years old or above, which covers a wide age range. To support the extraction of more attributes with finer granularity, we plan to optimize the current algorithm or seek new suitable and efficient algorithms for future studies.
Conclusions

Through large-scale Twitter data mining, this study revealed that salient disparities exist among population groups in terms of their concerns and sentiments regarding COVID-19-related issues. Therefore, it is suggested that government agencies and social organizations should devote specialized attention and support to each population group based on their varied concerns and sentiments experienced during the pandemic. The open source code developed in this study, which was publicly released via GitHub [22], can be easily employed to explore the evolution of population groups regarding their wants, needs, and thoughts during the pandemic for future follow-ups. It can also be repurposed for research and interventions used in combating other public health emergencies, thanks to the efficient and economic nature of its operation.

Acknowledgments

This research is supported by the National Natural Science Foundation of China (Grant Nos. 61876150 and 12026609) and the Science and Technology Program of the City of Xi’an (Grant Nos. 20YXYJ0009-12 and XA2020-RKXYJ-0105).

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplemental information about the M3 (multimodal, multilingual, and multi-attribute) model.

[DOCX File, 32 KB - jmir_v23i3e26482_app1.docx ]

Multimedia Appendix 2

Extended details on the data analyses.

[DOCX File, 31 KB - jmir_v23i3e26482_app2.docx ]

References


Abbreviations
- **DenseNet**: dense convolutional network
- **M3**: multimodal, multilingual, and multi-attribute
- **OR**: odds ratio
- **POMS**: Profile of Mood States
- **VADER**: Valence Aware Dictionary and Emotional Reasoner
Original Paper

Comparing Public Perceptions and Preventive Behaviors During the Early Phase of the COVID-19 Pandemic in Hong Kong and the United Kingdom: Cross-sectional Survey Study

Leigh Bowman¹, PhD; Kin On Kwok²,³,⁴, PhD; Rozlyn Redd⁵, PhD; Yuanyuan Yi², MPH; Helen Ward¹,⁵, PhD; Wan In Wei², MPhil; Christina Atchison⁵, PhD; Samuel Yeung-Shan Wong², MD

¹MRC Centre for Global Infectious Disease Analysis and Abdul Latif Jameel Institute for Disease and Emergency Analytics (J-IDEA), School of Public Health, Imperial College, London, United Kingdom
²JC School of Public Health and Primary Care, The Chinese University of Hong Kong, Hong Kong, Hong Kong
³Stanley Ho Centre for Emerging Infectious Diseases, The Chinese University of Hong Kong, Hong Kong, Hong Kong
⁴Shenzhen Research Institute, The Chinese University of Hong Kong, Hong Kong, Hong Kong
⁵Patient Experience Research Centre, School of Public Health, Imperial College London, London, United Kingdom

Corresponding Author:
Kin On Kwok, PhD
JC School of Public Health and Primary Care
The Chinese University of Hong Kong
Room 419, 4/F, JC School of Public Health and Primary Care Building, Prince of Wales Hospital
Shatin, New Territories
Hong Kong
Hong Kong
Phone: 852 22528405
Email: kkokwok@cuhk.edu.hk

Abstract

Background: Given the public health responses to previous respiratory disease pandemics, and in the absence of treatments and vaccines, the mitigation of the COVID-19 pandemic relies on population engagement in nonpharmaceutical interventions. This engagement is largely driven by risk perception, anxiety levels, and knowledge, as well as by historical exposure to disease outbreaks, government responses, and cultural factors.

Objective: The aim of this study is to compare psychobehavioral responses in Hong Kong and the United Kingdom during the early phase of the COVID-19 pandemic.

Methods: Comparable cross-sectional surveys were administered to adults in Hong Kong and the United Kingdom during the early phase of the epidemic in each setting. Explanatory variables included demographics, risk perception, knowledge of COVID-19, anxiety level, and preventive behaviors. Responses were weighted according to census data. Logistic regression models, including effect modification to quantify setting differences, were used to assess the association between the explanatory variables and the adoption of social distancing measures.

Results: Data from 3431 complete responses (Hong Kong, 1663; United Kingdom, 1768) were analyzed. Perceived severity of symptoms differed by setting, with weighted percentages of 96.8% for Hong Kong (1621/1663) and 19.9% for the United Kingdom (366/1768). A large proportion of respondents were abnormally or borderline anxious (Hong Kong: 1077/1603, 60.0%; United Kingdom: 812/1768, 46.5%) and regarded direct contact with infected individuals as the transmission route of COVID-19 (Hong Kong: 94.0%-98.5%; United Kingdom: 69.2%-93.5%; all percentages weighted), with Hong Kong identifying additional routes. Hong Kong reported high levels of adoption of various social distancing measures (Hong Kong: 32.6%-93.7%; United Kingdom: 17.6%-59.0%) and mask-wearing (Hong Kong: 98.8% (1647/1663); United Kingdom: 3.1% (53/1768)). The impact of perceived severity of symptoms and perceived ease of transmission of COVID-19 on the adoption of social distancing measures varied by setting. In Hong Kong, these factors had no impact, whereas in the United Kingdom, those who perceived their symptom severity as “high” were more likely to adopt social distancing (adjusted odds ratios [aORs] 1.58-3.01), and those who perceived transmission as “easy” were prone to adopt both general social distancing (aOR 2.00, 95% CI 1.57-2.55) and contact avoidance (aOR 1.80, 95% CI 1.41-2.30). The impact of anxiety on adopting social distancing did not vary by setting.
Conclusions: Our results suggest that health officials should ascertain baseline levels of risk perception and knowledge in populations, as well as prior sensitization to infectious disease outbreaks, during the development of mitigation strategies. Risk should be communicated through suitable media channels—and trust should be maintained—while early intervention remains the cornerstone of effective outbreak response.

(J Med Internet Res 2021;23(3):e23231) doi:10.2196/23231

KEYWORDS
COVID-19; novel coronavirus; pandemic; behavioural response; risk perceptions; anxiety; comparative; Hong Kong; United Kingdom

Introduction

In December 2019, a novel coronavirus, SARS-CoV-2, emerged in Wuhan, Hubei Province, China, and spread rapidly worldwide, forming the second pandemic of the 21st century [1]. The progression of the disease has varied by region. As of August 2, 2020, there have been at least 17 million cases of COVID-19 and over 670,000 deaths globally [2].

Prior to the availability of effective treatments and vaccines, strategies to mitigate the impact of the pandemic have been primarily nonpharmaceutical [3], mainly focusing on public health promotion of using simple but effective preventive measures [4,5]. Many important control strategies currently promoted by governments require public participation, either through direct adoption of preventative behaviors, such as handwashing or wearing face masks, or through compliance with social distancing policies, such as recommendations to avoid public transport and mass gatherings.

Previous studies of the severe acute respiratory syndrome and influenza pandemics showed that governments should account for risk perception and anxiety when promoting preventative measures. There is evidence that higher perceived risk of infection is associated with increased adoption of precautionary measures [6,7], while increased anxiety has also been shown to increase the likelihood that people will engage in protective behaviors [8]. Moreover, longitudinal data suggest that these perceptions, behaviors and anxieties change with context and over time as uncertainty about disease severity decreases and knowledge of transmission increases [9].

During the current COVID-19 pandemic, researchers have examined public risk perceptions and knowledge in various countries, including Finland [10], Israel [11], Italy [12], Nigeria [13], the United States [14,15], South Korea [16] and Vietnam [17]. However, only a few studies have identified the factors associated with greater adoption of preventative measures or how these associations vary by context. In Hong Kong, both greater understanding of COVID-19 and increased anxiety were associated with greater adoption of social distancing behaviors [5], whereas in the United Kingdom, there was a significant socioeconomic gradient in the ability to adopt and comply with social distancing measures, specifically the ability to work from home and the ability to self-isolate [18].

This initial evidence that there is variation across context in affective responses, risk perceptions, and the impact of sociodemographic factors on the uptake of preventative behaviors has significant implications when tailoring policies.

To elucidate these relationships, a more thorough comparative analysis is required. However, studies in different countries often use different metrics to measure the same behavior, which can lead to difficulty when interpreting the significance of heterogeneous contexts.

In this study, we examined and compared public perception and adoption of preventive behaviors in response to the early phase of the COVID-19 pandemic in two different settings: Hong Kong and the United Kingdom. We further investigated the factors associated with greater adoption of different types of social distancing measures. Our results have immediate implications on how health officials plan and communicate strategies to mitigate the ongoing COVID-19 pandemic to communities.

Methods

Study Design and Recruitment

In Hong Kong and the United Kingdom, cross-sectional surveys were conducted during the early phase of the COVID-19 pandemic, when limited government-level interventions were in place [5,18]. The survey period in Hong Kong was from January 24 to February 13, 2020, and that in the United Kingdom was from March 17 to 18, 2020. In Hong Kong, the first laboratory-confirmed case of COVID-19 was reported on January 23, 2020, and the number of cases rose to 53 by February 13, 2020 [19]; meanwhile, in the United Kingdom, the first two laboratory-confirmed cases were reported on January 31, 2020, and the number of cases rose to 2626 by March 18, 2020 [20].

In Hong Kong, all 452 district councilors were invited to distribute an open web-based survey by sharing a survey link and promotion messages on their webpages, social media platforms, or any channels which they usually used to convey information to their targeted residents. Individuals aged ≥18 years who understood Chinese and lived in Hong Kong were eligible to participate [5]. Respondents were compensated with HK $10 (US $1.29) in the form of a cash coupon. In the United Kingdom, the web-based survey was not open (users were required to log in) and was administered by YouGov, a market research company, to members of its panel of ≥800,000 individuals (aged ≥18 years) as part of their omnibus survey [21]. Our UK sample was obtained through a nonprobabilistic active sampling method, and emails were sent to randomly selected individuals with particular characteristics to match the proportions of people with those characteristics in the 2011 UK census.

https://www.jmir.org/2021/3/e23231
census. No incentive was involved in the UK survey. More details of the survey design are described elsewhere [5,18].

Study Instruments
The study instruments are freely available on the web (Hong Kong: [22]; United Kingdom: [23]). The UK questionnaire was adapted from the Hong Kong version, with feedback from 20 members of the public (of different backgrounds) to improve its relevance and usability in the UK context. This process led to some discrepancies in the questions or answer choices; however, the two questionnaires were largely similar.

Sociodemographic variables included age, sex, educational attainment, and employment status. Anxiety level was measured using the Hospital Anxiety and Depression scale–Anxiety (HASD-A) (0-7=normal; 8-10=borderline abnormal; 11-21=abnormal) [24]. Risk perception toward COVID-19 was measured by perceived severity of symptoms if the respondent was infected with COVID-19 (Hong Kong, question 35; United Kingdom, question GIC_Q29). Knowledge of COVID-19 was assessed by asking whether COVID-19 could be transmitted through various routes (Hong Kong, question 45; United Kingdom, question GIC_Q33), including direct human exposure (eg, physical contact or a face-to-face conversation with someone who is infected with SARS-CoV-2 with or without symptoms) and other types of exposure (eg, visiting wet markets or consumption of wild animal meat). From knowledge of COVID-19, perceived ease of transmission was regarded as “easy” if the virus was deemed to be transmitted through face-to-face conversation with asymptomatic infectees and as “difficult” otherwise. Respondents were also asked about the sources from which they retrieved information about COVID-19 and their perceived reliability of these sources (Hong Kong, questions 40 and 43; United Kingdom, questions GIC_Q30 and GIC_Q32). In addition, they were asked about the adoption of preventative behaviors to prevent the transmission of COVID-19 (Hong Kong, question 46; United Kingdom, questions GIC_Q34a and GIC_Q34b). Three types of preventative measures were considered: personal hygiene, social distancing, and travel avoidance.

Data Analysis
Descriptive statistics for all variables present the number of respondents and the raw or weighted percentages. In this manuscript, weighted percentages were used for description except for demographics. The responding samples were weighted to be representative of the United Kingdom (2011 census [25]) and Hong Kong (2016 by-census [26]) adult populations using the raking method [27]. Each data point was given a weight so that the marginal proportions of the demographics in the survey (age, sex, region, education level, and [United Kingdom only] social grade) were similar to those in the census. Chi-square goodness-of-fit tests were used for comparing characteristics across settings. Multivariate logistic regression models were used to identify sociodemographic and psychosocial factors associated with the adoption of three types of social distancing: (1) general measures, specified by avoiding crowded places, social events and going out; (2) contact measures, specified by avoiding contact with individuals who had fever or respiratory symptoms and who had been to affected areas recently; and (3) work measures, specified by avoiding going to work.

Common and comparable sociodemographic factors considered in separate analytical studies [5,18] were included in this comparative analysis. These factors were considered as confounders in the association between psychosocial factors (including anxiety level, perceived severity, and perceived ease of transmission) and adoption of social distancing measures.

Further, these associations (between each aforementioned psychosocial factor and each type of social distancing measure) were considered a priori to be affected by setting. Therefore, we examined the effect modifications due to setting using interaction terms in the baseline models, which can be interpreted as the difference in the estimated effects of psychosocial factors on adopting social distancing measures due to different settings. Adjusted odds ratios (aORs) and 95% confidence intervals were estimated. Associations with \( P < 0.05 \) in the adjusted analyses were considered to be statistically significant. Analyses were conducted in R, version 3.6.3 (the R Project) and STATA, version 11 (StataCorp LLC).

Ethical Approval
The study was approved by the Imperial College London Research Ethics Committee (reference number: 20IC5861) and the Survey and Behavioral Research Ethics Committee of The Chinese University of Hong Kong (reference number: SBRE-19-625).

Results
Survey Responses
In Hong Kong, there were initially 2478 clicks on the survey link. After removing 763 cases with missing demographics and 52 cases with ambiguous responses on the perceived ease of transmission, 1663 complete cases were included in the analysis. In the United Kingdom, 2500 individuals were approached, and the response rate was 84.3% (2108/2500). After excluding cases with missing demographics or perceived severity and cases with ambiguous responses on the perceived ease of transmission, 1768 cases were included in the analysis.

Demographic Differences
There were significant differences in the sociodemographic characteristics of the study respondents between the two settings. Hong Kong respondents were younger, with 26.0% (433/1663) aged 18-24 years, compared with 9.4% (166/1768) for the United Kingdom (\( P < 0.001 \)) (Table 1).
Table 1. Characteristics of the study respondents in the United Kingdom and Hong Kong (all P values <.001 as determined by chi-square goodness-of-fit test).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>United Kingdom (n=1768)</th>
<th>Hong Kong (n=1663)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%) (unweighted)</td>
<td>% (weighted)</td>
</tr>
<tr>
<td></td>
<td>n (%) (unweighted)</td>
<td>% (weighted)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>166 (9.4)</td>
<td>433 (26.0)</td>
</tr>
<tr>
<td>25-34</td>
<td>243 (13.7)</td>
<td>535 (32.2)</td>
</tr>
<tr>
<td>35-44</td>
<td>335 (18.9)</td>
<td>370 (22.2)</td>
</tr>
<tr>
<td>45-54</td>
<td>300 (17.0)</td>
<td>193 (11.6)</td>
</tr>
<tr>
<td>≥55</td>
<td>724 (41.0)</td>
<td>132 (7.9)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>936 (52.9)</td>
<td>1141 (68.6)</td>
</tr>
<tr>
<td>Male</td>
<td>832 (47.1)</td>
<td>522 (31.4)</td>
</tr>
<tr>
<td><strong>Education attainment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No formal qualification/lower secondary or below</td>
<td>100 (5.7)</td>
<td>53 (3.2)</td>
</tr>
<tr>
<td>Secondary level qualification/higher secondary</td>
<td>738 (41.7)</td>
<td>292 (17.6)</td>
</tr>
<tr>
<td>Postsecondary but below degree</td>
<td>334 (18.9)</td>
<td>267 (16.1)</td>
</tr>
<tr>
<td>Degree or above</td>
<td>596 (33.7)</td>
<td>1051 (63.2)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employer/employee</td>
<td>1025 (58.0)</td>
<td>1135 (68.3)</td>
</tr>
<tr>
<td>Full-time student</td>
<td>90 (5.1)</td>
<td>278 (16.7)</td>
</tr>
<tr>
<td>Unemployed/not working</td>
<td>172 (9.7)</td>
<td>206 (12.4)</td>
</tr>
<tr>
<td>Retired</td>
<td>481 (27.2)</td>
<td>44 (2.6)</td>
</tr>
<tr>
<td><strong>Perceived severity</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 1</td>
<td>96 (5.4)</td>
<td>1071 (64.4)</td>
</tr>
<tr>
<td>Level 2</td>
<td>270 (15.3)</td>
<td>550 (33.1)</td>
</tr>
<tr>
<td>Level 3</td>
<td>1058 (59.8)</td>
<td>32 (1.9)</td>
</tr>
<tr>
<td>Level 4</td>
<td>320 (18.1)</td>
<td>7 (0.4)</td>
</tr>
<tr>
<td>Level 5</td>
<td>24 (1.4)</td>
<td>3 (0.2)</td>
</tr>
<tr>
<td><strong>Worry about COVID-19</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very worried</td>
<td>536 (30.3)</td>
<td>852 (51.2)</td>
</tr>
<tr>
<td>Fairly worried</td>
<td>858 (48.5)</td>
<td>723 (43.5)</td>
</tr>
<tr>
<td>Neutral/don’t know</td>
<td>5 (0.3)</td>
<td>40 (2.4)</td>
</tr>
<tr>
<td>Not very worried</td>
<td>295 (16.7)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Not at all worried</td>
<td>74 (4.2)</td>
<td>47 (2.8)</td>
</tr>
<tr>
<td><strong>Anxiety level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>956 (54.1)</td>
<td>586 (35.2)</td>
</tr>
<tr>
<td>Borderline abnormal</td>
<td>336 (19.0)</td>
<td>512 (30.8)</td>
</tr>
<tr>
<td>Abnormal</td>
<td>476 (26.9)</td>
<td>565 (34.0)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Level 1=very serious (Hong Kong)/life-threatening (United Kingdom); Level 2=serious (Hong Kong)/severe (eg, may need care and treatment in hospital) (United Kingdom); Level 3=neutral (Hong Kong)/moderate (eg, may need self-care and rest in bed) (United Kingdom); Level 4=not serious (Hong Kong)/mild (eg, can go about daily tasks normally) (United Kingdom); Level 5=not serious at all (Hong Kong)/no symptoms (United Kingdom).
The Hong Kong sample contained a greater proportion of women (Hong Kong: 1141/1663, 68.6%, vs United Kingdom: 936/1768, 52.9%; \( P < 0.01 \)), and respondents educated to university degree level or above (Hong Kong: 1051/1663, 63.2%, vs United Kingdom: 596/1768, 33.7%; \( P < 0.01 \)). Employment status reflected the age structure of the respondents in each setting, with a greater proportion of UK respondents in the retired category (Hong Kong: 44/1663, 2.6%, vs United Kingdom: 481/1768, 27.2%; \( P < 0.01 \)) (Table 1).

**Perceptions and Beliefs**

Higher perceived severity of COVID-19 was observed among Hong Kong respondents, with 96.8% (1621/1663) rating the symptoms of COVID-19 infection as serious or very serious compared with only 19.9% (366/1768) of the UK respondents. In terms of levels of concern, 92.6% (1575/1663) of the Hong Kong sample responded that they felt very or fairly worried, compared with 78.5% (1394/1768) of the UK sample. The HADS-A scores reflected similar trends, with 60.0% (1077/1663) of the Hong Kong sample recording an abnormal or borderline abnormal result, compared with 46.5% (812/1768) of the UK sample (Table 1).

**Knowledge and Information Sources**

The majority of respondents regarded direct contact with infected individuals (Hong Kong: 94.0%-98.5%; United Kingdom: 69.2%-93.5%) or virus-contaminated environments (Hong Kong: 1594/1663, 96.3%; United Kingdom: 1411/1768, 79.5%) as the primary means of virus transmission (Table 2). However, respondents from Hong Kong identified a far broader scope of transmission routes. A much larger proportion of Hong Kong respondents regarded wild animal meat (Hong Kong: 1546/1663, 93.4%; United Kingdom: 199/1768, 11.3%), wet markets (Hong Kong: 1342/1663, 81.1%; United Kingdom: 374/1768, 21.5%), imported seafood (Hong Kong: 1199/1663, 70.9%; United Kingdom: 258/1768, 14.8%) and imported goods (Hong Kong: 1101/1663, 66.6%; United Kingdom: 209/1768, 12.1%) as potential exposure sources than their UK counterparts. There was also significant variation across use and reliability of information sources (Table S1 in Multimedia Appendix 1). The majority of respondents deemed health professionals to be reliable (>80% in both Hong Kong and the United Kingdom); however, few could access them (Hong Kong: 86/1663, 4.8%; United Kingdom: 202/1768, 11.5%). In addition, most UK respondents (1602/1768, 90.7%) considered official websites to be reliable, compared to 15.6% (260/1663) among Hong Kong respondents at the beginning of the pandemic.
Table 2. Knowledge of COVID-19 transmission.

<table>
<thead>
<tr>
<th>“Are the following transmission routes of COVID-19?”</th>
<th>Respondents answering “yes”</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>United Kingdom (n=1768)</td>
<td>Hong Kong (n=1663)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>% (unweighted)</td>
<td>% (weighted)</td>
</tr>
<tr>
<td>Contact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face-to-face conversation (no physical contact)</td>
<td>1234</td>
<td>69.8</td>
<td>69.2</td>
</tr>
<tr>
<td>with someone who has SARS-CoV-2 but no symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face-to-face conversation (no physical contact)</td>
<td>1398</td>
<td>79.1</td>
<td>78.7</td>
</tr>
<tr>
<td>with someone who has SARS-CoV-2 with symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical contact with someone who has SARS-CoV-2</td>
<td>1580</td>
<td>89.4</td>
<td>89.0</td>
</tr>
<tr>
<td>but no symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical contact with someone with SARS-CoV-2</td>
<td>1657</td>
<td>93.7</td>
<td>93.5</td>
</tr>
<tr>
<td>who has symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transmission mode</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Droplets</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Aerosol when infected people cough or sneeze</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Being in close contact (ie, within 2 meters) with</td>
<td>1604</td>
<td>90.7</td>
<td>90.4</td>
</tr>
<tr>
<td>someone who has SARS-CoV-2 when they cough or</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sneeze</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Being further away (ie, further than 2 meters)</td>
<td>615</td>
<td>34.8</td>
<td>34.8</td>
</tr>
<tr>
<td>from someone who has SARS-CoV-2 when they cough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or sneeze</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact with virus-contaminated environment</td>
<td>1411</td>
<td>79.8</td>
<td>79.5</td>
</tr>
<tr>
<td>Consumption of wild animal meat</td>
<td>199</td>
<td>11.3</td>
<td>11.3</td>
</tr>
<tr>
<td>Visiting a wet market</td>
<td>374</td>
<td>21.2</td>
<td>21.5</td>
</tr>
<tr>
<td>Consumption of seafood imported from specific</td>
<td>258</td>
<td>14.6</td>
<td>14.8</td>
</tr>
<tr>
<td>regions⁠⁠b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumption/use of products imported from specific</td>
<td>209</td>
<td>11.8</td>
<td>12.1</td>
</tr>
<tr>
<td>regions⁠⁠b</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

⁠⁠aN/A: not applicable.
⁠⁠bSpecific regions refer to China (United Kingdom)/Wuhan (Hong Kong).

**Adoption of Social Distancing Measures**

There were variations in the weighted proportions of Hong Kong and the UK respondents who adopted precautionary measures against COVID-19 (Figure 1; Table S2 in Multimedia Appendix 1). Hong Kong respondents reported higher levels of adoption across all social distancing and personal hygiene measures. In particular, 98.8% (1647/1663) of Hong Kong respondents reported wearing a face mask, compared to 3.1% (53/1768) among the UK respondents. General measures were adopted by 63.1%-87.2% and 37.8%-59.0% of respondents in Hong Kong and the United Kingdom, respectively. Contact measures were adopted by 83.8%-93.7% and 33.7%-50.1% of respondents in Hong Kong and the United Kingdom, respectively. Work measures were reported by 32.6% (402/1135) and 22.5% (231/1025) of respondents in Hong Kong and the United Kingdom, respectively.
Figure 1. Adoption of precautionary measures against COVID-19. “Affected areas” refers to China (Hong Kong)/affected areas in the world (United Kingdom); “Specific regions in a limited period” refers to Wuhan in the past one month (Hong Kong)/affected areas in the past 14 days (United Kingdom). The “Going to work” category only included respondents who were employees or employers (n=2160), and the “Going to school/letting your children go to school” category only included respondents who were full-time students or had at least one child (n=1239).

Sociodemographic factors were associated with the three social distancing measures (Table S3 in Multimedia Appendix 1; Table 3). The UK respondents were significantly less likely than their Hong Kong counterparts to adopt social distancing measures (Table S3 in Multimedia Appendix 1, OR 0.08-0.53, P<.001; Table 3, aOR 0.08-0.70, P<.001). When adjusting for differences between settings, general measures were less likely to be adopted by male respondents (aOR 0.82; 95% CI 0.71-0.95) but more likely to be adopted by the unemployed (aOR 1.65; 95% CI 1.30-2.09) or retired (aOR 1.92; 95% CI 1.43-2.59). Contact measures were less likely to be adopted by male respondents (aOR 0.74; 95% CI:0.63-0.88) but more likely to be adopted by those who were retired (aOR 1.40; 95% CI 1.03-1.91). Finally, work measures were less likely to be adopted by respondents aged ≥55 years (aOR 0.60; 95% CI 0.39-0.93).
Table 3. Factors associated with the adoption of different social distancing measures.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Types of social distancing measures</th>
<th>General (n=3431) (Model 1)</th>
<th>Contact (n=3431) (Model 2)</th>
<th>Work (n=2160) (Model 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>aOR (95% CI)</td>
<td>aOR (95% CI)</td>
<td>aOR (95% CI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P value</td>
<td>P value</td>
<td>P value</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>25-34</td>
<td>1.54 (1.16-2.05)</td>
<td>.003</td>
<td>0.96 (0.68-1.35)</td>
<td>.81</td>
</tr>
<tr>
<td>35-44</td>
<td>1.25 (0.93-1.68)</td>
<td>.13</td>
<td>0.74 (0.53-1.05)</td>
<td>.09</td>
</tr>
<tr>
<td>45-54</td>
<td>1.30 (0.95-1.79)</td>
<td>.10</td>
<td>0.67 (0.47-0.97)</td>
<td>.03</td>
</tr>
<tr>
<td>55+</td>
<td>0.99 (0.70-1.41)</td>
<td>.97</td>
<td>0.81 (0.55-1.19)</td>
<td>.28</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Male</td>
<td>0.82 (0.71-0.95)</td>
<td>.01</td>
<td>0.74 (0.63-0.88)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Education attainment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No formal qualification/lower</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>secondary or below</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary level qualification</td>
<td>0.99 (0.68-1.44)</td>
<td>.96</td>
<td>0.96 (0.64-1.44)</td>
<td>.85</td>
</tr>
<tr>
<td>higher secondary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postsecondary but below degree</td>
<td>1.06 (0.72-1.55)</td>
<td>.78</td>
<td>1.12 (0.74-1.71)</td>
<td>.58</td>
</tr>
<tr>
<td>Degree or above</td>
<td>1.27 (0.87-1.83)</td>
<td>.21</td>
<td>0.98 (0.66-1.47)</td>
<td>.94</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
<td>N/A</td>
</tr>
<tr>
<td>Full-time student</td>
<td>1.35 (0.98-1.85)</td>
<td>.07</td>
<td>1.08 (0.73-1.59)</td>
<td>.70</td>
</tr>
<tr>
<td>Unemployed</td>
<td>1.65 (1.30-2.09)</td>
<td>&lt;.001</td>
<td>1.20 (0.91-1.58)</td>
<td>.20</td>
</tr>
<tr>
<td>Retired</td>
<td>1.92 (1.43-2.59)</td>
<td>&lt;.001</td>
<td>1.40 (1.03-1.91)</td>
<td>.03</td>
</tr>
<tr>
<td>Setting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>0.35 (0.30-0.41)</td>
<td>&lt;.001</td>
<td>0.08 (0.07-0.10)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*General: avoiding going to crowded areas; going to social events; and going out.

*Contact: avoiding contacting individuals who had a fever or respiratory symptoms and had been to Wuhan in the past month (Hong Kong)/affected areas in the past 14 days (United Kingdom).

*Work: avoiding going to work.

*aOR: adjusted odds ratio.

*N/A: not applicable.

The impact of perceived severity of infection (Table 4) and perceived ease of transmission (Table 5) on the adoption of social distancing behaviors varied by setting. In Hong Kong, these factors had no impact, whereas in the United Kingdom, those who perceived COVID-19 infection as serious were more likely to adopt all social distancing measures (aOR 1.58-3.01), and those who perceived transmission of SARS-CoV-2 as easy were more likely to adopt both general social distancing measures (Model 4.2, aOR 2.00, 95% CI 1.57-2.55) and contact measures (Model 5.2, aOR 1.80, 95% CI 1.41-2.30). On the other hand, the impact of anxiety on the adoption of social distancing behaviors did not significantly differ by setting (Table 6). Those with borderline abnormal (Hong Kong, aOR 1.26-1.62; United Kingdom, aOR 1.36-1.48) or abnormal (Hong Kong, aOR:1.82-2.09; United Kingdom, aOR:1.40-2.40) HADS-A scores were more likely to adopt all three types of social distancing measures compared to those with normal anxiety levels.
Table 4. Setting-specific effects and effect modification (by setting) of perceived severity on the adoption of social distancing measures. The models have been adjusted for all covariates.

<table>
<thead>
<tr>
<th>Settings and variables</th>
<th>Types of social distancing</th>
<th>Model 4.1</th>
<th>Model 5.1</th>
<th>Model 6.1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>General&lt;sup&gt;a&lt;/sup&gt; (n=3431)</td>
<td>aOR&lt;sup&gt;d&lt;/sup&gt; (95% CI)</td>
<td>P value</td>
<td>aOR (95% CI)</td>
</tr>
<tr>
<td>Hong Kong</td>
<td></td>
<td>N/A&lt;sup&gt;f&lt;/sup&gt;</td>
<td>Reference</td>
<td>N/A&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>Not serious&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td>0.93 (0.50-1.74)</td>
<td>.82</td>
<td>1.71 (0.85-3.47)</td>
</tr>
<tr>
<td>Serious&lt;sup&gt;e&lt;/sup&gt;</td>
<td></td>
<td>3.01 (2.35-3.86)</td>
<td>&lt;.001</td>
<td>1.90 (1.48-2.43)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td>3.24 (1.65-6.35)</td>
<td>&lt;.001</td>
<td>1.11 (0.52-2.34)</td>
</tr>
</tbody>
</table>

<sup>a</sup>General: avoiding going to crowded areas and social events and going out.
<sup>b</sup>Contact: avoiding contacting individuals who had a fever or respiratory symptoms and had been to Wuhan in the past one month (Hong Kong) or affected areas in the past 14 days (United Kingdom).
<sup>c</sup>Work: avoiding going to work.
<sup>d</sup>aOR: adjusted odds ratio.
<sup>e</sup>For perceived severity, “not serious” refers to levels 3-5 (neutral to not serious at all, Hong Kong; moderate to no symptoms, United Kingdom).
<sup>f</sup>N/A: not applicable.
<sup>g</sup>For perceived severity, “serious” refers to levels 1-2 (very serious to serious, Hong Kong; life-threatening to severe, United Kingdom).
<sup>h</sup>Measures the difference of the effect being considered due to difference in setting; its value is the ratio of the two setting-specific effects.
Table 5. Setting-specific effects and effect modification (by setting) of perceived ease of transmission on the adoption of social distancing measures. The models have been adjusted for all covariates.

<table>
<thead>
<tr>
<th>Settings and variables</th>
<th>Types of social distancing</th>
<th>Model 4.2</th>
<th>Model 5.2</th>
<th>Model 6.2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>General(^a) (n=3431)</td>
<td>aOR(^d) (95% CI)</td>
<td>P value</td>
<td>aOR (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Contact(^b) (n=3431)</td>
<td>aOR (95% CI)</td>
<td>P value</td>
<td>aOR (95% CI)</td>
</tr>
<tr>
<td></td>
<td>Work(^c) (n=2160)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>N/A</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>Easy</td>
<td>1.15 (0.77-1.74)</td>
<td>.50</td>
<td>1.00 (0.58-1.71)</td>
</tr>
<tr>
<td></td>
<td>Difficult</td>
<td>1.34 (0.96-1.87) &lt;.001</td>
<td></td>
<td>1.80 (1.41-2.30) &lt;.001</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>N/A</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
</tr>
<tr>
<td></td>
<td>Easy</td>
<td>2.00 (1.57-2.55) &lt;.001</td>
<td></td>
<td>1.81 (1.00-3.28) .05</td>
</tr>
<tr>
<td></td>
<td>Effect modification(^h)</td>
<td>1.73 (1.07-2.79) .02</td>
<td></td>
<td>2.18 (1.18-4.04) .01</td>
</tr>
</tbody>
</table>

\(^a\)General: avoiding going to crowded areas and social events and going out.

\(^b\)Contact: avoiding contacting individuals who had a fever or respiratory symptoms and had been to Wuhan in the past one month (Hong Kong) or affected areas in the past 14 days (United Kingdom).

\(^c\)Work: avoiding going to work.

\(^d\)aOR: adjusted odds ratio.

\(^e\)For perceived ease of transmission, “difficult” means that the virus cannot be transmitted by face-to-face conversation with someone who has SARS-CoV-2 but no symptoms.

\(^f\)N/A: not applicable.

\(^g\)For perceived ease of transmission, “easy” means that the virus can be transmitted by face-to-face conversation with someone who has SARS-CoV-2 but no symptoms.

\(^h\)Measures the difference of the effect being considered due to difference in setting; its value is the ratio of the two setting-specific effects.
Table 6. Setting-specific effects and effect modification (by setting) of anxiety level on the adoption of social distancing measures. The models have been adjusted for all covariates.

<table>
<thead>
<tr>
<th>Settings and variables</th>
<th>Types of social distancing</th>
<th>Model 4.3</th>
<th>Model 5.3</th>
<th>Model 6.3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>General(^a) (n=3431)</td>
<td>aOR(^d) (95% CI)</td>
<td>P value</td>
<td>aOR (95% CI)</td>
</tr>
<tr>
<td>Hong Kong</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>Reference</td>
<td>N/A(^e)</td>
<td>Reference</td>
<td>N/A</td>
</tr>
<tr>
<td>Borderline abnormal</td>
<td>1.62 (1.27-2.06)</td>
<td>&lt;.001</td>
<td>1.26 (0.93-1.70)</td>
<td>.14</td>
</tr>
<tr>
<td>Abnormal</td>
<td>2.09 (1.64-2.66)</td>
<td>&lt;.001</td>
<td>1.85 (1.34-2.56)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>Reference</td>
<td>N/A</td>
<td>Reference</td>
<td>N/A</td>
</tr>
<tr>
<td>Borderline abnormal</td>
<td>1.48 (1.11-1.96)</td>
<td>.01</td>
<td>1.36 (1.02-1.80)</td>
<td>.03</td>
</tr>
<tr>
<td>Abnormal</td>
<td>2.40 (1.87-3.09)</td>
<td>&lt;.001</td>
<td>1.76 (1.37-2.27)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Effect modification(^f) (borderline abnormal)</td>
<td>0.91 (0.63-1.33)</td>
<td>.64</td>
<td>1.08 (0.71-1.63)</td>
<td>.71</td>
</tr>
<tr>
<td>Effect modification (abnormal)</td>
<td>1.15 (0.82-1.62)</td>
<td>.42</td>
<td>0.95 (0.63-1.42)</td>
<td>.80</td>
</tr>
</tbody>
</table>

\(^a\)General: avoiding going to crowded areas and social events and going out.
\(^b\)Contact: avoiding contacting individuals who had a fever or respiratory symptoms and had been to Wuhan in the past one month (Hong Kong) or affected areas in the past 14 days (United Kingdom).
\(^c\)Work: avoiding going to work.
\(^d\)aOR: adjusted odds ratio.
\(^e\)N/A: not applicable.
\(^f\)Measures the difference of the effect being considered due to difference in setting; its value is the ratio of the two setting-specific effects.

Discussion

Principal Results

This study compared the initial public perceptions and preventative behaviors during the COVID-19 pandemic across Hong Kong and the United Kingdom. The adoption of social-distancing measures was higher in Hong Kong than in the United Kingdom. Risk perception and knowledge of COVID-19 were consistently and significantly higher in Hong Kong; however, for the United Kingdom, respondents' adoption of preventive behaviors was associated with two metrics: if transmission was considered to be “easy” and the perceived severity was “severe.” UK respondents were more likely to adopt preventive behaviors. Anxiety was a driver of behavior change in both settings: those who were more anxious were more likely to adopt preventative measures. This behavior is consistent with the wider literature surrounding the adoption of precautionary measures [6,7] and provides further evidence that anxiety drives protective behaviors, such as handwashing [8], an effective intervention against the transmission of respiratory diseases [28].

Implications

This study has three implications. First, health officials should account for context-specific baseline levels of risk perception and knowledge when designing and promoting mitigation strategies. The evidence presented in this study demonstrates that geographical and sociocultural context is important in terms of both how people understand risk and how risk drives behavior. Although the social, historical, and cultural heterogeneity between Hong Kong and the United Kingdom likely contributes to the results of this study, the importance of intrinsic factors such as population sensitization via past infectious disease outbreaks and state-led health promotion campaigns should not be underestimated. In other studies, public perceptions of these factors have been found to be significant drivers of adopting preventative behaviors during previous epidemics [29], while conceptions of personal risk have been connected to individuals’ understanding of local disease prevalence and severity [30-32]. Therefore, assessment of the baseline population knowledge, attitudes, and practices (KAP) and subsequent continual monitoring throughout the pandemic are essential to effective context-specific pandemic preparedness plans.

Second, risk communication should build upon baseline KAP outcomes, and trust should be developed across suitable media channels. Significant contextual heterogeneity in the public reliance on information sources provides insight here. Hong Kong reported greater reliance on social media and far less trust in official websites, suggesting that official messaging in Hong

https://www.jmir.org/2021/3/e23231
Kong did not likely drive individual behavior change; by contrast, the UK results suggested that although the UK government possessed an effective platform to influence public health behavior, government health messaging was insufficient to attain similar baseline knowledge levels to those in Hong Kong, particularly in the absence of prior population sensitization to infectious disease outbreaks. Therefore, there is a pressing need to tailor communication approaches, likely on a graduated scale, but at a minimum in a binary fashion to accommodate both “naïve” and “experienced” populations.

Third, the comparative snapshots of initial community responses captured by this study demonstrate the diversity in approaches and pandemic responses during the early phases of the COVID-19 pandemic. Across many contexts, national lockdowns became commonplace as the true magnitude of transmission became apparent; however, the associated indirect costs render blanket strategies untenable in the medium term. As national lockdowns are lifted, countries worldwide face the challenge of resuming cases and must consider nuanced approaches to prevent additional harm. Driven by anxiety, high perceived severity and knowledge, Hong Kong conducted widespread preventive measures early and en masse. Together with early government actions [33], the strategies adopted by the Hong Kong community were successful during the initial phase of the pandemic. Considering this—and that national populations are now highly sensitized to COVID-19 transmission—tailored public health messaging, early regional containment, and increased health capacity should ensure more effective public health responses with less indirect impact on national economies.

**Study Strengths and Limitations**

From a methodological perspective, the UK sampling approach enabled the sample size to be achieved quickly, thereby accurately capturing prevailing sentiment and behavior across a short time frame (2 days). However, this approach likely came at the expense of excluding participants without access to the internet, and it contrasted with the survey period in Hong Kong (3 weeks); this likely led to some sampling bias, especially during the initial phase of the pandemic (when there was much uncertainty about the disease). Additionally, both samples varied across the demographic spectrum; thus, although responses were weighted, caution should be taken when extrapolating study findings to wider populations. Moreover, given the incompatibility of region-specific weights and the controversy in estimating standard errors when survey weights are involved [34], unweighted regression results were presented; however, they should be interpreted with caution. Last but not least, although both surveys were conducted early locally, the difference in surrounding international events during the survey periods (eg, the Hong Kong survey was conducted before COVID-19 was formally declared a pandemic, but the UK survey was launched after this declaration) may have introduced bias in the survey responses.

**Conclusions**

This study compared the initial community responses to COVID-19 in Hong Kong and the United Kingdom. In line with the high baseline level of risk perception and knowledge and with historical exposure to respiratory disease outbreaks, the adoption of preventive measures was higher in Hong Kong. However, the UK sample demonstrated that this adoption could be improved by heightened risk perception and knowledge, best driven by improved public health campaigns. Together, these results suggest that health officials should ascertain baseline levels of risk perception and knowledge, as well as prior sensitization to infectious disease outbreaks, when developing mitigation strategies. Risk communication should be performed through suitable media channels—and trust should be maintained—while early intervention remains the cornerstone of effective outbreak response.

**Acknowledgments**

The study was supported by Imperial NIHR Research Capability Funding and the internal funding of The Chinese University of Hong Kong. HW is a National Institute for Health Research (NIHR) Senior Investigator and receives funding from the Imperial NIHR Biomedical Research Centre, the NIHR Applied Research Collaborative North West London, the NIHR School for Public Health Research, and the Wellcome Trust. KOK would like to acknowledge the Research Fund for the Control of Infectious Diseases, Hong Kong (number:INF-CUHK-1); General Research Fund (number:14112818); Early Career Scheme (number:24104920); Health and Medical Research Fund (numbers:17160302, 18170312); The Wellcome Trust (number: 200861/Z/16/Z); and a Direct Grant for Research of The Chinese University of Hong Kong (CUHK) (number: 2019.020).

**Authors' Contributions**

LRB, KOK, HW, CA, and SYSW conceived the study; KOK, WIW, and CA collected the data; KOK, YYY, and WIW analyzed the data; LRB, KOK, RER, HW, WIW, CA, and SYSW interpreted the data; LRB wrote the first draft of the manuscript; and KOK, RER, YYY, HW, WTW, CA, and SYSW edited the manuscript. LRB and KOK contributed equally as the joint first author. CA and SYSW also contributed equally as the joint last author. KOK and CA also contributed equally as the joint corresponding author.

**Conflicts of Interest**

None declared.

Multimedia Appendix 1
References


15. Clements JM. Knowledge and behaviors toward COVID-19 among US residents during the early days of the pandemic: cross-sectional online questionnaire. JMIR Public Health Surveill 2020 May 08;6(2):e19161 [FREE Full text] [doi: 10.2196/19161] [Medline: 32369759]


Abbreviations
aOR: adjusted odds ratio
HASD-A: Hospital Anxiety and Depression scale–Anxiety
KAP: knowledge, attitudes, and practices

©Leigh Bowman, Kin On Kwok, Rozlyn Redd, Yuanyuan Yi, Helen Ward, Wan In Wei, Christina Atchison, Samuel Yeung-Shan Wong. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 08.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
A Comprehensive Overview of the COVID-19 Literature: Machine Learning–Based Bibliometric Analysis

Alaa Abd-Alrazaq¹, PhD; Jens Schneider¹, PhD; Borbala Mifsud², PhD; Tanvir Alam¹, PhD; Mowafa Househ¹, PhD; Mounir Hamdi¹, PhD; Zubair Shah¹, PhD

¹Division of Information and Computing Technology, College of Science and Engineering, Hamad Bin Khalifa University, Qatar Foundation, Doha, Qatar
²College of Health and Life Sciences, Hamad Bin Khalifa University, Qatar Foundation, Doha, Qatar

Corresponding Author:
Zubair Shah, PhD
Division of Information and Computing Technology, College of Science and Engineering
Hamad Bin Khalifa University
Qatar Foundation
P.O. Box 5825, Doha Al Luqta St, Ar-Rayyan
Doha, 00000 Qatar
Phone: 974 55708549
Email: zshah@hbku.edu.qa

Abstract

Background: Shortly after the emergence of COVID-19, researchers rapidly mobilized to study numerous aspects of the disease such as its evolution, clinical manifestations, effects, treatments, and vaccinations. This led to a rapid increase in the number of COVID-19–related publications. Identifying trends and areas of interest using traditional review methods (eg, scoping and systematic reviews) for such a large domain area is challenging.

Objective: We aimed to conduct an extensive bibliometric analysis to provide a comprehensive overview of the COVID-19 literature.

Methods: We used the COVID-19 Open Research Dataset (CORD-19) that consists of a large number of research articles related to all coronaviruses. We used a machine learning–based method to analyze the most relevant COVID-19–related articles and extracted the most prominent topics. Specifically, we used a clustering algorithm to group published articles based on the similarity of their abstracts to identify research hotspots and current research directions. We have made our software accessible to the community via GitHub.

Results: Of the 196,630 publications retrieved from the database, we included 28,904 in our analysis. The mean number of weekly publications was 990 (SD 789.3). The country that published the highest number of COVID-19–related articles was China (2950/17,270, 17.08%). The highest number of articles were published in bioRxiv. Lei Liu affiliated with the Southern University of Science and Technology in China published the highest number of articles (n=46). Based on titles and abstracts alone, we were able to identify 1515 surveys, 733 systematic reviews, 512 cohort studies, 480 meta-analyses, and 362 randomized control trials. We identified 19 different topics covered among the publications reviewed. The most dominant topic was public health response, followed by clinical care practices during the COVID-19 pandemic, clinical characteristics and risk factors, and epidemic models for its spread.

Conclusions: We provide an overview of the COVID-19 literature and have identified current hotspots and research directions. Our findings can be useful for the research community to help prioritize research needs and recognize leading COVID-19 researchers, institutes, countries, and publishers. Our study shows that an AI-based bibliometric analysis has the potential to rapidly explore a large corpus of academic publications during a public health crisis. We believe that this work can be used to analyze other eHealth-related literature to help clinicians, administrators, and policy makers to obtain a holistic view of the literature and be able to categorize different topics of the existing research for further analyses. It can be further scaled (for instance, in time) to clinical summary documentation. Publishers should avoid noise in the data by developing a way to trace the evolution of individual publications and unique authors.

(J Med Internet Res 2021;23(3):e23703) doi:10.2196/23703
Introduction

Background
In December 2019, Wuhan city in China registered several cases of an unknown disease characterized by pneumonia, dry cough, fatigue, and fever [1]. The investigations revealed that a novel coronavirus (2019-nCoV) was the causative agent of the disease, which was subsequently named COVID-19 [1]. Since then, COVID-19 has spread around the globe, leading the World Health Organization to classify it as a pandemic [2]. This highly contagious pathogen has affected almost every aspect of our daily lives, such as education, traveling, business, transportation, sports, and health care [3]. Most importantly, the COVID-19 pandemic has claimed more than 775,000 lives as of August 19, 2020 [4]. To curb the impact of COVID-19, authorities need to implement effective public health measures related to COVID-19 surveillance, diagnostics, vaccines, treatments, and research [5].

Given the novelty and, consequently, the lack of knowledge about the disease, research can play a crucial role in the fight against the COVID-19 pandemic. Scientists have rapidly mobilized to manage and slowdown the growth of the pandemic. The scientific literature in this domain area has exponentially increased [6,7]. By the end of May 2020, Arisotivnik et al [6] and Doanvo et al [8] retrieved 10,344 and 18,412 COVID-19–related publications written in the English language, respectively, from the Scopus database and the COVID-19 Open Research Dataset (CORD-19). In addition, as of July 13, 2020, more than 1711 clinical trials were registered in different clinical trial registries (eg, NCT, EUCTR, and ISRCTN) [9].

It is very important to have a comprehensive overview of the current state of the literature on COVID-19 for several reasons, namely: (1) to organize and coordinate the literature; (2) to explore research topics addressed; (3) to prioritize research needs or gaps; (4) to understand the evolution of the literature; (5) to recognize the leading researchers, institutes, and countries in this area; and (6) to explore connections between research topics and areas.

Research Problem and Aim
Manually conducting a comprehensive review of the thousands of COVID-19–related publications is a daunting and time-consuming task. Artificial intelligence (AI) methods can play a pivotal role in rapidly surveying the enormous number of publications and extracting critical insights from them. Therefore, in March 2020, the White House strongly recommended researchers to exploit AI methods in COVID-19 research [8].

Several studies have used AI methods to conduct a bibliometric analysis of research on the COVID-19 pandemic [6-8,10-12]. However, we identified the following research gaps in these studies. First, publications analyzed in most studies were dated, approximately to the first three months after the onset of the COVID-19 outbreak; thus, numerous studies published afterward were not analyzed [7,10-16]. Second, several studies analyzed publications related to all types of coronaviruses instead of focusing on COVID-19 [7,10-12,17,18]; hence, the results related to COVID-19 were aggregated with those related to other coronaviruses. Third, several studies included only a few (ranging from 38 to 1482) of the large number of publications related to COVID-19 available in the search period [7,10,12-16,19]. Fourth, most studies did not examine the topics that previous studies had addressed, instead they assessed only the metadata of those studies (eg, countries, authors, number of citations, and published journals) [13,14,16-19]. Fifth, topic identification among various studies was conducted using manual screening instead of AI methods [13-15]. To fill the abovementioned gaps, this study aims to conduct an extensive bibliometric analysis to provide a comprehensive overview of the existing COVID-19 literature.

Methods

Study Data Collection
For this study, we used CORD-19, generated by the Allen Institute for AI [20]. The dataset is updated daily to include the latest published articles on COVID-19. We used the update corresponding to the timestamp of July 21, 2020, which contained over 196,630 scholarly articles related to COVID-19 and the coronavirus family of viruses. Allen Institute for AI used the following search terms to retrieve studies on all coronaviruses: “COVID-19” OR “Coronavirus” OR “Corona virus” OR “2019-nCoV” OR “SARS-CoV” OR “MERS-CoV” OR “Severe Acute Respiratory Syndrome” OR “Middle East Respiratory Syndrome”. The search was conducted on PubMed, PubMed Central, and bioRxiv and medRxiv preprint servers. The dataset included a CSV (comma-separate values) file with metadata of all the articles in the dataset, such as article ID, title, abstract, names of authors, and publication date. The articles in the dataset were represented by a single JSON (JavaScript Object Notation) file that consisted of the article ID, title, abstract, body text, and relevant metadata. The metadata of the dataset was analyzed using Python in a Jupyter Notebook environment. We have made our software accessible to the community via GitHub [21]. The CSV metadata file was loaded into a data frame provided by Python’s pandas library. We removed records with empty and non-English abstracts. We also removed duplicate articles and any articles that were published before January 1, 2020. We then used the search terms “novel coronavirus,” “coronavirus 2019,” “2019-nCoV,” “COVID-19,” “COVID 2019,” “severe acute respiratory syndrome coronavirus 2,” and “SARS-COV-2” to select only COVID-19–related articles. Thus, we were able to identify a total of 28,904 abstracts of scholarly articles published after January 1, 2020, that were related to COVID-19 for the downstream analysis.
Data Preprocessing
The 28,904 selected abstracts were cleaned by removing punctuations and alphanumeric characters. Singular and plural uppercased abstract sectioning keywords such as “BACKGROUND,” “OBJECTIVE,” “METHOD,” “RESULT,” and “CONCLUSION” were also removed. The data cleaning was performed using Python programming language in Jupyter Notebook environment. The Python libraries used to clean the data include pandas, NumPy, langdetect, re, string, and TextBlob. The abstracts were then converted to lowercased text.
After that, we used the Python Natural Language Toolkit library to tokenize the abstracts and remove the stop words. We then applied the SnowballStemmer model to convert words to their stems. The clean text of the abstracts derived after applying the abovementioned pre-processing steps was used for clustering.

Document Clustering
For document clustering, we first converted each document (ie, abstract) to a feature vector, where features were defined by term (ie, words) frequency–inverse document frequency (TF-IDF) weights. TF-IDF represents the importance of a word relative to a document in a corpus. This importance increases proportionally to the number of times the word appears in the document but is offset by the frequency of that word in the corpus. This ensures that TF-IDF–based similarity measures between documents are influenced mainly by discriminative words with relatively low frequencies in the corpus [22]. For TF-IDF representation of the abstracts, we used TfidfVectorizer module of the Python scikit library.

The TfidfVectorizer algorithm has two important threshold parameters that cut off low and high word frequencies. The minimum document frequency parameter (min_df) was set to 10 to ignore sporadic terms occurring in less than 10 documents (absolute count). The maximum document frequency parameter (max_df) was set to 0.9 to ignore terms that appear in more than 90% (26,014/28,904) of the documents (relative count). The reason is that we wished to exclude terms that are either too rare to be used in finding document clusters or too common to be discriminative enough to distinguish documents. Based on these parameters (min_df and max_df), the TfidfVectorizer algorithm extracted a vector of 42,061 unique terms to represent each of the 28,904 abstracts, with each term containing a TF-IDF score. This generated a feature matrix of size 28,904x42,061, which was, subsequently, used to feed into a clustering algorithm. We used the k-means clustering algorithm from Python’s scikit library to categorize the abstracts into internally coherent but well-separated clusters. To identify the number of clusters in the k-means clustering algorithm, we used the elbow method to determine the number of clusters in the corpus [23]. Thus, we found 26 to be the optimal number of clusters for this corpus.

Results
Search Results
By July 21, 2020, the CORD-19 dataset comprised 196,630 articles (Figure 1). Of those, we excluded 167,726 articles for the following reasons: (1) abstracts were unavailable (n=56,300); (2) the articles were published before January 1, 2020 (n=99,665); (3) the articles were written in a language other than English (n=587); (4) the articles were not related to COVID-19, as their titles and abstracts did not contain our search terms (n=10,364); and (5) they had duplicate entries (n=810). Consequently, we included 28,904 articles in the analysis in this study.
Characteristics of Publications

The first paper was published on January 2, 2020. As shown in Figure 2, the number of publications in each week increased considerably since then, until a peak was reached in week 22 (2276 publications). Thereafter, the number of research papers published began to decrease. The mean number of publications for each week was 990 (SD 789.3). The country of publication was identified for 17,270 publications, which were conducted across 221 countries and territories. The country that published the highest number of articles was China (2950/17,270, 17.08%), followed by the United States (1357/17,270, 7.86%), Italy (1157/17,270, 6.70%), Saudi Arabia (978/17,270, 5.66%), and India (854/17,270, 4.94%) (Table 1).

The selected articles were published in about 2500 journals. The highest number of articles were published in bioRxiv (n=1374), the most prominent preprint server for biology. The top 10 sites for publishing COVID-19–related articles (journals
and preprint servers) are shown in Table 2. The publications included in this analysis were authored by 150,600 authors. Among those authors, Lei Liu published the highest number of articles (n=46; see Table 3). Based on titles and abstracts alone, we were able to identify 1515 surveys, 733 systematic reviews, 512 cohort studies, 480 meta-analyses, 362 randomized control trials, 199 case studies, 79 scoping reviews, and 62 case-control studies (Table 4). Note that these numbers include only the top 8 study methods for those publications that mention the study method in either the abstract or the title.

Figure 2. Number of publications in each week (2020).

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Publications, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>China</td>
<td>2950 (17.08)</td>
</tr>
<tr>
<td>2</td>
<td>United States</td>
<td>1357 (7.86)</td>
</tr>
<tr>
<td>3</td>
<td>Italy</td>
<td>1157 (6.70)</td>
</tr>
<tr>
<td>4</td>
<td>Saudi Arabia</td>
<td>978 (5.66)</td>
</tr>
<tr>
<td>5</td>
<td>India</td>
<td>854 (4.94)</td>
</tr>
<tr>
<td>6</td>
<td>Canada</td>
<td>671 (3.89)</td>
</tr>
<tr>
<td>7</td>
<td>United Kingdom</td>
<td>525 (3.04)</td>
</tr>
<tr>
<td>8</td>
<td>Germany</td>
<td>449 (2.60)</td>
</tr>
<tr>
<td>9</td>
<td>Australia</td>
<td>403 (2.33)</td>
</tr>
<tr>
<td>10</td>
<td>France</td>
<td>383 (2.22)</td>
</tr>
</tbody>
</table>
Table 2. Top 10 sites (journals and preprint servers) where COVID-19–related articles (N=28,904) were published.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Journal or server</th>
<th>Publications, n (%), n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>bioRxiv</td>
<td>1374 (4.75)</td>
</tr>
<tr>
<td>2</td>
<td>Journal of Medical Virology</td>
<td>468 (1.6)</td>
</tr>
<tr>
<td>3</td>
<td>medRxiv</td>
<td>340 (1.18)</td>
</tr>
<tr>
<td>4</td>
<td>International Journal of Environmental Research and Public Health</td>
<td>223 (0.77)</td>
</tr>
<tr>
<td>5</td>
<td>Clinical Infectious Diseases</td>
<td>195 (0.67)</td>
</tr>
<tr>
<td>6</td>
<td>International Journal of Infectious Diseases</td>
<td>184 (0.64)</td>
</tr>
<tr>
<td>7</td>
<td>Science of the Total Environment</td>
<td>165 (0.57)</td>
</tr>
<tr>
<td>8</td>
<td>Cureus</td>
<td>148 (0.51)</td>
</tr>
<tr>
<td>9</td>
<td>Psychological Trauma: Theory, Research, Practice, and Policy</td>
<td>138 (0.48)</td>
</tr>
<tr>
<td>10</td>
<td>Medical Hypotheses</td>
<td>136 (0.47)</td>
</tr>
</tbody>
</table>

Table 3. Top 10 authors (N=15,600) by the number of COVID-19–related publications.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Author name</th>
<th>Publications, n</th>
<th>Author affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lei Liu</td>
<td>46</td>
<td>Southern University of Science and Technology, China</td>
</tr>
<tr>
<td>2</td>
<td>Kwok-Yung Yuen</td>
<td>34</td>
<td>The University of Hong Kong, China</td>
</tr>
<tr>
<td>3</td>
<td>Christian Drosten</td>
<td>31</td>
<td>Charité University Medicine Berlin, Germany</td>
</tr>
<tr>
<td>4</td>
<td>Ralph S Baric</td>
<td>31</td>
<td>University of North Carolina at Chapel Hill, USA</td>
</tr>
<tr>
<td>5</td>
<td>Gerardo Chowell</td>
<td>30</td>
<td>Georgia State University, USA</td>
</tr>
<tr>
<td>6</td>
<td>Hongzhou Lu</td>
<td>30</td>
<td>Fudan University, Shanghai, China</td>
</tr>
<tr>
<td>7</td>
<td>Giuseppe Lippi</td>
<td>29</td>
<td>University of Verona, Italy</td>
</tr>
<tr>
<td>8</td>
<td>Jasper Fuk-Wo Chan</td>
<td>27</td>
<td>The University of Hong Kong, China</td>
</tr>
<tr>
<td>9</td>
<td>Kelvin Kai-Wang To</td>
<td>25</td>
<td>The University of Hong Kong, China</td>
</tr>
<tr>
<td>10</td>
<td>Valerie A Canady</td>
<td>23</td>
<td>Mental Health Weekly, USA</td>
</tr>
</tbody>
</table>

Table 4. Eight most common study methods extracted from the publications mentioning the study design used in the abstract.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Study method</th>
<th>Publications, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Survey</td>
<td>1515</td>
</tr>
<tr>
<td>2</td>
<td>Systematic review</td>
<td>733</td>
</tr>
<tr>
<td>3</td>
<td>Cohort study</td>
<td>512</td>
</tr>
<tr>
<td>4</td>
<td>Meta-analysis</td>
<td>480</td>
</tr>
<tr>
<td>5</td>
<td>Randomized control trial</td>
<td>362</td>
</tr>
<tr>
<td>6</td>
<td>Case study</td>
<td>199</td>
</tr>
<tr>
<td>7</td>
<td>Scoping review</td>
<td>79</td>
</tr>
<tr>
<td>8</td>
<td>Case-control study</td>
<td>62</td>
</tr>
</tbody>
</table>

Results of Topics Modelling

Overview

The analysis generated 26 clusters from the included publications. We were able to identify the topic of 21 clusters, whereas the remaining 5 clusters were not labeled as they contained publications with very diverse topics that belonged to other clusters. Therefore, publications in these 5 clusters were moved to the most appropriate cluster among the 21 clusters. Four of the 21 clusters contained publications addressing only two different topics; thus, we further merged the 4 clusters to form 2 different clusters. Overall, we identified 19 different topics addressed in the included publications (Table 5).
Table 5. COVID-19–related topics addressed by the included publications (N=28,904).

<table>
<thead>
<tr>
<th>Number</th>
<th>Topic</th>
<th>Articles, n (%)</th>
<th>Top 20 unigrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Public health response</td>
<td>5393 (18.66)</td>
<td>covid, pandemic, health, coronavirus, disease, public, data, world, spread, social, study, global, outbreak, countries, cases, measures, virus, sars, results, people</td>
</tr>
<tr>
<td>2</td>
<td>Clinical care practices for patients during the COVID-19 pandemic</td>
<td>5118 (17.71)</td>
<td>covid, pandemic, patients, care, disease, coronavirus, health, patient, infection, risk, healthcare, clinical, sars, cov, management, medical, respiratory, hospital, cases, acute</td>
</tr>
<tr>
<td>3</td>
<td>Clinical characteristics and risk factors of COVID-19</td>
<td>3313 (11.46)</td>
<td>covid, patients, disease, coronavirus, severe, clinical, study, results, age, data, risk, respiratory, hospital, sars, infection, cov, cases, acute, mortality, higher</td>
</tr>
<tr>
<td>4</td>
<td>Epidemic models for COVID-19 spread</td>
<td>2964 (10.25)</td>
<td>covid, model, data, cases, number, epidemic, disease, time, results, spread, pandemic, coronavirus, based, countries, infected, infection, rate, study, measures, outbreak</td>
</tr>
<tr>
<td>5</td>
<td>Therapies and vaccines for COVID-19</td>
<td>1845 (6.38)</td>
<td>sars, cov, covid, drug, coronavirus, drugs, viral, antiviral, virus, potential, disease, pandemic, respiratory, treatment, protease, molecular, compounds, severe, based, inhibitors</td>
</tr>
<tr>
<td>6</td>
<td>Host immune response</td>
<td>1837 (6.36)</td>
<td>covid, cov, sars, disease, coronavirus, infection, severe, respiratory, patients, acute, syndrome, immune, viral, cells, virus, clinical, inflammatory, response, pandemic, cell, cytokine</td>
</tr>
<tr>
<td>7</td>
<td>Diagnosis of COVID-19 using PCR(^a)</td>
<td>1602 (5.54)</td>
<td>cov, sars, covid, pcr, positive, coronavirus, testing, respiratory, results, patients, rt, disease, infection, detection, samples, test, clinical, viral, time, negative</td>
</tr>
<tr>
<td>8</td>
<td>Mental health and disorders during the COVID-19 pandemic</td>
<td>915 (3.17)</td>
<td>covid, health, mental, pandemic, anxiety, psychological, study, coronavirus, stress, depression, results, social, disease, risk, impact, related, people, survey, symptoms, outbreak</td>
</tr>
<tr>
<td>9</td>
<td>Diagnosis of COVID-19 based on chest imaging</td>
<td>874 (3.02)</td>
<td>covid, ct, patients, chest, disease, coronavirus, pneumonia, clinical, diagnosis, results, imaging, findings, lung, cases, ground, glass, tomography, computed, features, images</td>
</tr>
<tr>
<td>10</td>
<td>Social distancing measures</td>
<td>868 (3)</td>
<td>covid, social, distancing, pandemic, measures, spread, contact, disease, data, health, model, number, transmission, cases, control, population, coronavirus, time, tracing, public</td>
</tr>
<tr>
<td>11</td>
<td>Virus genomics</td>
<td>816 (2.82)</td>
<td>sars, cov, coronavirus, virus, genome, cov, viral, analysis, sequences, respiratory, severe, pandemic, human, disease, sequence, acute, syndrome, genomes, china, study</td>
</tr>
<tr>
<td>12</td>
<td>Protein structures of 2019-nCoV(^b)</td>
<td>706 (2.44)</td>
<td>cov, sars, spike, protein, binding, coronavirus, cov, receptor, virus, human, viral, pandemic, ace, domain, cell, vaccine, infection, disease, host, development</td>
</tr>
<tr>
<td>13</td>
<td>Host cell entry</td>
<td>584 (2.02)</td>
<td>ace, sars, cov, covid, angiotensin, enzyme, converting, receptor, coronavirus, disease, infection, expression, respiratory, cells, severe, human, syndrome, entry, cell, virus</td>
</tr>
<tr>
<td>14</td>
<td>Clinical care practices for patients with cancer</td>
<td>441 (1.53)</td>
<td>cancer, covid, patients, pandemic, treatment, risk, care, disease, coronavirus, infection, health, clinical, patient, management, cov, sars, severe, therapy, high, oncology</td>
</tr>
<tr>
<td>15</td>
<td>Detection of 2019-nCoV antibodies</td>
<td>411 (1.42)</td>
<td>cov, sars, igg, covid, antibodies, patients, antibody, igm, infection, results, positive, disease, coronavirus, samples, study, test, assay, serological, sensitivity, clinical</td>
</tr>
<tr>
<td>16</td>
<td>Personal protective equipment</td>
<td>350 (1.21)</td>
<td>covid, masks, mask, pandemic, protective, equipment, face, personal, respirators, health, coronavirus, healthcare, workers, sars, cov, respiratory, surgical, disease, study,ppe</td>
</tr>
<tr>
<td>17</td>
<td>Diabetes mellitus and COVID-19</td>
<td>336 (1.16)</td>
<td>covid, pandemic, patients, diabetes, disease, care, risk, coronavirus, health, nursing, nurses, infection, management, severe, results, data, study, clinical, high, methods</td>
</tr>
<tr>
<td>18</td>
<td>Pregnancy and childbirth during the COVID-19 pandemic</td>
<td>312 (1.08)</td>
<td>women, pregnant, cov, pregnancy, infection, sars, coronavirus, cov, disease, severe, clinical, maternal, patients, cases, data, transmission, respiratory, pandemic, delivery, results</td>
</tr>
<tr>
<td>19</td>
<td>Organ transplantation during the COVID-19 pandemic</td>
<td>219 (0.76)</td>
<td>covid, transplant, recipients, patients, disease, coronavirus, pandemic, cov, sars, infection, transplantation, kidney, severe, organ, clinical, risk, respiratory, acute, liver, patient</td>
</tr>
</tbody>
</table>

\(^a\)PCR: polymerase chain reaction.

\(^b\)2019-nCoV: novel coronavirus.

**Topic 1: Public Health Response**

This topic was addressed by 18.66% (5393/28,904) of the publications. The publications in this cluster mainly discussed how public health authorities in various countries responded to the COVID-19 pandemic (eg, [24-28]). The top 5 authors in terms of the highest number of publications related to this topic were Claudine McCarthy (n=8), Valerie A Canady (n=6), Alison Knopf (n=6), Alimuddin Zumla (n=6), and Nima Rezaei (n=6). The top 5 journals and preprint servers hosting the highest number of publishing articles related to this topic were the International Journal of Environmental Research and Public Health.
Health (n=82), Science of the Total Environment (n=80), New Scientist (n=56), Journal of Medical Virology (n=53), and bioRxiv (n=50). The first paper related to this topic was published on January 10, 2020. The number of publications in each week increased significantly until it reached a peak in week 23 (n=434); it then decreased noticeably (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 183.6 (SD 151.5).

**Topic 2: Clinical Care Practices During the COVID-19 Pandemic**

A total of 17.71% (5118/28,904) of all included publications were mainly about clinical care practices for non–COVID-19 patients during the COVID-19 pandemic (eg, [29-33]). The following authors published the highest number of publications related to this topic: Karthik Rajasekaran (n=14), Francesco Esperto (n=12), Raju Vaishya (n=9), Namrata Sharma (n=8), and Santosh G Honavar (n=8). The top 5 journals publishing articles related to this topic were Otologyrhinology-Head and Neck Surgery (n=115), the Journal of the European Academy of Dermatology and Venereology (n=45), Cureus Journal of Medical Science (n=41), Anaesthesia (n=40), and World Neurosurgery (n=35). In this cluster, the first article was published on January 3, 2020. There was a considerable rise in the number of weekly publications from week 12 until it reached a peak in week 23 (n=479); this was followed by a sharp decrease (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 175.2 (SD 159.6).

**Topic 3: Clinical Characteristics and Risk Factors of COVID-19**

This topic was discussed in 11.46% (3313/28,904) of the publications (eg, [34-38]). The top 5 authors who published the highest number of publications in this cluster were Lei Liu (n=25), Lanjuan Li (n=13), Jifang Sheng (n=10), Giuseppe Lippi (n=9), and Nanshan Zhong (n=9). The top 5 journals and preprint servers publishing articles related to this topic were the Journal of Medical Virology (n=109), medRxiv (n=57), Cureus Journal of Medical Science (n=35), Clinical Infectious Diseases (n=33), and the International Journal of Infectious Diseases (n=32). The first article related to this topic was published on January 17, 2020. The mean number of weekly publications in this cluster was 113.7 (SD 98.9), and the highest number of weekly publications was 266 in week 20 (Multimedia Appendix 1).

**Topic 4: Epidemic Models for COVID-19 Spread**

A total of 10.25% (2964/28,904) of the included publications were related to this topic (eg, [39-43]). The 5 most prominent authors in this cluster were Gerardo Chowell (n=22), Benjamin J Cowling (n=18), Kenji Mizumoto (n=14), Shi Zhao (n=13), and Rosalind M Eggo (n=13). The most common journals and preprint servers where the articles related to this topic were published included Chaos, Solitons & Fractals (n=73), medRxiv (n=66), the International Journal of Infectious Diseases (n=36), Zhonghua liuxingbingxue zazhi (n=30), and bioRxiv (n=26). The first paper related to this topic was published on the January 19, 2020. Although there was a sharp increase in the number of weekly publications between weeks 12 and 15, the trend was almost stable from week 15 to week 22. Then, a rapid decline in the number of weekly publications was noticed (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 101.6 (SD 68.2).

**Topic 5: Therapies and Vaccines for COVID-19**

In all, 6.38% (1845/28,904) of the publications were about the development and repurposing of therapies and vaccines for COVID-19 (eg, [44-47]). The following authors published the highest number of articles related to this topic: Wei Zhang (n=13), Xiuna Yang (n=9), Haitao Yang (n=9), Zhe Rao (n=9), and Yao Zhao (n=8). The journals and preprint servers publishing the highest number of studies in this cluster were bioRxiv (n=174), the Journal of Biomolecular Structure and Dynamics (n=74), Trials (n=49), the Journal of Medical Virology (n=20), and Clinical Pharmacology & Therapeutics (n=14). In this cluster, the first article was published on January 6, 2020. The number of weekly publications increased dramatically from week 14 until a peak was reached in week 22 (n=144); thereafter, it decreased noticeably (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 62.9 (SD 52.3).

**Topic 6: Host Immune Response to 19-nCoV**

This topic was discussed in about 6.36% (1837/28,904) of the publications (eg, [48-52]). Authors who had the highest number of publications related to this topic were Alessandro Sette (n=7), Stanley Perlman (n=6), Nima Rezaei (n=6), Ifran Rahman (n=5), and Akiko Iwasaki (n=6). The top 5 journals and preprint servers in terms of publishing articles related to this topic were bioRxiv (n=199), Medical Hypotheses (n=50), the Journal of Medical Virology (n=49), Frontiers in Immunology (n=22), and the British Journal of Haematology (n=19). The earliest article related to this topic was published on January 2, 2020. From that date until week 14, there was a slight increase in the number of weekly publications before it increased markedly, peaking in week 25 (n=155) (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 62.8 (SD 54.6).

**Topic 7: Diagnosis of COVID-19 Using Polymerase Chain Reaction**

Using polymerase chain reaction (PCR) for diagnosing COVID-19 was a key topic discussed in 5.54% (1602/28,904) of the publications (eg, [53-57]). The most common authors writing about this topic were Alexander L Greninger (n=11), Kwok-Yung Yuen (n=10), Jasper Fuk-Woo Chan (n=9), Kelvin Kai-Wang To (n=9), and Cyril Chik-Yan Yip (n=9). The top 5 journals and preprint servers that published the highest number of studies related to this topic were bioRxiv (n=136), the Journal of Medical Virology (n=53), the Journal of Clinical Virology (n=40), medRxiv (n=31), and Clinical Infectious Diseases (n=30). The earliest study in this cluster was published at the beginning of week 3. The highest number of weekly publications was 119 in weeks 22 and 23 (Multimedia Appendix 1). The mean number of weekly publications related to this topic was 54.8 (SD 45.6).

https://www.jmir.org/2021/3/e23703

J Med Internet Res 2021 | vol. 23 | iss. 3 | e23703 | p.630

(page number not for citation purposes)
**Topic 8: Mental Health and Disorders During the COVID-19 Pandemic**

This topic is about COVID-19–related mental health and disorders, which was explored by 3.17% (915/28,904) of the publications (eg, [58-62]). The top 5 authors in terms of number of publications related to this topic were Valerie A Canady (n=15), Mark D Griffiths (n=8), Stephen X Zhang (n=6), Zhilei Shang (n=5), and Modesto Leite Rolim Neto (n=5). The top 5 journals publishing studies related to this topic were Psychological Trauma: Theory, Research, Practice, and Policy (n=101); Psychiatry Research (n=48); the International Journal of Environmental Research and Public Health (n=37); the Journal of Affective Disorders (n=23); and Mental Health Weekly (n=23). In this cluster, the first article was published at the beginning of week 8. There was a considerable rise in the number of weekly publications from week 14 until a peak was reached in week 23 (n=94); this was followed by a steep decline (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 31.1 (SD 30.9).

**Topic 9: Diagnosis of COVID-19 Based on Chest Imaging**

Diagnosis of COVID-19 based on chest imaging (eg, x-ray and computed tomography) was the main topic in 3.02% (874/28,904) of the included publications (eg, [63-67]). The 5 most prominent authors in this topic were Liming Xia (n=14), Michael Chung (n=12), Hongjun Li (n=11), Dinggang Shen (n=11), and Fuhua Yan (n=11). The top 5 journals in this cluster were European Radiology (n=38), Radiology (n=21), the American Journal of Roentgenology (n=17), Radiology: Cardiothoracic Imaging (n=16), and Clinical Nuclear Medicine (n=16). The first article about this topic was published on February 3, 2020. The mean number of weekly publications in this cluster was 29.9 (SD 21.4), and the highest number of weekly publications was 60 in week 18 (Multimedia Appendix 1).

**Topic 10: Social Distancing Measures**

A total of 3% (868/28,904) of the articles discussed the topic of social distancing measures used to fight against the COVID-19 pandemic (eg, [68-72]). Authors who had the highest number of publications related to this topic were Lei Zhang (n=7), Adam J Kucharski (n=6), Amy Gimma (n=5), Gerardo Chowell (n=5), and Petra Klepac (4). The top 5 journals and preprint servers in terms of publishing articles related to this topic were medRxiv (n=28); Chaos, Solitons & Fractals (n=6); Morbidity and Mortality Weekly Report (n=5); Science (n=5); and Disaster Medicine and Public Health Preparedness (n=5). The earliest article related to this topic was published in week 7. There was a dramatic rise in the number of weekly publications between week 12 and week 19; thereafter, the trend was unstable from week 20 to week 29 (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 29.8 (SD 26.8).

**Topic 11: Virus Genomics**

Around 2.82% (816/28,904) of the publications were about genome sequences of 2019-nCoV (eg, [73-77]). The most common authors writing about this topic were Massimo Ciccozzi (n=11), Andrew Rambaut (n=11), Marta Giovanetti (n=10), Silvia Angeletti (n=10), and Domenico Benvenuto (n=9). The top 5 journals and preprint servers that published the highest number of studies in this cluster were bioRxiv (n=295); the Journal of Medical Virology (n=32); Microbiology Resource Announcements (n=14); Viruses (n=13); and Infection, Genetics and Evolution (n=12). The earliest study in this cluster was published at the beginning of week 4. The mean number of weekly publications in this cluster was 27.7 (SD 18.2). The highest number of weekly publications was 56 in week 24 (Multimedia Appendix 1).

**Topic 12: Protein Structures of 2019-nCoV**

About 2.44% (706/28,904) of the included publications focused on structures and functions of 2019-nCoV proteins (eg, [78-82]). The top 5 authors in terms of number of publications related to this topic were Ralph S Baric (n=14), Jason S Mellcallan (n=12), Shibo Jiang (n=10), James Brett Case (n=10), and Daniel Wrapp (n=10). The journals and preprint servers publishing the highest number of studies in this cluster were bioRxiv (n=333), the Journal of Virology (n=15), the Journal of Biomolecular Structure & Dynamics (n=15), Science (n=13), and the Journal of Medical Virology (n=11). The earliest study related to this topic was published on January 3, 2020. The mean number of weekly publications in this cluster was 24.2 (SD 18.6). The highest number of weekly publications was 68 in week 25 (Multimedia Appendix 1).

**Topic 13: Host Cell Entry**

A total of 2.42% (584/28,904) of the reviewed publications (eg, [83-87]). The 5 most prominent authors in this cluster were Serpil Erzurum (n=4), Giuseppe Lippi (n=4), Daniel Batlle (n=4), Hong Gao (n=4), and Claudio Cavallini (n=3). The most common journals and preprint servers in this cluster were bioRxiv (n=117), the Journal of Medical Virology (n=11), Medical Hypotheses (n=10), European Respiratory Journal (n=8), and medRxiv (n=7). The first article related to this topic was published in the mid of week 4. The number of weekly publications was almost stable between weeks 4 and 13. Thereafter, a sharp increase was noticed between weeks 14 and 16, but it was not stable from then until week 29 (Multimedia Appendix 1). The number of publications in week 20 was the highest (n=50). The mean number of weekly publications in this cluster was 19.9 (SD 16.6).

**Topic 14: Patients With Cancer During the COVID-19 Pandemic**

A total of 1.53% (441/28,904) of the included publications were about patients with cancer during the COVID-19 pandemic (eg, [88-91]). The following authors published the highest number of articles related to this topic: Solange Peters (n=6), Umberto Ricardi (n=5), Conghua Xie (n=5), Giuseppe Curigliano (n=5), and Alessio Cortellini (n=4). The top 5 journals in terms of publishing articles related to this topic were Head & Neck (n=16), ecancermedicalscience (n=15), Radiotherapy and Oncology (n=10), Advances in Radiation Oncology (n=8), and Cancer Discovery (n=8). From week 1 to 7, only 1 study related to this topic was published. The highest number of weekly
publications was in week 22 (n=49), but since then, the number of weekly publications declined steeply (Multimedia Appendix 1). The mean number of weekly publications related to this topic was 15.2 (SD 14.4).

**Topic 15: Detection of 2019-nCoV Antibodies**

Detection of antibodies against 2019-nCoV using serological assays was a topic discussed in 1.42% (411/28,904) of all publications (eg, [92-96]). The top 5 authors writing about this topic were Florian Kramer (n=6), Jing Wang (n=6), Yong Zhang (n=5), Juan Chen (n=5), and Viviana Simon (n=5). The top 5 journals and preprint servers that published the highest number of studies in this cluster were bioRxiv (n=30), medRxiv (n=20), the Journal of Medical Virology (n=18), the Journal of Clinical Virology (n=14), and the Journal of Clinical Microbiology (n=7). Only 1 study in this cluster was published in the first 6 weeks. There was a dramatic increase in the number of weekly publications between weeks 16 and 21. Although the number of weekly publications slightly decreased from week 22 until week 26, it increased rapidly until reaching the peak in weeks 28 and 29 (n=36) (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 14.1 (SD 12.8).

**Topic 16: Personal Protective Equipment**

Around 1.21% (350/28,904) of the publications focused on personal protective equipment in the COVID-19 era (eg, [97-100]). Authors who published the most in this cluster were Holly Seale (n=3), Keith K Wannomae (n=3), Lei Liao (n=3), Wang Xiao (n=3), and Steven Chu (n=3). The highest numbers of studies were published in the following journals and preprint servers: the American Journal of Infection Control (n=8), the Journal of Hospital Infection (n=7), Anaesthesia (n=6), the Journal of the European Academy of Dermatology and Venereology (n=6), ACS Nano (n=5), and medRxiv (n=5). No articles in this cluster were published before week 9. The mean number of weekly publications in this cluster was 11.9 (SD 11.6). The highest number of weekly publications was 34 in week 23 (Multimedia Appendix 1).

**Topic 17: Diabetes Mellitus and COVID-19**

Health care management, clinical characteristics, and risk factors for mortality of COVID-19 patients with diabetes was discussed in 1.16% (336/28,904) of the included articles (eg, [101-104]). The 5 most prominent authors in this cluster were Hui Wang (n=5), Sam Foster (n=4), Anoop Misra (n=4), Béatrice Bouhanick (n=3), and Kamlesh Khunti (n=3). The most common journals in this cluster were Diabetes Research and Clinical Practice (n=20), Diabetology & Metabolic Syndrome (n=17), the British Journal of Nursing (n=10), the Journal of the American Medical Directors Association (n=7), and Diabetes Technology & Therapeutics (n=6). Only 4 articles related to this topic were published between weeks 1 and 12. However, there was a substantial increase in the number of weekly publications from week 17 until the peak was reached in week 20 (n=35); this was followed by a slight decrease (Multimedia Appendix 1). The mean number of weekly publications in this cluster was 11.4 (SD 11.6).

**Topic 18: Pregnancy and Childbirth During the COVID-19 Pandemic**

About 1.08% (312/28,904) of the publications focused on numerous aspects of pregnancy and childbirth during the COVID-19 pandemic (eg, [105-109]). The most common authors writing about this topic were Ling Feng (n=7), Jiafu Li (n=6), Olivier Picone (n=5), Dunjin Chen (n=5), and Guoqiang Sun (n=5). The top 5 journals in terms of publishing articles in this cluster were the International Journal of Gynaecology and Obstetrics (n=18), The Journal of Maternal-Fetal & Neonatal Medicine (n=16), the American Journal of Obstetrics and Gynecology (n=20), Obstetrics and Gynecology (n=10), and the American Journal of Perinatology (n=9). The earliest article in this cluster was published on February 10, 2020. The mean number of weekly publications related to this topic was 10.8 (SD 8.9), and the highest number of weekly publications was 27 in week 21 (Multimedia Appendix 1).

**Topic 19: Organ Transplantation During the COVID-19 Pandemic**

Organ transplantation in the era of COVID-19 was a key topic in 0.76% (219/28,904) of the included articles (eg, [110-113]). The top 5 authors in terms of number of publications related to this topic were Paolo Cravedi (n=4), Zhishui Chen (n=4), Luciano De Carlis (n=4), Lai Wei (n=4), and Ashley Fan (n=3). The top 5 journals in terms of publishing articles related to this topic were the American Journal of Transplantation (n=69), Transplant Infectious Disease (n=35), Transplant International (n=11), Transplantation Proceedings (n=10), and Liver Transplantation (n=5). Only one study in this cluster was published before week 12. The mean number of weekly publications related to this topic was 7.5 (SD 8.3), and the highest number of weekly publications was 26 in week 24 (Multimedia Appendix 1).

**Discussion**

**Principal Findings**

We found that 5.92% (1714/28,904) of the included published articles were hosted on preprint servers (bioRxiv or medRxiv). Although these servers are not the only preprint servers available in the academic publishing landscape (many journals publish articles online before they go into print, and we have also observed a rise of purely online journals), they are indicative of the pace with which new knowledge is made available by the international research community. Since such preprint servers do not undergo formal peer reviewing and are, thus, not regarded publications in the traditional academic sense, many researchers are using this device to make findings available and to solicit feedback from the international community before undergoing formal peer-reviewing by journals—a process that takes at least 2 months to get the submitted paper published.

Among the peer-reviewed journals, the Journal of Medical Virology has published the highest number of COVID-19–related articles (n=468). Aristovnik et al and Hossain also listed the Journal of Medical Virology in the top-5 journals publishing COVID-19–related articles [6,14]. The Journal of Medical Virology clearly stands out, as it has...
published more than twice the number of papers compared to the second-ranked journal—the International Journal of Environmental Research and Public Health (n=223). Aristovnik et al [6] listed the International Journal of Environmental Research and Public Health among the 10 top-ranked journals based on COVID-19–related research articles [6]. The source normalized impact per paper (SNIP), in the year 2019, was 0.780 for the Journal of Medical Virology [114] and 1.248 for the International Journal of Environmental Research and Public Health [115], and the average time from the submission to the first decision was about 6 weeks [116] and 3 weeks [117], respectively. We believe the speed of the reviewing process of these journals may have motivated the authors to submit their work to these journals.

Considering the study methods, we found that the highest number of studies (n=1515) were surveys, followed by reviews (systematic review, scoping review, or meta-analyses), as shown in Table 3. As the number of research studies on COVID-19 is rapidly increasing, review articles are of utmost importance to summarize the ongoing effort and progress to combat against COVID-19. We found case-control studies to be the lowest represented study design (n=62 only). We speculate that the lack of available data was the main reason for the scarcity of this type of research study. Interestingly, 362 randomized control trials in 7 months indicate the enormous effort made by the scientific community to combat this pandemic.

Furthermore, we grouped the 19 topics addressed in the included studies into six thematic areas (summarized in Table 6). The dominant thematic clusters were “Clinical aspects” (29.17%) and “Epidemiology” (28.91%). The “Clinical aspects” theme covers multiple aspects of the clinical practices for patient care and risk factors related to COVID-19. It consists of two topics (ie, “clinical care practices for patients during the COVID-19 pandemic” and “clinical characteristics and risk factors of COVID-19”). Interestingly, the “Epidemiology” theme also comprises only two topics (ie, “Public health response” and “Epidemic models for COVID-19 spread”), further underscoring the dominance of these topics.

### Table 6. Topics grouped by thematic cluster, including the percentage of articles by topic and cluster.

<table>
<thead>
<tr>
<th>Thematic cluster, topic number, and title</th>
<th>Articles (N=28,904), n</th>
<th>Topic dominance (%)</th>
<th>Cluster dominance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical aspects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2) Clinical care practices for patients during the COVID-19 pandemic</td>
<td>5118</td>
<td>17.71</td>
<td>29.17</td>
</tr>
<tr>
<td>(3) Clinical characteristics and risk factors of COVID-19</td>
<td>3313</td>
<td>11.46</td>
<td></td>
</tr>
<tr>
<td>Epidemiology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) Public health response</td>
<td>5393</td>
<td>18.66</td>
<td>28.91</td>
</tr>
<tr>
<td>(4) Epidemic models for COVID-19 spread</td>
<td>2964</td>
<td>10.25</td>
<td></td>
</tr>
<tr>
<td>Therapeutics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(5) Therapies and vaccines for COVID-19</td>
<td>1845</td>
<td>6.38</td>
<td>21.03</td>
</tr>
<tr>
<td>(6) Host immune response</td>
<td>1837</td>
<td>6.36</td>
<td></td>
</tr>
<tr>
<td>(11) Virus genomics</td>
<td>816</td>
<td>2.82</td>
<td></td>
</tr>
<tr>
<td>(12) Protein structures of 2019-nCoV</td>
<td>706</td>
<td>2.44</td>
<td></td>
</tr>
<tr>
<td>(13) Host cell entry</td>
<td>584</td>
<td>2.02</td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(7) Diagnosis of COVID-19 using PCR</td>
<td>1602</td>
<td>5.54</td>
<td>9.98</td>
</tr>
<tr>
<td>(9) Diagnosis of COVID-19 based on chest imaging</td>
<td>874</td>
<td>3.02</td>
<td></td>
</tr>
<tr>
<td>(15) Detection of 2019-nCoV antibodies</td>
<td>411</td>
<td>1.42</td>
<td></td>
</tr>
<tr>
<td>Related conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(8) Mental health and disorders during the COVID-19 pandemic</td>
<td>915</td>
<td>3.17</td>
<td>7.70</td>
</tr>
<tr>
<td>(14) Patients with cancer during the COVID-19 pandemic</td>
<td>441</td>
<td>1.53</td>
<td></td>
</tr>
<tr>
<td>(17) Diabetes mellitus and COVID-19</td>
<td>336</td>
<td>1.16</td>
<td></td>
</tr>
<tr>
<td>(18) Pregnancy and childbirth during the COVID-19 pandemic</td>
<td>312</td>
<td>1.08</td>
<td></td>
</tr>
<tr>
<td>(19) Organ transplantation during the COVID-19 pandemic</td>
<td>219</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>Prevention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(10) Social distancing measures</td>
<td>868</td>
<td>3</td>
<td>4.21</td>
</tr>
<tr>
<td>(16) Personal protective equipment</td>
<td>350</td>
<td>1.21</td>
<td></td>
</tr>
</tbody>
</table>
The third most prominent theme “Therapeutics” (21.03%) comprises five topics, making it the most diverse theme; the topics in this theme range from “host cell entry” to drug discovery-related terms such as “Protein structures of 2019-nCoV” and “Virus genomics,” as well as “Therapies and vaccines for COVID-19.” This theme highlights the initiatives of the scientific community to discover drugs and vaccines and understand the underlying virus-host mechanism to pave the way for effective therapeutic solutions for COVID-19. Considering the severity of COVID-19, we believe there still may be a lack of publications in this theme, despite comprising slightly more than 20% of all articles. We believe that, as clinical practices and public health responses mature, this theme will receive more research articles in the near future.

Almost 10% of articles form the “Diagnostics” theme. This theme focuses on the diagnosis of COVID-19 based on PCR, radiological images, or antibodies. PCR is among the most accurate technologies to diagnose COVID-19 [114], which explains the numerous relevant publications. Due to the advancement of deep learning techniques, radiological image-based diagnosis is becoming more effective and has the potential to save time in clinical environments [115]. As a result, we observed a large number of publications on radiological image-based analyses, which is captured under the topic “Diagnosis of COVID-19 based on chest imaging.” Antibodies, developed in hosts combatting the novel coronavirus, can be considered a detection mechanism that may play an important role complementary to PCR testing [116]. It can be very effective for the diagnosis of patients with asymptomatic COVID-19 or negative RT–PCR results [117]. We also noticed many publications on antibody responses against COVID-19, which are covered by the topic “Detection of 2019-nCoV antibodies”.

The interplay between COVID-19 and related medical conditions is captured by the “Related conditions” theme. This theme not only comprises articles discussing related conditions caused by COVID-19 but also other conditions that may elevate the COVID-19 risk for the patients with those conditions. About 8% of all articles fall into this theme, covering topics such as mental disorder, diabetes, cancer, pregnancy, childbirth complications, and organ transplantation.

Only slightly more than 4% of all articles fall into the “Prevention” theme. This may be surprising, since prevention is of utmost importance while vaccines and treatments are still under development. However, we believe that this theme is not covered by more studies due to the recent wide acceptance and effectiveness of social distancing and personal protective equipment. Consequently, we expect the percentage of articles grouped in this theme to further reduce in the future. Further insights into the research landscape and the shift in themes over time is summarized in Multimedia Appendix 2.

We noticed that biomedical informatics had a crucial role in the COVID-19 pandemic. Further, mobile applications, including contact tracing apps, were one of the main social distancing measures described in these studies. AI-based models were used in multiple studies to predict protein structures of 2019-nCoV to understand the underlying mechanism of drug-target interaction. Many studies proposed novel AI-based models to discover COVID-19 drugs and vaccines and repurpose existing drugs approved by the Food and Drug Administration as a part of the treatment plan for COVID-19.

**Strengths and Limitations**

**Strengths**

To the best of our knowledge, our study covers the largest collection of COVID-19–related articles (N=28,904, after considering the inclusion and exclusion criteria) published in the period of 7 months (January to mid-July 2020). The main strength of this study is that it demonstrates the feasibility of mostly automated, AI-based data mining at scale. We believe this is of utmost importance because articles on COVID-19 are published faster than nonautomatic surveys can organize, analyze, and present them to the scientific community.

**Limitations**

All the publications were collected from only one specific database (CORD-19), so we may have missed some studies or preprints that were not considered in this database. Given the substantial number of publications included in our analysis, we are confident that a large part of the COVID-19 literature was covered. Further, we did not conduct a detailed manual analysis of studies published in journals such as Journal of Medical Internet Research and the International Journal of Medical Informatics to evaluate the use of eHealth technologies for COVID-19, which we believe is beyond the scope of our work and requires other study methodologies such as systematic or scoping review. However, readers are referred to several studies and reviews, which have been conducted to explore eHealth technologies used in the fight against the COVID-19 pandemic [118-121].

We only considered the articles published in the English language, which may introduce some bias in our analysis. Additionally, articles published after mid-July 2020 were not considered in this study. Moreover, due to the inherent limitation of the bibliographic analysis, which enabled high-level profiling of the text from the corpus of literature, we cannot provide any evidence-based solution for the diagnosis and treatment of COVID-19. Further analysis of the articles that fall under each topic should be considered more carefully.

For this study, we only analyzed article titles, abstracts, and author data. As a result, we could not identify the country of publication for 11,634 articles (around 40%). Although we removed duplicates, academic publications undergo subtle morphology changes. These come in the form of revisions, preprints, follow-up studies, among others. Given only the abstract and title were screened, we cannot rule out that some publications may have substantial overlaps. Finally, there exist ambiguities with respect to author and journal names because authors with the same name can only be resolved uniquely by affiliation or, in some cases, other identifiers such as ORCID. If such elucidating identifiers are missing, automatic
disambiguation is not possible. Likewise, journals may be referred to by a plethora of acronyms. Therefore, our study may have merged multiple authors into one person and split journals into multiple entities.

**Practical and Research Implications**

**Practical Implications**

This study demonstrates the feasibility of AI-based, largely automatic data mining of large corpora of academic publications. Given the pace and dynamics at which COVID-19 research is being conducted at this time, attempts to manually survey the literature will almost certainly fall behind the state-of-the-art, unless specific and confined subtopics are under scrutiny. Automatic data mining, on the other hand, is hindered by the inherent noise in the data (eg, lack of ORCIDs and inability to track genesis and evolution of articles properly). This means that results accurate to every single paper and author are impossible to extract, unless publishers (eg, using blockchain technology) develop a way to trace genesis and evolution of individual publications and unique authors. It is therefore important to stress that such automatic textual analysis is performed at scale. If conducted at scale, we would argue that exact numbers may not matter as much as they once may have, considering that being off by as many as 30 individual publications while screening of almost 29,000 publications means that being off by as many as 30 individual publications is would still constitute a negligible fraction of the overall corpus. We, therefore, believe the numbers we have presented in this report to be aggregates that are representative of a vibrant and rapidly evolving research landscape and that they highlight trends and shifting interests in topics. Whereas automated data mining excels at providing up-to-date, broad overviews of the field as a whole, manual surveys excel at providing detailed overviews of specific topics. We, therefore, see this study complementing previous manual reviews.

**Research Implications**

This study highlighted the effectiveness of AI methods in the analysis of a large corpus of literature, which researchers can use to perform machine learning–based bibliometric analysis of eHealth-related literature to explore the use of eHealth technologies for COVID-19.

Among the research themes summarized in Table 6, we see the direst need for more research in the “Therapeutics” theme, as clinical aspects and epidemiological aspects are better understood and best practices continue to be more commonly implemented. Consequently, we see this shift in the proportion of articles at the expense of the “Clinical Aspects” and “Epidemiology” themes, as well as the “Prevention” theme. The reason is that the impact of related topics “Social distancing” and “Personal preventive equipment” should be well understood and implemented by now.

In the context of performing bibliometric reviews based on automatically extracted topics, the most important research challenge is to develop methods that are more robust against noise and can process not only abstracts, titles, and author lists, but the entire full text of the publications. Although computationally extremely demanding, this would allow assessing any overlaps between publications, which is a stronger measure than the binary decision of duplicity.

**Conclusions**

This study provides a comprehensive overview of the COVID-19 literature. Specifically, we identified the main COVID-19–related topics addressed in the existing literature; weekly trends of publications; and top countries, authors, and publishers. This study will help the research community to understand the evolution of the COVID-19–related literature; prioritize research needs; and recognize the leading researchers, institutes, countries, and publishers for each topic. AI-based bibliometric analysis has the potential to rapidly explore large corpora of academic publications. Publishers should avoid noise in the data by developing a way to trace the evolution of individual publications and unique authors.

**Conflicts of Interest**

None declared.

---

**Multimedia Appendix 1**

Number of publications for each topic.

[DOCX File, 102 KB - jmir_v23i3e23703_app1.docx ]

---

**Multimedia Appendix 2**

Number of publications for each theme.

[DOCX File, 43 KB - jmir_v23i3e23703_app2.docx ]

---

**References**


17. Ahammad S, Samad M. Information mining for COVID-19 research from a large volume of scientific literature. arXiv. Preprint posted online April 5, 2020 [FREE Full text]


86. South AM, Brady TM, Flynn JT. ACE2 (angioteins-convertin enzyme 2), COVID-19, and ACE inhibitor and Ang II (angiotsins II) receptor blocker use during the pandemic. Hypertension 2020 Jul;76(1):16-22. [doi: 10.1161/hypertensionaha.120.15291]


Abbreviations

AI: artificial intelligence
CORD-19: COVID-19 Open Research Dataset
CSV: comma-separated values
JSON: JavaScript Object Notation
PCR: polymerase chain reaction
TF-IDF: term frequency–inverse document
Virtual Health Care for Community Management of Patients With COVID-19 in Australia: Observational Cohort Study

Owen Rhys Hutchings¹, MBBS; Cassandra Dearing¹, BN, LLB, MHS; Dianna Jagers¹, BN, MHI; Miranda Jane Shaw¹, MHA; Freya Raffan¹, MHS; Aaron Jones²,³, MCE; Richard Taggart², MPH; Tim Sinclair², DBA; Teresa Anderson², PhD; Angus Graham Ritchie²,³, MBBS

¹Royal Prince Alfred Virtual Hospital, Sydney Local Health District, Camperdown, Australia
²Sydney Local Health District, Camperdown, Australia
³Faculty of Medicine and Health, University of Sydney, Sydney, Australia
⁴Menzies Centre for Health Policy, University of Sydney, Sydney, Australia

Abstract

Background: Australia has successfully controlled the COVID-19 pandemic. Similar to other high-income countries, Australia has extensively used telehealth services. Virtual health care, including telemedicine in combination with remote patient monitoring, has been implemented in certain settings as part of new models of care that are aimed at managing patients with COVID-19 outside the hospital setting.

Objective: This study aimed to describe the implementation of and early experience with virtual health care for community management of patients with COVID-19.

Methods: This observational cohort study was conducted with patients with COVID-19 who availed of a large Australian metropolitan health service with an established virtual health care program capable of monitoring patients remotely. We included patients with COVID-19 who received the health service, could self-isolate safely, did not require immediate admission to an in-patient setting, had no major active comorbid illness, and could be managed at home or at other suitable sites. Skin temperature, pulse rate, and blood oxygen saturation were remotely monitored. The primary outcome measures were care escalation rates, including emergency department presentation, and hospital admission.

Results: During March 11-29, 2020, a total of 162 of 173 (93.6%) patients with COVID-19 (median age 38 years, range 11-79 years), who were diagnosed locally, were enrolled in the virtual health care program. For 62 of 162 (38.3%) patients discharged during this period, the median length of stay was 8 (range 1-17) days. The peak of 100 prevalent patients equated to approximately 25 patients per registered nurse per shift. Patients were contacted a median of 16 (range 1-30) times during this period. Video consultations (n=1902, 66.3%) comprised most of the patient contacts, and 132 (81.5%) patients were monitored remotely. Care escalation rates were low, with an ambulance attendance rate of 3% (n=5), emergency department attendance rate of 2.5% (n=4), and hospital admission rate of 1.9% (n=3). No deaths were recorded.

Conclusions: Community-based virtual health care is safe for managing most patients with COVID-19 and can be rapidly implemented in an urban Australian setting for pandemic management. Health services implementing virtual health care should anticipate challenges associated with rapid technology deployments and provide adequate support to resolve them, including strategies to support the use of health information technologies among consumers.

(J Med Internet Res 2021;23(3):e21064) doi:10.2196/21064

KEYWORDS
COVID-19; digital health; health; informatics; remote monitoring; telehealth; virtual health care
Introduction

Australia has been remarkably successful in controlling the COVID-19 pandemic, having reported some of the lowest numbers of cases and deaths among other high-income countries [1]. This success is attributed to a rapid nationwide coordinated public health response to implement strong control measures that include widespread testing and contact tracing, social distancing, prohibition of public gatherings, use of face masks, and restrictions on international and domestic travel, including a mandatory quarantine period for those arriving from other countries [2,3]. The Australian government has also implemented nationwide funding for telehealth services, which is now a permanent reform, leading to rapid adoption of telehealth services [4].

COVID-19 manifests relatively mildly in most cases; however, approximately 14% of infected individuals develop severe disease that requires hospitalization, and 5% require admission to an intensive care unit [2]. The vast majority of COVID-19 cases in Australia have been actively monitored and managed by the public health system, and this arrangement was sustainable owing to the small number of cases and effective contact tracing systems. However, it was initially speculated that the Australian health care system had inadequate acute care facilities and intensive care unit beds to manage the high expected case load, which led to the rapid exploration of new models of acute care [5,6].

Virtual health care (VHC) is a model of health service delivery, which substitutes in-person consultations with telephonic or video consultations and often includes asynchronous data collection from the patient via survey tools with or without real-time remote monitoring. VHC is emerging as a central strategy to manage large numbers of medical patients affected by the COVID-19 pandemic, as this can maximize the use of limited clinical resources, reduce pressure on acute care facilities, and reduce the risk of health care–associated infections [7]. Studies have reported high satisfaction rates for telehealth services among patients and clinicians, with comparable clinical and service outcomes for chronic diseases [8]. Smith et al [9] reported on telehealth deployments in other crises including hurricanes Harvey and Irma. VHC-based models of acute care for COVID-19 management in high-income countries are emerging [10-17]. However, few models that include continuous remote monitoring of clinical observations and extensive utilization of videoconferencing platforms have been reported.

This study describes the rapid deployment of a VHC model that includes remote monitoring of clinical observations and routine use of videoconferencing platforms within a large Australian metropolitan public health service for managing outpatients with COVID-19.

Methods

Setting

Sydney Local Health District (SLHD) is a large metropolitan public health service in New South Wales, Australia, encompassing 5 hospitals, 4 large community health centers, and 12,000 staff. SLHD is responsible for the health and well-being of approximately 700,000 individuals living within its geographic boundaries and approximately 1,000,000 individuals who travel to the city each day for work, study, and recreation [18].

SLHD has been implementing telehealth and VHC modalities for several years. On February 3, 2020, SLHD commenced operations of the Royal Prince Alfred Virtual Hospital (rpavirtual), Australia’s first metropolitan virtual hospital [19]. This service was established as a 12-month pilot program providing at-home and remote web-based nursing services. The initial patient cohorts included those seeking palliative care, adult patients with cystic fibrosis, and those at the risk of recurrent lower leg wounds. Rpavirtual has a robust operational and clinical governing body including a general manager and a clinical director to oversee its operations, and it is embedded in the organizational structure of the health service, which includes a dedicated public health unit (PHU).

Colocated in the Royal Prince Alfred Hospital campus in Camperdown, New South Wales, rpavirtual is a 24/7 care center with technology-enabled multidisciplinary team rooms, handover areas, tracking boards, and several care pods. The care pods provide access to the electronic medical record (EMR) and shared care planning and remote monitoring tools. They are equipped with videoconferencing and telephone facilities and are staffed by nurses who can remotely monitor multiple patients simultaneously. The facility has medical staff on site and is under the supervision of a clinical director and director of nursing. A team of >100 community nurses are available to deliver in-home nursing care to complement VHC services.

On March 5, 2020, in response to the COVID-19 pandemic in Australia, rpavirtual began a rapid redesign of care systems to provide VHC to patients with COVID-19 managed in the community. The first patients were enrolled on March 11, 2020. This study describes the early experience with VHC use to manage patients with COVID-19 in the community up to and including March 29, 2020. The original patient cohorts continued receiving VHC and their outcomes are described separately.

The SLHD ethics review committee reviewed this study, and no ethical concerns were raised regarding the study or publication of the results.

Population

Patients who attended COVID-19 testing clinics of the SLHD and tested positive were informed of their outcomes by the local PHU and referred to the rpavirtual care center. The care center conducted an initial telephonic clinical assessment to ascertain suitability for VHC. Inclusion criteria and relative exclusion criteria are listed in Textbox 1.
### Inclusion criteria
- The public health unit is satisfied that the patient can self-isolate safely and understands how to manage self-isolation.
- The clinical team is satisfied that it is clinically appropriate to manage the patient at home and a caregiver can safely provide care to the patient with appropriate personal protective equipment, or the patient can provide care to himself/herself, and a member of the clinical team carries out daily monitoring and follow-up evaluation.

### Relative exclusion criteria
- Individuals over 65 years of age with significant comorbidity including, but not limited to, cancer, cardiovascular disease, diabetes, heart failure, immunosuppression, stroke, liver disease, renal disease, and lung disease.
- Individuals under 65 years of age with one or more of the following comorbidities: lung disease, cardiovascular disease, renal disease (including stage 5 chronic kidney disease or requiring renal replacement therapy including renal transplantation).
- Uncontrolled hypertension.
- Individuals at residential aged care facilities.
- Individuals aged <18 years.
- Pregnant women.

Patients matching one of the relative exclusion criteria were still accepted into VHC subject to further discussion with their treating physicians or an emergency medicine specialist. To be able to use the supplied technology and videoconferencing facilities, patients required access to a smartphone, tablet device, or personal computer with an internet connection and video capability.

Patients unable to self-isolate at home were offered alternative accommodation managed by the health service. Non–English-speaking patients were accepted with the support of interpreters. Patients deemed ineligible or unsuitable for VHC were required to be hospitalized. Multimedia Appendix 1 provides a schematic representation of the eligibility assessment process of rpavirtual for patients with COVID-19.

### Model of Care
The rpavirtual COVID-19 VHC model was based on early detection of deterioration and managed care escalation for deteriorating patients.

Vital signs, including respiratory rate, oxygen saturation, pulse rate, and temperature, were monitored at home. Blood pressure monitoring was not required. The care center contacted patients at pre-arranged intervals thrice a day, including a video consultation with the patient twice every 24 hours, thus facilitating further assessment of symptoms and signs of deterioration (Textbox 2) based on standard nursing assessment approaches [20,21].
Clinical progress

- Do you feel feverish or have chills?
- Do you have a cough?
- Do you feel short of breath or find it difficult to talk?
- Do you have any other symptoms?

Psychological screening

- How are you managing your home isolation?
- How are you coping generally?

Clinical assessment

- Airway
- Breathing: respiratory distress, respiratory rate, oxygen saturation, and other respiratory symptoms
- Cardiovascular system: appearance and heart rate
- Disability: alertness, cognition, mental state, and mobility
- Exposure (temperature): temperature
- Fluid balance: fluid and food intake and gastrointestinal symptoms and losses
- Glycemic control (if diabetic): blood glucose levels

Vital signs were recorded electronically in the EMR and tracked against a standardized early warning system known as “Between The Flags,” using the standard criteria for observing adults in the general population (Multimedia Appendix 2) [22,23].

Clinical escalation of deteriorating patients was carried out through managed transfer to the local emergency department in an ambulance if clinically indicated. The ambulance service was notified of the patient’s infectious status and advised to contact the receiving emergency department prior to arrival. In the event of escalation, the care center also notified the hospital executive and the local PHU.

An escalation communication pathway was activated if a patient could not be contacted by the care center. If a patient could not be contacted after one telephone call, a text message was sent. If the patient did not revert within 1 hour, a second text message was sent, which expressed concern for their welfare. If the patient did not respond to a third telephone call, the New South Wales Police was contacted to conduct a welfare check.

Medical officers at rpavirtual were consulted through referral from the care center staff to discuss patient deterioration, escalation decision-making, medical certification, and prescribing medications, although medication management was not a component of the model of care.

Discharge from VHC was managed in accordance with the following “release from isolation” criteria [24]: the individual has been afebrile for the previous 48 hours, the acute illness resolved in the previous 24 hours, at least 7 days have elapsed since the onset of the acute illness, and a negative result was obtained on RT–PCR with at least two consecutive respiratory specimens collected 24 hours apart after the acute illness has resolved.

Patients meeting the first three criteria were referred to a COVID-19 testing clinic for repeat testing. On obtaining negative results, the patient was discharged from VHC and referred to their general practitioner for ongoing care.

Patient Experience

The use of technology by patients and their caregivers is central to care delivery by rpavirtual. Once enrolled in VHC, new patients were provided with a welcome pack containing the following items: a welcome letter and videoconferencing instructions, pulse oximeter and instructions for its use, a temperature monitoring device and instructions for its use, New South Wales Government COVID-19 factsheets, and a patient responsibilities pamphlet.

Personal protective equipment (PPE) was provided immediately after COVID-19 testing and then resupplied with the welcome pack.

The welcome pack was delivered by a “Flying Squad” of health informatics staff wearing appropriate PPE upon completion of a home visit risk assessment. The rpavirtual Flying Squad instructed patients to wear PPE when answering the door and notified patients when they were 5 minutes away from their homes.

Patients interacted with the rpavirtual team through video consultations and a tollfree telephone service that operated 24/7. Calls were scheduled with the patient to collect their self-observations. Patients were advised to call the rpavirtual call center or an ambulance if they experienced deterioration.
Remote Monitoring Technology

Remote monitoring devices were evaluated to collect patient-generated health data from patients with COVID-19 in accordance with defined criteria (Textbox 3).

Textbox 3. Criteria of the Royal Prince Alfred Virtual Hospital for remote patient monitoring technology (in random order).

- Capable of measuring the desired clinical parameters (ie, heart rate, oxygen saturation, temperature, and respiratory rate)
- Capable of remote data collection and transmission (or able to be read by the patient)
- Usability for the medical team at Royal Prince Alfred Virtual Hospital
- Usability for patients with COVID-19 admitted to the Royal Prince Alfred Virtual Hospital
- Training and support requirements for the health informatics staff of Sydney Local Health District
- Listed on the Australian Register of Therapeutic Goods of the Therapeutic Goods Administration (Department of Health, Australian Government) or able to be fast-tracked (eg, Conformité Européenne– or US Food and Drug Administration–marked)
- Supply chain availability to meet the scale, speed, and demand of the COVID-19 response
- Cost
- Compliance with cyber security, data security, and privacy and infection control requirements

No suitable single device that met all vital sign monitoring requirements in accordance with the aforementioned criteria was identified. Two devices were selected for use in the COVID-19 program: a pulse oximeter and temperature patch (Figure 1). No reliable device for measuring the respiratory rate was identified; respiratory rate was measured through videoconference consultations.

Figure 1. Remote monitoring equipment provided to patients for measurement of pulse, blood oxygen saturation, and temperature.

A wireless pulse oximeter (iHealth Air pulse oximeter PO3M, iHealth Labs, Inc.) facilitated peripheral oxygen saturation and pulse rate measurements. Pulse oximeters were only used by one patient; they were not reused as they could not be adequately disinfected. A single-use, wearable temperature monitor (Temp'Traq Clinical, Blue Spark Technologies, Inc.) was self-applied in the axilla and facilitated continuous temperature monitoring. The device fed data continuously into a web-based dashboard, providing the care center with an overview of all patients. Each patch lasted 72 hours, and each patient was provided with 3 patches to cover the first 9-11 days of isolation.
Both devices had Bluetooth connectivity, but only the temperature monitor required connection with a compatible Apple or Android smartphone to be read; readings from the pulse oximeter were read directly from the device and reported through video consultations. Both devices were approved by the US Food and Drug Administration and Conformité Européenne–marked and either registered with the Therapeutic Goods Administration (Department of Health, Australian Government) or able to be fast-tracked but had only limited prior evaluation in the clinical setting [25,26].

The Flying Squad prepared devices for delivery, including precharging of the pulse oximeters and registering of all 3 temperature monitoring patches against the specific patient in the monitoring portal. After delivery, they telephonically contacted the patient to help them download and set up the required mobile app, allowing temperature readings to be fed continuously into a web-based dashboard. The care center had access to an overview of all prevalent monitored patients with color-coded parameters to identify patients with an abnormal temperature or patches that did not function normally (Figure 2).

![Temperature Monitoring Portal Screenshot](https://example.com/temperature_portal.png)

**Figure 2.** Screenshot of the temperature monitoring portal. This figure is from a demonstration system, and the temperature color indicators shown here are configured differently from the version in use: ≥38.0°C=red, 37.5°C-37.9°C=orange, 36.0°C-37.4°C=green, <36.0°C=blue. Expired or nonfunctioning patches are indicated in grey.

Patient-reported observations were manually documented in the EMR (Cerner Millennium, Cerner Corp) in purpose-built sections to allow them to be differentiated from other sources of vital signs.

**Video Consultations**

Video consultations were carried out to visually assess the patient, confirm vital signs recorded by wearable devices, and to estimate the respiratory rate.

The rpavirtual care pods were fitted with high-definition webcams and Bluetooth-enabled headsets to allow the patient to see and hear the nurse. The care pods were configured to facilitate privacy during conversations with the patients. Pull-up backgrounds and feature walls were present behind each nurse to minimize distractions on video.

A commercial web-based video conferencing solution Pexip (Pexip AS) was used for remote video consultations. This platform functioned on both desktop and mobile devices and was endorsed by eHealth NSW, the state government agency overseeing the use of technology in health care. Patients called in to video consultations using their own computer or mobile device.

**Results**

In March 11-29, 2020, 5821 individuals were tested for COVID-19 at SLHD COVID-19 testing clinics, and 173 individuals tested positive. Of them, 162 (93.6%) were enrolled in the rpavirtual program, and the remaining individuals were admitted to hospital or referred to another health service. The median age of the admitted patients was 38 (range 11-79) years; 3 patients aged <18 years and 2 pregnant women were admitted to VHC.

The median number of admissions per day was 6 (range 1-30). A total of 62 (38.3%) patients were discharged during this period, with a median length of stay of 8 (range 1-17) days. At the end of this period, 100 prevalent patients received VHC.

The care center commenced operations with 4 full-time–equivalent registered nurses and gradually increased to 9.5 full-time–equivalent at the end of the period, which...
equated to a ratio of approximately 25 patients per registered nurse per shift.

Patients were contacted 2865 times, with a median of 16 (range 1-50) contacts per patient. Video consultations (n=1902, 66.3%) comprised the majority of patient contact, and telephonic consultations (n=688, 24.0%) accounted for the remainder of patient contact. The ratio of telephonic-to-video consultations was 1:2.8. The median duration of each contact was 8.5 (IQR 5-15) minutes for telephonic consultations and 15 (IQR 13-15) minutes for video consultations.

During March 18-29, 2020, the rpvirtual Flying Squad delivered welcome packs with remote monitoring equipment to 132 of 162 (81.5%) patients.

Ambulances were called to attend to 5 patients, and 4 patients were transferred to the emergency department for assessment. In total, 3 patients were subsequently admitted, and 1 was discharged to continue with VHC at home. No deaths or police welfare checks were recorded. However, one individual was subject to a public health order for failing to adhere to self-isolation requirements. Detailed patient outcomes will be reported separately.

Discussion

Principal Findings

This study describes the rapid implementation of a model of care and technology to deliver VHC for community management of patients with COVID-19. We found that by excluding high-risk patients with COVID-19, we could include most individuals testing positive upon local diagnosis. Through remote clinical appraisal, supported by remote monitoring of clinical observations, we observed low rates of deterioration, with few patients requiring clinical escalation and no patient deaths. The program also enrolled pregnant women and pediatric patients, expanding the range of patients who may be suitable for VHC for COVID-19 as an alternative to hospital in-patient admission.

A range of technical and operational issues were expected with the rapid implementation of video consultations [8]. Our model of care required 3 patient contacts per day, with at least 2 contacts on video, to ensure adequate surveillance of signs of deterioration and to measure the respiratory rate directly. Initially, patients were scheduled for 10-minute video and telehealth consultations. On encountering a problem with video consultation, which the staff could not rapidly resolve, a telephonic consultation was carried out instead. This is an example of workaround—a common phenomenon when using health information technology that is driven by the need to resolve conflicting goals in a timely manner [27]. In this case, the workaround was driven by the need to adhere to the schedule of appointments rather than delaying to resolve the issue. Improving the user experience for staff and patients required both technical and workflow changes, and fixed appointment slots were abandoned. The optimal approach to training and support in VHC to avoid workarounds, particularly with a rapid increase in staff redeployed from other areas of the business (in the context of high service demands) requires further consideration.

The need for enhanced support for patients to use health information technologies was identified early in the implementation. The model of care relied on the ability of patients or their caregivers to use medical technology (pulse oximeter and temperature patch) and digital health applications (for temperature monitoring and video consultations). The use of health information technology by consumers, known as consumer health informatics, has a strong focus on usability and accessibility [28,29]. We immediately realized that patients enrolled in VHC could not easily download the temperature monitoring application and connect it with the patches with the instructions provided in the welcome pack alone. The welcome packs delivered by the Flying Squad, a multidisciplinary health informatics team, were ideally suited for providing additional support. A process was established to contact patients shortly after delivery of the welcome pack and support them in achieving the goal of transmitting temperature readings to the cloud-based monitoring panel. If consumer health technology is to be relied on for health care delivery, health services will require strategies to support it. While this has been explored in the chronic disease setting, in which patients can avail of in-person health services, this is not feasible during an infectious disease pandemic [30]. Managed mobile health care platforms, in which patients are provided with a tablet computer with all relevant applications pre-installed and connected to relevant peripherals, may simplify and improve the patient experience, and rpvirtual has used this approach with other patient cohorts. The role of health informaticians in supporting consumer health informatics has received limited attention and warrants further exploration.

A uniform model of care for all patients, regardless of care needs or the risk of deterioration, may not be appropriate or necessary. Risk stratification upon admission with enhanced monitoring of patients at a higher risk of deterioration was considered, although at the time, limited empirical evidence was available to guide that strategy [31]. Pulse oximetry appears to be a useful tool for risk stratification. Patients with COVID-19 experience deterioration typically on day 7 of symptom onset, which was the median period of hospitalization for patients who developed an associated pneumonia [32]. Patient-reported pulse oximetry measurements are effective for detecting silent hypoxia and predicting hospitalization; this supports the use of this technology for patient monitoring and risk stratification [16]. In addition to the primary management of COVID-19, pulse oximetry has effectively facilitated decisions on the early discharge of patients from hospital for a cohort of patients with severe COVID-19, with particular benefits among patients with a persistent need for oxygen therapy [13]. A risk-stratified care pathway has now been developed and is being used to guide ongoing patient management (Multimedia Appendix 3).

Rapid changes to the EMR are required to support VHC for patients with COVID-19. EMRs are potentially useful tools for rapid deployment of standardized processes, including responses to the COVID-19 pandemic [33]. To support the redesign of rpvirtual to provide care to patients with COVID-19, new locations and patient lists were generated in the EMR. Access...
to the electronic Between the Flags record for detecting signs of deterioration, previously only used in the in-patient setting, was extended to all care center staff for community use. Clinical documentation templates, simple reports, and modifications to the results flowsheet to facilitate recording and clinical review of patient-reported and remotely monitored clinical observations were designed and implemented. However, communication systems were managed separately from the EMR, with separate systems used for text messaging, telephone calls, and videoconferencing. A patient portal would have aided communication and recording of patient-reported measures, as previously reported [14,34]. A comprehensive and integrated suite of digital health care tools would reduce fragmentation of information systems and workflows and improve service delivery by automating manual processes.

Mental health and well-being issues require further consideration in the provision of VHC to patients with COVID-19 in Australia owing to extensive quarantine and self-isolation periods. Such measures for controlling infectious diseases have been associated with negative psychological effects including posttraumatic stress symptoms, confusion, and anger, with the potential to be long-lasting [35]. Two questions directed toward psychological assessment were included in the model to help recognize mental health concerns. The psychological impact of self-isolation in one’s own home may be different from that of individuals placed in mandatory quarantine in hotels after arriving from other countries, which has been a key strategy in Australia [3]. This issue requires further study with consideration to provide access to social workers, psychologists, and psychiatrists through VHC. The key learnings from our experience are summarized in Textbox 4.

Textbox 4. Key learnings from the use of virtual health care for acute management of patients with COVID-19 in Australia.

- The acute nature of COVID-19 and the potential for rapid patient deterioration required 24/7 operations.
- A ratio of approximately 1 nurse per 25 patients per shift was required to support a model of care with high extensive of videoconferencing and continuous monitoring of patient observations with 24/7 operations; however, this could be reduced during low-activity periods such as during nighttime when patient contact was not scheduled.
- There was a high administrative burden in managing communication and interactions with enrolled patients when virtual health care is used without a digital patient engagement platform, such as a patient portal or other customer relationship management system with an integrated communications suite.
- Pulse oximetry appears to be an important tool in virtual care models for COVID-19 management for risk stratification and detection of deterioration and is feasible to use in the community. Readings that can be directly obtained from the device are useful.
- Consumers should be provided education, training, and support to use health technology if it is to be relied on for monitoring and management in virtual care settings.
- Social isolation measures introduce mental health risks that need to be considered within models of care, including screening tools and virtual access to appropriate services.

Comparison With Previous Studies
The use of VHC for managing outpatients with COVID-19 has been widely reported with small cohorts, at single centers, or in health systems. A consistent finding is that VHC is safe and effective for hospital avoidance, with low rates of clinical care escalation to the emergency department or other in-person observations. However, there is significant heterogeneity in the models of care and technology models, with few reports on programs that highly utilize video consultations combined with remote patient monitoring of clinical observations, including pulse oximetry and temperature, along with 24/7 support.

The only other study from Australia, which described the generation and use of a virtual ward within an existing hospital, involved the referral of patients by the local public health service, and patients were contacted once or twice a day only by telephone [17].

Studies on the use of VHC for COVID-19 management in the United States have reported the extensive use of patient portals, patient-reported symptoms and observations, and the use of telephonic consultations, with a reduced use of remote patient monitoring systems and videoconferencing. One large health system used symptom questionnaires on a daily basis to stratify and prioritize enrolled patients with suspected or confirmed COVID-19 for telephonic consultations. This system reported low rates of escalation to the emergency department; however, there was no access to remote monitoring or video consultations. With increasing experience, a triage system was adopted to exclude low-risk patients owing to the low incidence of deterioration [14]. Another institution reported the need to expand their workforce to provide a 24-hour service because they found that the enrolled patients were sending text messages to their remote patient monitoring app after the service was discontinued each day at 5 PM [12].

Expansion of a model of VHC to the in-patient setting, based on continuous video observation, has also been described. Patients admitted for COVID-19 management were placed in negative pressure rooms equipped with video monitoring systems to facilitate 2-way video and audio communication with ward health care staff [34]. This reduced the exposure of health care workers to COVID-19 and the consumption of PPE.

Limitations
This study has several limitations. First, this study has a small cohort, relative to other studies, and describes short-term experiences. Second, the technology used in this study was selected on the basis of pragmatic considerations, limiting opportunity for more thorough evaluation prior to use in practice. Finally, this study describes early results from a single health system in Australia and may not be generalizable to other...
locations. Australia has seen relatively smaller COVID-19 caseloads than other high-income countries, implying that the demand for health services did not exceed their current capacity to the same extent as that in other countries. Significant heterogeneity has been in described virtual health models of care for COVID-19, which are strongly influenced by context, pragmatism, and local constraints. Even so, sharing our experience may help inform others as they continue dealing with the pandemic.

**Conclusions**

In summary, community-based VHC is a feasible and safe approach for managing less severe cases of COVID-19 and can be rapidly implemented in the Australian context for pandemic management with strong operational and clinical governance, including integration with clinical specialists. Health services implementing VHC should anticipate challenges with rapid technology implementations and provide adequate support to resolve them, including strategies to support consumer use of health information technologies.

**Conflicts of Interest**

None declared.

Multimedia Appendix 1

Care centre eligibility criteria decision tree for COVID-19 management by rpavirtual.

[PDF File (Adobe PDF File), 529 KB - jmir_v23i3e21064_app1.pdf ]

Multimedia Appendix 2

Printout of 48h view of Standard Adult General Observation Chart with recorded clinical observations as shown in the electronic medical record.

[PDF File (Adobe PDF File), 272 KB - jmir_v23i3e21064_app2.pdf ]

Multimedia Appendix 3

rpavirtual COVID-19 risk stratification and clinical pathways.

[PDF File (Adobe PDF File), 113 KB - jmir_v23i3e21064_app3.pdf ]

**References**


Abbreviations

- **EMR**: electronic medical record
- **PPE**: personal protective equipment
- **rpavirtual**: Royal Prince Alfred Virtual Hospital
- **SLHD**: Sydney Local Health District
- **VHC**: virtual health care

©Owen Rhys Hutchings, Cassandra Dearing, Dianna Jagers, Miranda Jane Shaw, Freya Raffan, Aaron Jones, Richard Taggart, Tim Sinclair, Teresa Anderson, Angus Graham Ritchie. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 09.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Behavioral Intention to Receive a COVID-19 Vaccination Among Chinese Factory Workers: Cross-sectional Online Survey

Ke Chun Zhang¹, MSc; Yuan Fang², PhD; He Cao¹, MSc; Hongbiao Chen¹, MSc; Tian Hu¹, BSc; Yaqi Chen¹, BSc; Xiaofeng Zhou¹, BSc; Zixin Wang³, PhD

¹Longhua District Center for Disease Control and Prevention, Shenzhen, China
²Department of Early Childhood Education, The Education University of Hong Kong, Hong Kong, China
³JC School of Public Health and Primary Care, The Chinese University of Hong Kong, Hong Kong, China

Corresponding Author:
Zixin Wang, PhD
JC School of Public Health and Primary Care
The Chinese University of Hong Kong
Room 508, School of Public Health, Prince of Wales Hospital, Shatin, N.T.
Hong Kong, 666888
China
Phone: 852 22528740
Email: wangzx@cuhk.edu.hk

Abstract

Background: COVID-19 vaccines will become available in China soon. Understanding communities’ responses to the forthcoming COVID-19 vaccines is important. We applied the theory of planned behavior as the theoretical framework.

Objective: This study investigates the prevalence of and factors associated with behavioral intention to receive self-financed or free COVID-19 vaccinations among Chinese factory workers who resumed work during the pandemic. We examined the effects of factors including sociodemographics, perceptions related to COVID-19 vaccination, exposure to information about COVID-19 vaccination through social media, and COVID-19 preventive measures implemented by individuals and factories.

Methods: Participants were full-time employees 18 years or older who worked in factories in Shenzhen. Factory workers in Shenzhen are required to receive a physical examination annually. Eligible workers attending six physical examination sites were invited to complete a survey on September 1-7, 2020. Out of 2653 eligible factory workers, 2053 (77.4%) completed the online survey. Multivariate two-level logistic regression models and ordinal logistic regression models were fitted.

Results: The prevalence of behavioral intention to receive a COVID-19 vaccination was 66.6% (n=1368, conditional on 80% vaccine efficacy and market rate) and 80.6% (n=1655, conditional on 80% vaccine efficacy and free vaccines). After adjusting for significant background characteristics, positive attitudes toward COVID-19 vaccination (adjusted odds ratio [AOR] 1.20, 95% CI 1.15-1.25 and AOR 1.24, 95% CI 1.19-1.30), perceived support from significant others for getting a COVID-19 vaccination (AOR 1.43, 95% CI 1.32-1.55 and AOR 1.37, 95% CI 1.25-1.50), and perceived behavioral control to get a COVID-19 vaccination (AOR 1.51, 95% CI 1.32-1.73 and AOR 1.28, 95% CI 1.09-1.51) were positively associated with both dependent variables (conditional on 80% vaccine efficacy and market rate or free vaccines, respectively). Regarding social media influence, higher frequency of exposure to positive information related to COVID-19 vaccination was associated with a higher intention to receive a COVID-19 vaccination at market rate (AOR 1.53, 95% CI 1.39-1.70) or a free vaccination (AOR 1.52, 95% CI 1.35-1.71). Higher self-reported compliance with wearing a face mask in the workplace (AOR 1.27, 95% CI 1.02-1.58 and AOR 1.67, 95% CI 1.24-2.27) and other public spaces (AOR 1.80, 95% CI 1.42-2.29 and AOR 1.34, 95% CI 1.01-1.77), hand hygiene (AOR 1.21, 95% CI 1.00-1.47 and AOR 1.52, 95% CI 1.19-1.93), and avoiding social gatherings (AOR 1.22, 95% CI 1.01-1.47 and AOR 1.55, 95% CI 1.23-1.95) and crowded places (AOR 1.24, 95% CI 1.02-1.51 and AOR 1.73, 95% CI 1.37-2.18) were also positively associated with both dependent variables. The number of COVID-19 preventive measures implemented by the factory was positively associated with the intention to receive a COVID-19 vaccination under both scenarios (AOR 1.08, 95% CI 1.04-1.12 and AOR 1.06, 95% CI 1.01-1.11).

Conclusions: Factory workers in China reported a high behavioral intention to receive a COVID-19 vaccination. The theory of planned behavior is a useful framework to guide the development of future campaigns promoting COVID-19 vaccination.
Introduction

The COVID-19 pandemic remains out of control worldwide. As of September 20, 2020, there were 30,675,675 confirmed cases and 954,417 deaths [1]. Since immunization against COVID-19 is not yet available, the current means for pandemic control is to avoid exposure. These measures (eg, physical distancing and lockdown) are likely detrimental to the global economy. Except for China, all G20 countries, a group of the world’s largest economies, experienced a decrease in gross domestic product in the second quarter of 2020 due to the COVID-19 pandemic [2]. Moreover, implementation of these measures also results in substantial impairment in physical and psychological well-being [3]. There is a strong need for an effective vaccine to keep COVID-19 under control.

Development of the COVID-19 vaccines is on the way. According to the World Health Organization, there are 34 and 142 candidate vaccines in clinical and preclinical evaluation, respectively, as of September 3, 2020; four Chinese candidate vaccines have entered phase III clinical trials [4]. The interim analysis of the phase III trials of a China candidate COVID-19 vaccine (Beijing Institute of Biological Product’s inactivated vaccine Sinopharm) showed that it had 86% vaccine efficacy against COVID-19 [5]. The analysis also showed the vaccine had a 99% seroconversion rate of neutralizing antibodies and a 100% effectiveness in preventing moderate and severe cases of the disease with no serious safety concern [5]. The United Arab Emirates Ministry of Health and Prevention announced the official registration of the vaccine on December 9, 2020 [5]. On July 22, 2020, the National Health Commission of the People’s Republic of China authorized the emergency use of the COVID-19 vaccination and provided COVID-19 vaccines to workers, students, and diplomatic personnel who need to travel abroad, as well as health care workers and personnel working for pandemic and border control [6,7]. According to the recent press release, there were 56,000 Chinese people who had received COVID-19 vaccines developed by Sinopharm before travelling abroad. So far, none of them reported a SARS-CoV-2 infection [8]. It was estimated that at least one COVID-19 vaccine would become available in China by the end of 2020 [9-11]. The market rate will be set at around ¥1000 (about US $154) [10].

The effectiveness of pandemic vaccination campaigns is dependent on both the vaccines’ effectiveness and people’s willingness to be vaccinated. Simulation experiments have shown that, when the reproduction number ($R_0$) was 2.5 and vaccination occurred when 5% of the population had been exposed to SARS-CoV-2, a vaccine efficacy of 80% with 75% coverage could reduce the total number of SARS-CoV-2 cases by 85% without any other measures such as social distancing [12]. A systematic review showed that respondents’ willingness to receive a H1N1 influenza A vaccine ranged from 8%-67% [13]. Several factors consistently predict the behavioral intention to receive such a vaccine, including risk of infection, severity of the public health event and personal consequences from the illness, harm or adverse events from the vaccination, use of previous vaccination, and ethnicity [13]. To our knowledge, at least 11 published studies and preprints have investigated behavioral intention to receive a COVID-19 vaccination [14-24]. The impact of COVID-19 on the general population and specific groups is quite different, which may cause different responses to COVID-19 vaccination. For example, health care workers’ risk of COVID-19 infection was 9-11 times higher than the general population [25], and they had the highest priority to receive a COVID-19 vaccination [26]. Free vaccines are likely to be provided to them in the near future. However, prevalence of poor mental health status (eg, depression, anxiety, or posttraumatic stress disorders) caused by a high risk of infection, being overworked, frustration, discrimination, social isolation, and exhaustion were much higher in this group as compared to the general population [27]. This might explain the lower intention to receive COVID-19 vaccination among health care workers (63.0%-76.4%) [23,24] as compared to that of the general population (57.6%-94.3%) [14-17,20-22]. Factory workers who resumed work during the pandemic are another subpopulation at higher risk of COVID-19 infection than that of the general population, as many factories are crowded settings, making physical distancing challenging [28]. COVID-19 outbreaks in the workplace have been reported in China and other countries [28-30]. Moreover, most of the Chinese factory workers are young. Even if infected with COVID-19, many of them may be asymptomatic and unaware of their infection; they may become a driving force of COVID-19 transmission in the workplace and community [31,32]. Previous studies have reported that the prevalence of poor mental health status was similar for factory workers compared to that of the general population [11] and was much lower than health care workers [27]. It is expected that they have a higher motivation to receive a COVID-19 vaccination than the general population and health care workers. COVID-19 vaccination for factory workers is important to achieve a balance of work resumption and pandemic control.

Health promotion is needed even when free vaccinations are available. To develop effective health promotion campaigns, it is important to understand the facilitators and barriers of COVID-19 vaccination uptake among factory workers. Previous studies have found a number of factors associated with behavioral intention to receive a COVID-19 vaccination for the general population or health care workers, including sociodemographics (eg, age, gender, marital status, income, and history of influenza vaccination), presence of comorbid conditions, and trust in government. Moreover, perceptions related to COVID-19 (eg, risk of infection) and COVID-19 vaccination (eg, perceived efficacy, concerns of side effects, other’s acceptance, and confidence to receive vaccination)
 influenced their intention to receive a COVID-19 vaccination [14-24]. We considered these factors in this study. Theory-based interventions are more effective than those that are not [33]. In this study, we applied the theory of planned behavior (TPB) as the theoretical framework [34]. The TPB postulates that behavioral intention to adopt a health-related behavior (eg, uptake of a COVID-19 vaccination) is a strong predictor of actual behavior. To form such an intention, one would evaluate the pros and cons of the behavior (positive and negative attitudes), consider whether their significant others would support such behavior (perceived subjective norm), and appraise how much control one has over the behavior (perceived behavioral control) [34]. In recent studies, the TPB has been used to successfully explain behavioral intention and actual behaviors to receive human papillomavirus (HPV) and influenza vaccinations [35-37].

Across countries, it is common to encounter vaccination-related information on social media [38]. Previous studies have shown that over 60% of people in the United States used social media as a common source of information related to HPV and influenza vaccinations [39,40]. During the pandemic, people are also actively seeking information about COVID-19 vaccination on different social media platforms [41]. Several studies have reported that social media use would influence perceptions and behaviors related to vaccination. Four studies found a negative influence of social media on users’ perceptions related to vaccination (eg, increase doubt, fear, or barriers for vaccination) [42-45]. Regarding vaccination uptake, women in the United Kingdom who used social media to gather information reported lower pertussis vaccination uptake during pregnancy [46], while positive associations between information exposure through social media and vaccination were found among White and African American adults in the United States [40] and older adults in China [47]. Moreover, different contents related to COVID-19 may have varying effects on personal preventive measures [48]. In this study, we investigated the associations between exposure to different content related to COVID-19 vaccination on social media and behavioral intention to receive a vaccination.

To the best of our knowledge, there have been no studies investigating behavioral intention to receive a COVID-19 vaccination and associated factors among factory workers who resumed work during the COVID-19 pandemic. To address these gaps, this study investigated behavioral intention to receive a self-financed or free COVID-19 vaccination among a sample of factory workers in Shenzhen, China. We examined the effects of factors including sociodemographics, perceptions related to COVID-19 vaccination based on the TPB, exposure to COVID-19 specific information through different media, and COVID-19 preventive measures implemented by individuals and factories.

**Methods**

**Study Design**

We conducted a cross-sectional closed online survey of 2053 factory workers in Shenzhen, China on September 1-7, 2020.

Of the 13 million residents in Shenzhen in 2018, 65.1% were internal migrants and 34.3% were factory workers [49].

**Participants and Data Collection**

This study was conducted in the Longhua district of Shenzhen. In Shenzhen, the majority of the factories are located in Longhua. As of 2018, there are over 2000 factories and about one million factory workers in Longhua. Participants were full-time employees of factories in Shenzhen that were 18 years or older. In Shenzhen, factory workers are required to receive a physical examination at designated hospitals or the Centre for Disease Control and Prevention (CDC) annually. All five designated hospitals (three public and two private) and the one district CDC providing physical examination services to factory workers in Longhua were our study sites for recruitment. To avoid selection bias, the fieldworkers approached all adults attending these sites for physical examination during the study period. They briefed prospective participants about the study details, confirmed their eligibility, and invited them to join the study. Participants were guaranteed that participation was voluntary, refusal would have no effect on them, the survey would not collect personal contacts or identification, and data would be kept strictly confidential and only be used for research purposes. Verbal consent was obtained instead of written consent to allow participants to maintain anonymity. We developed an online questionnaire using Questionnaire Star, a commonly used online survey platform in China. Quick Response (QR) codes were generated to access the online questionnaire. Prospective participants were asked to scan the QR code on site to complete the survey. Each mobile device was only allowed to access the online questionnaire once to avoid duplicate responses. The participants were asked not to disseminate the QR codes to access the survey to other people. The survey had 66 items (about 15 items per page for four pages), which took about 15 minutes to complete. The Questionnaire Star performed completeness checks before the questionnaire was submitted. Participants were able to review and change their responses through a “Back” button. An e-coupon of ¥10 (US $1.54) was sent to participants upon completion. In case participants did not have internet access or a smartphone, the research team prepared a tablet computer in each study site for them to complete the online survey. All data was stored in the online server of Questionnaire Star and protected by a password. Only the corresponding author had access to the database. Ethics approval was obtained from the Longhua District CDC (reference: 20200001).

**Measures**

**Design of the Questionnaire**

A panel consisting of one CDC staff, two public health researchers, a health psychologist, a senior factory manager, and a factory worker was formed to develop the questionnaire used in this study. The questionnaire was pilot-tested among 10 factory workers to assess clarity and readability. These 10 workers did not participate in the actual survey. Based on the workers’ comments, the panel revised and finalized the questionnaire.
**Background Characteristics**

Participants were asked to report on sociodemographics such as age, gender, relationship status, whether they had a child, highest education level, monthly personal income, status as frontline workers or management, and type of factory they were working in. In addition, participants were also asked about history of seasonal influenza vaccination and whether they had a family member with a history of COVID-19.

**Behavioral Intention to Receive COVID-19 Vaccination Under Different Scenarios**

Participants were briefed with the following: “COVID-19 vaccines developed by China are likely to become available by the end of 2020.” We assessed behavioral intention to receive COVID-19 vaccination under four scenarios: (1) conditional on 50% vaccine efficacy and market rate (¥1000 or US $154), (2) conditional on 80% vaccine efficacy and market rate, (3) conditional on 50% vaccine efficacy and free vaccines, and (4) conditional on 80% vaccine efficacy and free vaccines. On June 2020, the US Food and Drug Administration released guidance for development and licensure of vaccines to prevent COVID-19, which stated that the primary efficacy end point estimate for a placebo-controlled efficacy trial for a COVID-19 vaccine should be at least 50% to ensure that a widely deployed vaccine is effective [50]. Therefore, we chose a threshold of 50% as the lowest estimate of COVID-19 vaccine efficacy in this study. Another study also measured behavioral intention to receive a COVID-19 vaccination conditional on 50% vaccine efficacy [51]. Based on the results of the simulation experiments mentioned in the previous paragraph, Bartsch et al [12] concluded that the vaccine has to have an efficacy of at least 80% to extinguish the COVID-19 epidemic without any other measures. Therefore, we chose a threshold of 80% as an optimal estimation of vaccine efficacy. The threshold of 80% was also close to the vaccine efficacy of the China candidate vaccine (86%) in phase III clinical trials [5]. The cost of COVID-19 vaccines was based on available information in the press release [10].

The response categories were 1 (very unlikely), 2 (unlikely), 3 (neutral), 4 (likely), and 5 (very likely). Behavioral intention was defined as “likely” or “very likely.” This definition has been commonly used in previous studies [51-53]. In this study, we measured behavioral intention to receive a COVID-19 vaccination under the condition that its efficacy and cost was made known to the participants. The process ensured that all participants received uniform information and, hence, allowed for better interpretation of the results.

**Perceptions Related to COVID-19 Vaccination Based on the TPB**

Three scales were constructed to assess perceptions related to COVID-19 vaccination based on the TPB. They were (1) the five-item Positive Attitude Scale (eg, COVID-19 vaccination is highly effective in protecting you from COVID-19), (2) the four-item Negative Attitude Scale (eg, COVID-19 vaccines will have severe side effects), and (3) the two-item Perceived Subjective Norm Scale (perceived support from doctors/nurses and family members/friends; response categories: 1, disagree; 2, neutral; and 3, agree). The Cronbach α of these scales ranged from .67 to .85; single factors were identified by exploratory factor analysis, explaining for 50.7%-54.0% of total variance. In addition, perceived behavioral control to receive a COVID-19 vaccination was measured by a single item (receiving a COVID-19 vaccination is easy for you if you want to; 1, disagree; 2, neutral; and 3, agree).

**Influence of Social Media**

Participants were asked to report the frequency of their exposure to the following information related to a COVID-19 vaccination on social media (WeChat, WeChat moments, Weibo, Tiktok, etc) in the past month (response categories: 1, almost never; 2, seldom; 3, sometimes; 4, always). Such information included positive information related to COVID-19 vaccination (eg, new vaccines entering clinical trials), negative information related to COVID-19 vaccination (eg, concerns about efficacies and supplies), testimonials given by participants of the COVID-19 clinical trials, and negative information about vaccine incidents in China (eg, selling problematic vaccines and severe side effects).

**COVID-19 Preventive Measures Implemented by Individuals and Factories**

Participants were asked to report frequency of wearing face masks when having close contact with others in a workplace and other public settings (public spaces or transportation) in the past month (response categories: every time, often, sometimes, never). Participants also reported frequency of sanitizing hands using soaps, liquid soaps, or alcohol-based hand rubs after returning from public spaces or touching public installations or equipment and whether they avoided social or meal gatherings with people who they do not live with and crowded places in the past month. The Shenzhen government advocated that eight preventive measures should be implemented in the factories, including (1) prohibiting nonemployees from entering workplaces, (2) taking body temperature and sanitizing hands for all employees before entering the workplace, (3) providing face masks to all employees, (4) keeping adequate distance (eg, >1 meter) between workstations, (5) requiring employees to wear face masks when they have close contact with other people, (6) disinfecting the workplace frequently, (7) maintaining adequate ventilation in the workplace, and (8) setting up partitions in factory canteens [54,55]. Participants reported whether their factory implemented these eight preventive measures. A composite indicator variable was constructed by counting the number of preventive measures implemented by the factory (ranging from 0 to 8). The English and Chinese versions of the questionnaire are shown in Multimedia Appendix 1.

**Sample Size Planning**

The target sample size was 2000. Given a statistical power of 0.80 and an alpha value of .05, and assuming the level of behavioral intention to receive a COVID-19 vaccination in the reference group (without a facilitating condition) to be 30%-70%, the sample size could detect a smallest odds ratio (OR) of 1.29 between those with and without such facilitating condition (PASS 11.0; NCSS, LLC).
Statistical Analysis

The binary variables on behavioral intention to receive a COVID-19 vaccination conditional on 80% vaccine efficacy and market rate and conditional on same efficacy and free vaccines were used as the dependent variables. Multilevel logistic regression models (level 1: study sites; level 2: individual participants) were used to analyze factors associated with the dependent variables. Random intercept models were used to allow the intercept of the regression model to vary across study sites, which could account for intracorrelated nested data. Multilevel logistic regression models are commonly used in studies with similar sampling methods [28,56]. A univariate two-level logistic regression model first assessed the significance of the association between each of the background characteristics and the dependent variables. Background characteristics with \( P < 0.05 \) in univariate analysis were adjusted in the multivariate two-level logistic regression model.

In addition, using behavioral intention to receive a COVID-19 vaccination conditional on 80% vaccine efficacy and market rate and conditional on same efficacy and free vaccines were used as ordinal dependent variables (from 1 to 5), and background characteristics were used as independent variables; ORs were obtained using ordinal logistic regressions. Adjustment for significant background characteristics, associations between independent variables of interest (perceptions, information exposure through social media, and preventive measures implemented by individuals and factories) and the dependent variables were then assessed by adjusted odds ratios (AORs). A similar approach was used in previous studies [57]. Principal component analysis with varimax rotation was used to perform explanatory factor analysis. Correlations between information exposure through social media and perceptions related to COVID-19 vaccination were also investigated. Pearson correlation coefficients (r) were obtained. SPSS version 26.0 (IBM Corp) was used for data analysis, with \( P < 0.05 \) considered statistically significant.

Results

Background Characteristics

Out of 2653 eligible factory workers (between 60 and 1200 across study sites) that were approached, 2053 completed the online survey (between 40 and 968 across study sites). The overall response rate was 77.4% (ranging from 66.7% to 80.7% at different sites). Main reasons for nonresponse were lack of time and other logistic reasons. All participants that were approached had access to the internet or a smartphone, and none of them used the tablet computers prepared by the research team. Over half of the participants were younger than 40 years (n=1490, 72.6%), were female (n=1179, 57.4%), were married (n=1455, 70.9%), had children (n=1466, 71.4%), did not receive tertiary education (n=1472, 71.7%), had a monthly income less than ¥5000 (US $773; n=1421, 69.2%), were frontline workers (n=1476, 71.9%), and were working for electronic device manufacturers (n=1473, 71.7%). Among the participants, 20.3% (n=416) had received a seasonal influenza vaccination at least once, and 1.6% (n=32) had at least one family member with a history of COVID-19 (Table 1).
Table 1. Background characteristics of the participants (N=2053).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Participants, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
</tr>
<tr>
<td>18-30</td>
<td>757 (36.9)</td>
</tr>
<tr>
<td>31-40</td>
<td>733 (35.7)</td>
</tr>
<tr>
<td>41-50</td>
<td>491 (23.9)</td>
</tr>
<tr>
<td>&gt;50</td>
<td>72 (3.5)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>874 (42.6)</td>
</tr>
<tr>
<td>Female</td>
<td>1179 (57.4)</td>
</tr>
<tr>
<td><strong>Relationships status</strong></td>
<td></td>
</tr>
<tr>
<td>Currently single</td>
<td>448 (21.8)</td>
</tr>
<tr>
<td>Having a stable boyfriend/girlfriend</td>
<td>150 (7.3)</td>
</tr>
<tr>
<td>Married</td>
<td>1455 (70.9)</td>
</tr>
<tr>
<td><strong>Have children</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>587 (28.6)</td>
</tr>
<tr>
<td>Yes</td>
<td>1466 (71.4)</td>
</tr>
<tr>
<td><strong>Highest education level attained</strong></td>
<td></td>
</tr>
<tr>
<td>Junior high or below</td>
<td>859 (41.8)</td>
</tr>
<tr>
<td>Senior high or equivalent</td>
<td>613 (29.9)</td>
</tr>
<tr>
<td>College/university or above</td>
<td>581 (28.3)</td>
</tr>
<tr>
<td><strong>Monthly personal income (¥; US $)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;3000 (463.84)</td>
<td>512 (24.9)</td>
</tr>
<tr>
<td>3000-4999 (463.84-772.92)</td>
<td>909 (44.3)</td>
</tr>
<tr>
<td>5000-6999 (773.07-1082.15)</td>
<td>359 (17.5)</td>
</tr>
<tr>
<td>7000-9999 (1082.30-1545.99)</td>
<td>150 (7.3)</td>
</tr>
<tr>
<td>≥10,000 (1546.14)</td>
<td>123 (6.0)</td>
</tr>
<tr>
<td><strong>Type of work</strong></td>
<td></td>
</tr>
<tr>
<td>Frontline workers</td>
<td>1476 (71.9)</td>
</tr>
<tr>
<td>Management staff</td>
<td>577 (28.1)</td>
</tr>
<tr>
<td><strong>Factory type</strong></td>
<td></td>
</tr>
<tr>
<td>Electronic devices manufacturers</td>
<td>1473 (71.7)</td>
</tr>
<tr>
<td>Other factories</td>
<td>580 (28.3)</td>
</tr>
<tr>
<td><strong>History of seasonal influenza vaccination</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1637 (79.7)</td>
</tr>
<tr>
<td>Yes</td>
<td>416 (20.3)</td>
</tr>
<tr>
<td><strong>Having at least one family member with a history of COVID-19</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2021 (98.4)</td>
</tr>
<tr>
<td>Yes</td>
<td>32 (1.6)</td>
</tr>
</tbody>
</table>

Behavioral Intention to Receive COVID-19 Vaccination Under Different Scenarios
The prevalence of behavioral intention to receive a COVID-19 vaccination was 53.5% (n=1099, conditional on 50% vaccine efficacy and market rate), 66.6% (n=1368, conditional on 80% vaccine efficacy and market rate), 75.6% (n=1551, conditional on 50% vaccine efficacy and free vaccines), and 80.6% (n=1655, conditional on 80% vaccine efficacy and free vaccines; Table 2).
Table 2. Perceptions related to COVID-19 vaccination and preventive measures taken up by participants and the factories they were working in (N=2053).

<table>
<thead>
<tr>
<th>Perceptions</th>
<th>Participants, n (%)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Behavioral intention to take up COVID-19 vaccination</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intention to get COVID-19 vaccines conditional on 50% efficacy and market rate (¥1000 or US $140)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Very unlikely | 222 (10.8) | N/A*
| Unlikely | 208 (10.1) |
| Neutral | 524 (25.5) |
| Likely | 543 (26.4) |
| Very likely | 556 (27.1) |
| Intention to get COVID-19 vaccines conditional on 80% efficacy and market rate (¥1000 or US $140) | | |
| Very unlikely | 155 (7.5) |
| Unlikely | 147 (7.2) |
| Neutral | 383 (18.7) |
| Likely | 639 (31.1) |
| Very likely | 729 (35.5) |
| Intention to get COVID-19 vaccines conditional on 50% efficacy and free vaccines | | |
| Very unlikely | 108 (5.3) |
| Unlikely | 98 (4.8) |
| Neutral | 296 (14.4) |
| Likely | 453 (22.1) |
| Very likely | 1098 (53.5) |
| Intention to get COVID-19 vaccines conditional on 80% efficacy and free vaccines | | |
| Very unlikely | 117 (5.7) |
| Unlikely | 77 (3.8) |
| Neutral | 204 (9.9) |
| Likely | 320 (15.6) |
| Very likely | 1335 (65.0) |
| **Perceptions related to COVID-19 vaccination based on the theory of planned behavior** | | |
| Positive attitudes toward COVID-19 vaccination | | |
| Positive Attitude Scaleb | 13.3 (2.3) | N/A |
| Negative attitudes toward COVID-19 vaccination | | |
| Negative Attitude Scalec | 8.0 (1.9) | N/A |
| Perceived subjective norm related to COVID-19 vaccination | | |
| Perceived Subjective Norm Scaled | 5.1 (1.2) | N/A |
| Perceived behavioral control to receive COVID-19 vaccination | | |
| Receiving COVID-19 vaccination is easy for you if you want to | 2.3 (0.7) | N/A |
| **Influence of social media related to COVID-19 vaccination** | | |
| Frequency of exposure to positive information related to COVID-19 vaccination (eg, new vaccines entering clinical trials, promising efficacies of the vaccines, and vaccines will enter the market soon) on social media | 2.8 (1.0) | N/A |
| Frequency of exposure to negative information related to COVID-19 vaccination (eg, concerns about efficacies and supplies, side effects of the vaccines, and receiving vaccines will cause COVID-19) on social media | 2.3 (0.9) | N/A |
| Frequency of exposure to testimonials given by participants of the COVID-19 vaccine clinical trials on social media | 1.9 (1.0) | N/A |
Perceptions Related to COVID-19 Based on the TPB and Influence of Social Media

Means and SDs of items and scales related to COVID-19 vaccination based on the TPB are described in Table 2 and Multimedia Appendix 2. Among the participants, 66.4% (n=1363) were sometimes or always exposed to positive information related to COVID-19 vaccinations in the past month, while fewer participants were sometimes or always exposed to negative information related to COVID-19 vaccinations (n=842, 41.0%) or other vaccines in China (n=571, 27.8%), or exposed to testimonials given by participants of COVID-19 vaccination clinical trials (n=594, 28.9%).

COVID-19 Preventive Measures Implemented by Individuals and Factories

In the past month, 74.0% (n=1519) and 81.6% (n=1675) of participants reported wearing a face mask every time they had close contact with other people in the workplace and in other public settings, respectively. More than half of the participants self-reported sanitizing hands (n=1217, 59.3%), avoiding social or meal gatherings (n=1165, 56.7%), and avoiding crowded places (n=1309, 63.8%; Table 2 and Multimedia Appendix 2).

Factors Associated With Behavioral Intention to Receive a COVID-19 Vaccination

In the univariate logistic regression analysis, age group, relationship status, having children, education level, monthly personal income, status as frontline workers or management staff, history of seasonal influenza vaccination, and having a family member with a history of COVID-19 were significantly associated with one or both dependent variables (Table 3).
Table 3. Associations between background characteristics and behavioral intention to receive COVID-19 vaccination under different scenarios (N=2053).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Conditional on 80% efficacy and market rate, OR&lt;sup&gt;a,b&lt;/sup&gt; (95% CI)</th>
<th>Conditional on 80% efficacy and free vaccines, OR&lt;sup&gt;a,b&lt;/sup&gt; (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-30</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>31-40</td>
<td>0.80 (0.64-1.01)</td>
<td>0.95 (0.72-1.25)</td>
</tr>
<tr>
<td>41-50</td>
<td>0.62 (0.48-0.79)&lt;sup&gt;***&lt;/sup&gt;</td>
<td>0.61 (0.42-0.76)&lt;sup&gt;***&lt;/sup&gt;</td>
</tr>
<tr>
<td>&gt;50</td>
<td>0.48 (0.29-0.79)&lt;sup&gt;**&lt;/sup&gt;</td>
<td>0.57 (0.32-1.02)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Female</td>
<td>1.16 (0.96-1.41)</td>
<td>0.99 (0.78-1.24)</td>
</tr>
<tr>
<td><strong>Relationships status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently single</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Having a stable boyfriend/girlfriend</td>
<td>1.44 (0.94-2.20)</td>
<td>1.55 (0.89-2.71)</td>
</tr>
<tr>
<td>Married</td>
<td>0.94 (0.74-1.18)</td>
<td>0.77 (0.58-1.02)</td>
</tr>
<tr>
<td><strong>Having children</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>0.77 (0.62-0.95)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>0.66 (0.50-0.86)&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Highest education level attained</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Junior high or below</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Senior high or equivalent</td>
<td>1.57 (1.26-1.96)&lt;sup&gt;***&lt;/sup&gt;</td>
<td>2.09 (1.60-2.73)&lt;sup&gt;***&lt;/sup&gt;</td>
</tr>
<tr>
<td>College/university or above</td>
<td>1.94 (1.52-2.47)&lt;sup&gt;***&lt;/sup&gt;</td>
<td>3.39 (2.69-5.01)&lt;sup&gt;***&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Monthly personal income (¥; US $)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;3000 (463.84)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>3000-4999 (463.84-772.92)</td>
<td>1.11 (0.89-1.40)</td>
<td>1.20 (0.89-1.50)</td>
</tr>
<tr>
<td>5000-6999 (773.07-1082.15)</td>
<td>1.36 (1.01-1.83)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>1.39 (0.99-1.97)&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>7000-9999 (1082.30-1545.99)</td>
<td>1.47 (0.97-2.21)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>1.76 (1.05-2.94)&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥10,000 (1546.14)</td>
<td>1.60 (1.01-2.56)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>4.82 (2.05-11.36)&lt;sup&gt;***&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Type of work</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frontline workers</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Management staff</td>
<td>1.24 (1.01-1.54)&lt;sup&gt;**&lt;/sup&gt;</td>
<td>1.66 (1.26-2.19)&lt;sup&gt;***&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Factory type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic devices manufacturer</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Other factories</td>
<td>1.27 (0.97-1.52)</td>
<td>1.09 (0.83-1.42)</td>
</tr>
<tr>
<td><strong>History of seasonal influenza vaccination</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1.29 (1.02-1.64)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>1.28 (0.95-1.71)</td>
</tr>
<tr>
<td><strong>Having a family member with history of COVID-19</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>4.85 (2.21-10.53)&lt;sup&gt;***&lt;/sup&gt;</td>
<td>6.49 (3.10-13.51)&lt;sup&gt;***&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup>OR: odds ratio.

<sup>b</sup>Crude ORs obtained by using univariate two-level logistic regression models.
*P<.05, **P<.01, ***P<.001.

After adjusting for these significant background characteristics, positive attitudes toward COVID-19 vaccination (AOR 1.20, 95% CI 1.15-1.25 and AOR 1.24, 95% CI 1.19-1.30), perceived support from significant others on COVID-19 vaccination uptake (AOR 1.43, 95% CI 1.32-1.55 and AOR 1.37, 95% CI 1.25-1.50), and perceived behavioral control to get a COVID-19 vaccination (AOR 1.51, 95% CI 1.32-1.73 and AOR 1.28, 95% CI 1.09-1.51) were positively associated with both dependent variables (dependent on 80% efficacy and market rate vaccines and dependent on 80% efficacy and free vaccines, respectively). Regarding social media influence, higher frequency of exposure to positive information related to a COVID-19 vaccination was associated with higher intention to receive a COVID-19 vaccination at market rate (AOR 1.53, 95% CI 1.39-1.70) or to receive a free vaccination (AOR 1.52, 95% CI 1.35-1.71). Higher self-reported compliance with wearing a face mask in the workplace (AOR 1.27, 95% CI 1.02-1.58 and AOR 1.67, 95% CI 1.24-2.27) and other public spaces (AOR 1.80, 95% CI 1.42-2.29 and AOR 1.34, 95% CI 1.01-1.77), hand hygiene (AOR 1.21, 95% CI 1.00-1.47 and AOR 1.52, 95% CI 1.19-1.93), and avoiding social and meal gatherings (AOR 1.22, 95% CI 1.01-1.47 and AOR 1.55, 95% CI 1.23-1.95) and crowded places (AOR 1.24, 95% CI 1.02-1.51 and AOR 1.73, 95% CI 1.37-2.18) were also positively associated with one or both dependent variables (dependent on 80% efficacy and market rate vaccines and dependent on 80% efficacy and free vaccines, respectively). A higher number of COVID-19 preventive measures implemented by the factory were significantly associated with a higher intention to receive COVID-19 vaccination under both scenarios (AOR 1.08, 95% CI 1.04-1.12 and AOR 1.06, 95% CI 1.01-1.11, respectively; Table 4).
Table 4. Factors associated with behavioral intention to receive a COVID-19 vaccination under different scenarios (N=2053).

<table>
<thead>
<tr>
<th>Factors</th>
<th>Conditional on 80% and market rate, AOR (^{ab}) (95% CI)</th>
<th>Conditional on 80% efficacy and free vaccines, AOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perceptions relate to COVID-19 vaccination based on the theory of planned behavior</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Attitude Scale</td>
<td>1.24 (1.19-1.30)***</td>
<td>1.24 (1.19-1.30)***</td>
</tr>
<tr>
<td>Negative Attitude Scale</td>
<td>0.98 (0.93-1.03)</td>
<td>1.00 (0.94-1.06)</td>
</tr>
<tr>
<td>Perceived Subjective Norm Scale</td>
<td>1.43 (1.32-1.55)***</td>
<td>1.37 (1.25-1.50)***</td>
</tr>
<tr>
<td>Perceived behavioral control to receive COVID-19 vaccination</td>
<td>1.51 (1.32-1.73)***</td>
<td>1.28 (1.09-1.51)***</td>
</tr>
<tr>
<td><strong>Influence of social media related to COVID-19 vaccination</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of exposure to positive information related to COVID-19 vaccination on social media</td>
<td>1.53 (1.39-1.70)**</td>
<td>1.52 (1.35-1.71)**</td>
</tr>
<tr>
<td>Frequency of exposure to negative information related to COVID-19 vaccination on social media</td>
<td>1.11 (0.99-1.23)</td>
<td>1.07 (0.95-1.21)</td>
</tr>
<tr>
<td>Frequency of exposure to testimonials given by participants of the COVID-19 vaccine clinical trials on social media</td>
<td>1.10 (0.99-1.21)</td>
<td>1.00 (0.89-1.11)</td>
</tr>
<tr>
<td>Frequency of exposure to negative information about vaccine incidents in China on social media</td>
<td>0.95 (0.86-1.04)</td>
<td>0.93 (0.83-1.05)</td>
</tr>
<tr>
<td><strong>Personal COVID-19 preventive measures in the past month</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistent use of face mask in public places/transportation other than the workplace</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1.80 (1.42-2.29)**</td>
<td>1.34 (1.01-1.77)**</td>
</tr>
<tr>
<td>Consistent use of face mask when you have close contact with other people in the workplace</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1.27 (1.02-1.58)**</td>
<td>1.67 (1.24-2.27)**</td>
</tr>
<tr>
<td>Self-reported sanitizing hands (using soaps, liquid soaps, or alcohol-based sanitizer) every time after returning from public spaces or touching public installation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1.21 (1.00-1.47)**</td>
<td>1.52 (1.19-1.93)**</td>
</tr>
<tr>
<td>Self-reported avoiding social gatherings with other people who do not live together</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1.22 (1.01-1.47)**</td>
<td>1.55 (1.23-1.95)**</td>
</tr>
<tr>
<td>Self-reported avoiding crowded places</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1.24 (1.02-1.51)**</td>
<td>1.73 (1.37-2.18)**</td>
</tr>
<tr>
<td>Number of preventive measures implemented by the factory</td>
<td>1.08 (1.04-1.12)**</td>
<td>1.06 (1.01-1.11)**</td>
</tr>
</tbody>
</table>

\(^{a}\)AOR: adjusted odds ratios
\(^{b}\)Background characteristics with \(P<.05\) in univariate two-level logistic regression analysis were adjusted in the multivariate two-level logistic regression models.

*\(P<.05\), **\(P<.01\), ***\(P<.001\).

When behavioral intention was treated as ordinal variables (from 1 to 5) and used as dependent variables, the same sets of associated factors were identified by univariate and multivariate ordinal logistic regression models. The results are presented in Multimedia Appendix 3.

**Correlation Between Information Exposure Through Social Media and Perceptions Related to COVID-19 Vaccination Based on the TPB**

Frequency of exposure to positive information related to COVID-19 vaccinations on social media was positively correlated with positive attitudes (\(r=0.083; P<.001\)), perceived

---

https://www.jmir.org/2021/3/e24673

J Med Internet Res 2021 | vol. 23 | iss. 3 | e24673 | p.663

(page number not for citation purposes)
subjective norm ($r=0.101; P<.001$), and perceived behavioral control ($r=0.064; P=.004$) related to a COVID-19 vaccination. A negative correlation was found between social media exposure and negative attitudes toward a COVID-19 vaccination ($r=-0.090; P<.001$). Moreover, frequency of exposure to positive information related to COVID-19 vaccines on social media was negatively correlated with positive attitudes ($r=-0.080; P<.001$), perceived subjective norm ($r=-0.107; P<.001$), and perceived behavioral control ($r=-0.069; P=0.002$) related to a COVID-19 vaccination. Furthermore, frequency of exposure to testimonials given by COVID-19 vaccine clinical trial participants on social media was negatively correlated with positive attitudes ($r=-0.052, P=0.02$) but was positively correlated with perceived behavioral control to get a COVID-19 vaccination ($r=0.062, P=.005$). In addition, frequency of exposure to negative information about other vaccines in China on social media was negatively correlated with positive attitudes ($r=-0.106, P<.001$) and perceived subjective norm ($r=-0.132, P<.001$) related to a COVID-19 vaccination (Multimedia Appendix 4).

**Discussion**

Our findings represent one of the latest estimates of COVID-19 vaccination acceptability in China and can be used to project future vaccine uptake. Factory workers’ behavioral intention to receive a COVID-19 vaccination was more sensitive to its cost than vaccine efficacy. Given the same vaccine efficacy, the behavioral intention varied from 53.6%–66.6% at market rate to about 80% for a free vaccination. However, small increases were observed (13.1% under market rate and 2% for free vaccination) when comparing behavioral intention conditional on 50% vaccine efficacy and those conditional on 80% vaccine efficacy. The prevalence of behavioral intention conditional on free vaccination was higher than that reported in the United States [16] and Saudi Arabia [22] but was lower than that of the general population in Malaysia [14] and China [23]. A meta-analysis showed that only 43%–62% of those with a behavioral intention would translate that into related actions [58]. Therefore, effective health promotion is needed when COVID-19 vaccines become available to achieve high coverage at a population level.

Our findings provide empirical insights to inform health promotion development. Similar strategies can be used to promote COVID-19 vaccinations at market rate or free vaccinations, as the associated factors of these two dependent variables were similar. Older participants had a lower intention to receive a COVID-19 vaccination. This finding is consistent with a previous study targeting the general population in the United States [20]. Younger people may be more receptive to innovations [59]. Participants with lower education had a lower intention to receive a COVID-19 vaccination compared to workers with higher levels of education. The former might find it difficult to understand information related to COVID-19 vaccination due to a lower literacy level. The finding for income coincides with previous studies that suggested that intention to receive COVID-19 vaccines and uptake of other vaccines were lower among individuals with lower income [20,60]. As compared to frontline workers, management staff were more willing to receive a COVID-19 vaccination. Studies among factory workers have shown that management staff were more likely to adopt personal measures to prevent COVID-19 [28]. Having children was associated with a lower intention to receive a COVID-19 vaccination; future studies should explore whether there are any specific barriers for parents. A history of seasonal influenza vaccination was associated with a higher intention to receive a COVID-19 vaccination at market rate but not with the intention to receive a free vaccination. In China, free seasonal influenza vaccination is provided to older adults, while out-of-pocket payment is required for other groups. Factory workers who had taken a seasonal influenza vaccination may have positive beliefs toward self-financed vaccination. Furthermore, having a family member with history of COVID-19 was strongly associated with a higher intention to receive a COVID-19 vaccination. This finding was expected, as these participants had direct experience related to COVID-19 and were more likely to perceive it as a serious health threat.

The TPB is a potentially useful framework to guide the development of future programs, as three of the four TPB constructs used in this study were significantly associated with both dependent variables in expected directions. It would be useful to increase positive attitudes toward COVID-19 vaccination, as this was found to be a facilitator. In addition to the beneficial effect for oneself (eg, preventing COVID-19 and returning to normal lives), health communication messages should also emphasize that COVID-19 vaccination uptake would result in herd immunization, which could contribute to COVID-19 control. Building up confidence related to the vaccine supply may also be a useful strategy. Over 60% of participants perceived that medical professionals, family, and friends would support them in taking the COVID-19 vaccination. This perception was also a facilitator. Future programs should consider involving the significant others of factory workers to create a subjective norm favoring COVID-19 vaccination uptake. It would also be useful to enhance perceived behavioral control, as this was another facilitator. There is more room for improvement. Outreach in the factories and providing vaccination on-site may be a useful strategy to improve perceived behavioral control among the workers. Relatively few participants had concerns related to cost, side effects, and duration of vaccine protection. The associations between these concerns and behavioral intention were not statistically significant. Addressing these concerns might not be a useful strategy in future promotion campaigns.

Our findings suggest that COVID-19 vaccination triggered intensive responses on social media, as about 60% of the participants sometimes or always were exposed to information specific to COVID-19 vaccination on different social media platforms. Our results showed that exposure to positive information related to COVID-19 vaccination through social media was positively correlated with positive perceptions (ie, positive attitudes, perceived subjective norm, and perceived behavioral control) related to COVID-19 vaccination. These positive perceptions were determinants of behavioral intention to get a COVID-19 vaccination in this study. It is possible that higher amounts of positive information exposure on social media would enhance these positive perceptions, which in turn...
increases behavioral intention to get a COVID-19 vaccination. Longitudinal studies are needed to test whether this pathway exists. Negative information about vaccines is uniquely attractive to social media. Studies have shown that a major vaccine incident (Changchun Changsheng) had significantly impaired the confidence of vaccines among Chinese people [61]. However in this study, negative information about these vaccine incidents did not influence participants’ behavioral intentions to receive a COVID-19 vaccination.

Factory workers who reported higher compliance to personal preventive measures were more willing to receive a COVID-19 vaccination. These people may have stronger motivation and self-efficacy to protect themselves, and a COVID-19 vaccination is likely to be considered as a useful means for protection. Preventive measures implemented by the factories also played important roles. More measures implemented by the factories was associated with a higher intention to receive a COVID-19 vaccination. Through implementation of these measures, factories could cultivate widely shared organizational norms to facilitate behavioral changes among the workers [28,62].

This study has some limitations. First, a direct measure of perceived behavioral control should assess self-efficacy and perceived controllability [63]. Previous studies have suggested these two constructs were differentially associated with behavioral intention and actual behaviors [63]. Due to the limited length of the questionnaire, we only used a single item to measure perceived behavioral control, which mainly covered self-efficacy. Failure to measure perceived controllability together with self-efficacy was one major limitation of this study. This limitation made this study less comparable to other studies using the TPB. Second, this study focused on factory workers and did not study the general population in Shenzhen. In addition, we only included factory workers in one Chinese city. Generalizations should be made cautiously to individuals working in other places in China. Third, since the study was anonymous and did not collect participants’ identification, we were not able to collect the information of those who refused to join the study. Factory workers who refused to join the study might have different characteristics as compared to study participants. Since most of the factory workers in Shenzhen are internal migrants, these is no accurate census data for this group. Therefore, we were not able to perform weighting for our sample; selection bias existed. However, our response rate was relatively high as compared to other online surveys of similar topics [23]. Fourth, data was self-reported and verification was not feasible. Recall bias might exist. Participants may have also overreported their intention and compliance with personal preventive measures due to social desirability. Fifth, most items and scales used in this study were self-constructed based on those from previous studies on H1N1 and seasonal influenza vaccination in China [64,65]. The internal reliability of these scales were acceptable, but these scales may require external validation. Moreover, casual relationships cannot be determined due to the cross-sectional design of this study.

In summary, factory workers in China reported a high behavioral intention to receive a COVID-19 vaccination. The behavioral intention was cost-sensitive, and the proposed market rate was accepted by the majority of the participants. The TPB is a useful framework to guide the development of future campaigns promoting COVID-19 vaccination in this group.

Acknowledgments
This study was funded by the Key Discipline of Infectious Diseases Control and Prevention of Long Hua (grant number 2020-2014).

Conflicts of Interest
None declared.

Multimedia Appendix 1
The English and Chinese versions of the questionnaire used in the online survey.

[DOCX File, 26 KB - imir_v23i3e24673_app1.docx ]

Multimedia Appendix 2
Item responses of perceptions related to COVID-19 vaccination and preventive measures taken up by participants and the factories they were working in.

[DOCX File, 17 KB - imir_v23i3e24673_app2.docx ]

Multimedia Appendix 3
Factors associated with behavioral intention to receive a COVID-19 vaccination obtained by using univariate and multivariate ordinal logistic regression models.

[DOCX File, 19 KB - imir_v23i3e24673_app3.docx ]

Multimedia Appendix 4
Correlations between information exposure through social media and perceptions related to COVID-19 vaccination based on the theory of planned behavior.

[DOCX File, 16 KB - imir_v23i3e24673_app4.docx ]
References


44. Luisi MLR. Who gives a “Like” about the HPV vaccine? Kansan parent/guardian perceptions and social media representations. KU ScholarWorks. 2018. URL: https://kuschosolarworks.ku.edu/handle/1808/26037 [accessed 2021-03-74]


Abbreviations

AOR: adjusted odds ratio
CDC: Centre for Disease Control and Prevention
HPV: human papillomavirus
OR: odds ratio
QR: Quick Response

https://www.jmir.org/2021/3/e24673 J Med Internet Res 2021 | vol. 23 | iss. 3 | e24673 | p.668 (page number not for citation purposes)
TPB: theory of planned behavior
Review

Digital Health Solutions to Control the COVID-19 Pandemic in Countries With High Disease Prevalence: Literature Review

Sharareh R Niakan Kalhori¹, PhD; Kambiz Bahaadinbeigy², PhD; Kolsoum Del Dar³, PhD; Marsa Gholamzadeh¹, MSc; Sadrieh Hajesmaeil-Gohari⁴, PhD; Seyed Mohammad Ayyoubzadeh¹, PhD

¹Department of Health Information Management, Tehran University of Medical Sciences, Tehran, Iran
²Modeling in Health Research Center, Institute for Future Studies in Health, Kerman University of Medical Sciences, Kerman, Iran
³School of Paramedicine, Shahroud University of Medical Sciences, Shahroud, Iran
⁴Medical Informatics Research Center, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran

Corresponding Author:
Seyed Mohammad Ayyoubzadeh, PhD
Department of Health Information Management
Tehran University of Medical Sciences
3rd Floor, School of Allied Medical Sciences
No #17, Farredanesh Alley, Ghods St, Enghelab Ave
Tehran
Iran
Phone: 98 2188983025
Email: s.m.ayyoubzadeh@gmail.com

Abstract

Background: COVID-19, the disease caused by the novel coronavirus SARS-CoV-2, has become a global pandemic, affecting most countries worldwide. Digital health information technologies can be applied in three aspects, namely digital patients, digital devices, and digital clinics, and could be useful in fighting the COVID-19 pandemic.

Objective: Recent reviews have examined the role of digital health in controlling COVID-19 to identify the potential of digital health interventions to fight the disease. However, this study aims to review and analyze the digital technology that is being applied to control the COVID-19 pandemic in the 10 countries with the highest prevalence of the disease.

Methods: For this review, the Google Scholar, PubMed, Web of Science, and Scopus databases were searched in August 2020 to retrieve publications from December 2019 to March 15, 2020. Furthermore, the Google search engine was used to identify additional applications of digital health for COVID-19 pandemic control.

Results: We included 32 papers in this review that reported 37 digital health applications for COVID-19 control. The most common digital health projects to address COVID-19 were telemedicine visits (11/37, 30%). Digital learning packages for informing people about the disease, geographic information systems and quick response code applications for real-time case tracking, and cloud- or mobile-based systems for self-care and patient tracking were in the second rank of digital tool applications (all 7/37, 19%). The projects were deployed in various European countries and in the United States, Australia, and China.

Conclusions: Considering the potential of available information technologies worldwide in the 21st century, particularly in developed countries, it appears that more digital health products with a higher level of intelligence capability remain to be applied for the management of pandemics and health-related crises.

(J Med Internet Res 2021;23(3):e19473) doi:10.2196/19473

KEYWORDS
COVID-19; digital health; information technology; telemedicine; electronic health

Introduction

The novel disease COVID-19, caused by the novel coronavirus SARS-CoV-2, was originally recognized in December 2019 as a case of pneumonia in Wuhan, China; it has since become a global pandemic, affecting most countries worldwide [1]. On March 11, the World Health Organization announced the outbreak of a pandemic and asked for coordinated mechanisms to support readiness and rapid response to the infection across the world’s health sectors [2]. As the incidence of COVID-19...
continues to rise, health care systems are rapidly facing growing clinical demands [3]. Operational management of a pandemic in the era of modern medicine requires novel technologies, such as digital health, that can support the management of COVID-19 cases in different stages [4]. Digital health as an application of information technology has already been used to improve health care organizations; for example, the National Health Service (NHS) in the United Kingdom has established the NHS Digital information center [5]. Digital health is defined as information technologies that can be applied in three aspects: digital patients, digital devices, and digital clinics. A digital patient is a patient who uses and engages with mobile health (mHealth) devices to change and sustain their behavior, including technologies such as telemedicine, patient self-measurements, and digital retention. Digital devices help solve clinical problems and include smartphone-connected rhythm monitoring devices, wireless and wearable devices, and implantable and ingestible sensors. The digital clinic aspect focuses on generating mHealth data, analyzing it so that it is clinically meaningful, and integrating it within clinical workflows. Aspects of digital clinics include precision-based mHealth and n-of-1 designs, population-based mHealth interventions in resource-limited areas, and mHealth regulation and integration [6].

During the COVID-19 pandemic, digital health–based tools may support organizations and societies more efficiently. They are useful for instant, widespread distribution of information, real-time transmission tracking, virtual venue creation for meetings and official day-to-day operations, and telemedicine visits for patients [7-12]. Such applications during the COVID-19 pandemic have been reported in several publications [13-15]. During the recent months of the COVID-19 outbreak, as countries and their responsible organizations such as health ministries and other officials have focused on controlling the pandemic, many supportive and reliable informatics infrastructures have been developed [12]. These infrastructures were applied in practice to prepare to manage an exponential increase in patients with COVID-19. Various digital health strategies have been used for disease control in different countries. A study conducted by Calton et al [16] provided some tips for applying telemedicine as a means to reduce the transmission of COVID-19. A study conducted by Moazzami et al [17] focused on employing telemedicine to prevent disease among health care providers. A study conducted by Keesara et al [18] referred to the capabilities and potential of digital health to fight COVID-19. However, they reviewed digital health–related solutions in general to address how this technology can support health care systems through introducing various strategic roles, such as surveillance, screening, triage, diagnosis, and monitoring, and contact tracing; no data regarding the use of this approach in practice for fighting COVID-19 were provided [19]. Fagherazzi et al [20] emphasized that the great potential of digital technology for COVID-19 control should be considered at the top level of health systems; they also discussed the challenges that policy makers may face in controlling the crisis using digital solutions. Furthermore, in a macro vision, they revealed the required societal and environmental restructuring required for successfully applying digital health technology to control COVID-19, including the health care system, government, public, industry, environment, and energy [15]. These reviews depict a general image regarding the requirement of digital system use and their applications worldwide [21], with no focus on any specific application in a specific country or region. Although these studies have shed light on the topic of applying digital health solutions for COVID-19 control, there is a gap of deep understanding regarding the application of these technologies in countries where COVID-19 is highly prevalent.

Therefore, this study aimed to review and analyze applied information technology and digital health–related strategies to control the COVID-19 pandemic in the 10 countries with the highest prevalence of the disease.

**Methods**

In this review study, the databases of Google Scholar, PubMed, Web of Science, and Scopus were searched in August 2020 to retrieve publications from December 2019 to August 15, 2020. The combination of keywords for searching is shown below:

("Corona virus" OR "COVID 19" OR "coronavirus") AND (computer OR internet OR web* OR mobile OR smart OR email OR video confer* OR telecommunication OR ICT OR "information technology" OR ehealth OR telehealth OR mHealth OR telecare OR telehealth OR telemedicine OR telemonitoring OR digital OR wearable OR IoT OR cloud) AND (Italy OR Spain OR USA OR France OR UK OR Iran OR China OR Netherlands OR Germany OR Belgium)

The inclusion criteria were publications that introduce digital health applications to manage and control COVID-19 in humans, and the exclusion criteria were non-English publications, publications with no abstract, research on data analysis and modeling for prediction of epidemiological parameters, letters to the editor, and review studies. Data were analyzed using descriptive methods. Qualitative analysis of the included studies was performed based on predefined categories. A summary of the reviewed articles is provided in Table 1. Several items were analyzed in each paper, including (1) publication month; (2) country (Italy, Spain, United States, France, United Kingdom, Iran, China, the Netherlands, Germany, and Belgium, as they were the countries where COVID-19 was most prevalent according to the Worldometer website [22]); (3) purpose of the study, including screening, prevention, diagnosis, treatment, and follow-up of cases (defined as follows: screening: no symptom + no contact with COVID-19 patients; prevention: no symptom + contact with COVID-19 patients with no symptoms; diagnosis: having disease symptoms; treatment of COVID-19 cases: decreasing symptoms dramatically; and follow-up: discharged cases with the fewest symptoms); (4) scope and territory (village, city, region/province, state, country, and international), (5) digital tools, including robots, the Internet of Things, videoconferencing, web-based systems, cloud-based systems, wearable devices, clinical decision support systems (CDSSs), intelligent systems, smartphones, mobile apps, telecommunication systems, websites, digital media, and digital quick response (QR) codes.
Table 1. Details of the reviewed papers that discussed the application of digital health tools to control the COVID-19 pandemic.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Meng et al [25]</td>
<td><em>International Journal of Clinical Pharmacy</em></td>
<td>April</td>
<td>China</td>
<td>Treatment</td>
<td>Region</td>
<td>Cloud-based systems, smartphones, telecommunication systems</td>
<td>Provision of pharmacetical care activities to patients and physicians by pharmacists</td>
</tr>
<tr>
<td>Ohannessian et al [26]</td>
<td><em>JMIR Public Health and Surveillance</em></td>
<td>February</td>
<td>France</td>
<td>Prevention</td>
<td>Country</td>
<td>Videoconferencing</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Pan et al [27]</td>
<td><em>Microbes and Infection</em></td>
<td>February</td>
<td>China</td>
<td>Prevention</td>
<td>Country</td>
<td>Mobile apps</td>
<td>Widespread distribution of information and real-time tracking of transmission</td>
</tr>
<tr>
<td>Pan et al [28]</td>
<td><em>Irish Journal of Medical Science</em></td>
<td>March</td>
<td>China</td>
<td>Screening and prevention</td>
<td>City and country</td>
<td>Mobile apps</td>
<td>Real-time tracking of transmission</td>
</tr>
<tr>
<td>Sun et al [29]</td>
<td><em>Annals of Intensive Care</em></td>
<td>March</td>
<td>China</td>
<td>Treatment</td>
<td>State</td>
<td>Intelligent systems</td>
<td>Early warning systems and screening procedures for patients</td>
</tr>
<tr>
<td>Hernández-Garcia and Gimenez-Julvez [30]</td>
<td><em>JMIR Public Health and Surveillance</em></td>
<td>April</td>
<td>Collaboration of the United States, Spain, Switzerland, the United Kingdom, Sweden, and Canada</td>
<td>Screening and prevention</td>
<td>International</td>
<td>Websites and digital media</td>
<td>Widespread distribution of information</td>
</tr>
<tr>
<td>Hua and Shaw [31]</td>
<td><em>International Journal of Environmental Research and Public Health</em></td>
<td>March</td>
<td>China</td>
<td>Screening, prevention, and follow-up</td>
<td>Region/province</td>
<td>Web-based systems, smartphones, websites, digital media, digital QR³ codes</td>
<td>Widespread distribution of information, real-time tracking of transmission, provision of information about “fake news” and rumors</td>
</tr>
<tr>
<td>Drew et al [32]</td>
<td><em>Science</em></td>
<td>May</td>
<td>United Kingdom, United States</td>
<td>Screening</td>
<td>International</td>
<td>Mobile app</td>
<td>Widespread distribution of information, real-time tracking of transmission</td>
</tr>
<tr>
<td>Franco et al [33]</td>
<td><em>Global Spine Journal</em></td>
<td>June</td>
<td>United States</td>
<td>Treatment</td>
<td>State</td>
<td>Videoconferencing, telephone</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Gilbert et al [34]</td>
<td><em>BMJ Open Quality</em></td>
<td>May</td>
<td>United Kingdom</td>
<td>Prevention</td>
<td>City</td>
<td>Videoconferencing, telephone</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Giudice et al [35]</td>
<td><em>International Journal of Environmental Research and Public Health</em></td>
<td>May</td>
<td>Italy</td>
<td>Follow-up</td>
<td>Region</td>
<td>Videoconferencing</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Gong et al [36]</td>
<td><em>Journal of Medical Internet Research</em></td>
<td>April</td>
<td>China</td>
<td>Prevention</td>
<td>Country</td>
<td>Telecommunication system</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------</td>
<td>--------------------------</td>
<td>------------------</td>
<td>-------------------------------</td>
<td>---------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Gong et al [37]</td>
<td>Journal of Medical Internet Research</td>
<td>April</td>
<td>China</td>
<td>Screening</td>
<td>City</td>
<td>Cloud-based system, mobile app, CDSS</td>
<td>Screening of cases and detection of patients</td>
</tr>
<tr>
<td>Goodman-Casanov et al</td>
<td>Journal of Medical Internet Research</td>
<td>April</td>
<td>Spain</td>
<td>Prevention</td>
<td>Country</td>
<td>Telecommunication system</td>
<td>Widespread distribution of information, support for home care and patient self-care</td>
</tr>
<tr>
<td>Grange et al [39]</td>
<td>Applied Clinical Informatics</td>
<td>April</td>
<td>United States</td>
<td>Prevention, diagnosis, treatment, screening</td>
<td>State</td>
<td>Videoconferencing, CDSS, telecommunication system</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Grenda et al [40]</td>
<td>Annals of Surgery</td>
<td>August</td>
<td>United States</td>
<td>Diagnosis, treatment</td>
<td>City</td>
<td>Telecommunication, videoconferencing</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Grossman et al [41]</td>
<td>Neurology</td>
<td>June</td>
<td>United States</td>
<td>Diagnosis, treatment</td>
<td>City</td>
<td>Smartphone, mobile apps</td>
<td>Offering telemedicine visits for patients</td>
</tr>
<tr>
<td>Hames et al [42]</td>
<td>Journal of Psychotherapy Integration</td>
<td>April</td>
<td>United States, Canada</td>
<td>Prevention</td>
<td>Country</td>
<td>Telecommunication system</td>
<td>Training</td>
</tr>
<tr>
<td>Hanna et al [43]</td>
<td>Modern Pathology</td>
<td>June</td>
<td>United States</td>
<td>Prevention, diagnosis</td>
<td>City</td>
<td>Telecommunication system</td>
<td>Diagnosis</td>
</tr>
<tr>
<td>Hom et al [44]</td>
<td>Journal of Psychotherapy Integration</td>
<td>April</td>
<td>United States</td>
<td>Prevention, treatment</td>
<td>City</td>
<td>Videoconferencing</td>
<td>Telemedicine visits for patients, training</td>
</tr>
<tr>
<td>Itamura et al [45]</td>
<td>OTO Open</td>
<td>April</td>
<td>United States</td>
<td>Prevention</td>
<td>Country</td>
<td>Videoconferencing</td>
<td>Telemedicine visits for patients</td>
</tr>
<tr>
<td>Judson et al [46]</td>
<td>Journal of the American Medical Informatics Association</td>
<td>June</td>
<td>United States</td>
<td>Prevention</td>
<td>State</td>
<td>Website</td>
<td>Screening of cases and detection of patients</td>
</tr>
<tr>
<td>Wu et al [47]</td>
<td>European Respiratory Journal</td>
<td>June</td>
<td>China, Italy, Belgium</td>
<td>Diagnosis</td>
<td>International</td>
<td>CDSS</td>
<td>Classification of patients in triage to find the best route</td>
</tr>
<tr>
<td>Wang et al [48]</td>
<td>JMIR mHealth and uHealth</td>
<td>June</td>
<td>China</td>
<td>Prevention</td>
<td>Country</td>
<td>Mobile app (WeChat)</td>
<td>Early tracing and quarantine of potential sources of infection</td>
</tr>
<tr>
<td>Timmers et al [49]</td>
<td>JMIR mHealth and uHealth</td>
<td>June</td>
<td>The Netherlands</td>
<td>Prevention</td>
<td>Country</td>
<td>Mobile app</td>
<td>Education, self-assessment, and symptom monitoring</td>
</tr>
<tr>
<td>Pepin et al [50]</td>
<td>Journal of Medical Internet Research</td>
<td>June</td>
<td>France</td>
<td>Prevention</td>
<td>International</td>
<td>Wearable devices and activity trackers</td>
<td>Definition of the level of quarantine</td>
</tr>
<tr>
<td>Rabuna et al [51]</td>
<td>Telemedicine and e-Health</td>
<td>June</td>
<td>Spain</td>
<td>Prevention</td>
<td>Rural area</td>
<td>TELEA digital web platform</td>
<td>Real-time tracking and monitoring of patients; follow-up of patients by telephone, videoconferencing, and email</td>
</tr>
<tr>
<td>Cheng et al [52]</td>
<td>Community Mental Health Journal</td>
<td>July</td>
<td>United States, Canada, Australia</td>
<td>Prevention</td>
<td>International</td>
<td>Mobile app</td>
<td>Peer-to-peer psychological support for Wuhan health care professionals at the front line of the crisis</td>
</tr>
<tr>
<td>Castaldi et al [53]</td>
<td>Acta Biomedica</td>
<td>July</td>
<td>Italy</td>
<td>Prevention</td>
<td>Region</td>
<td>Social media</td>
<td>Assessment of the dynamic burden of social anxiety through analysis of data from Facebook and Twitter</td>
</tr>
</tbody>
</table>
Provision of psycho-logically safe spaces for staff through pro-viding a three-step e-package with evi-dence-based guidance.

DICt: Digital learning package using agile methodology

Results

The search of scientific databases and manual searches retrieved 771 relevant articles. The titles and abstracts of all the retrieved publications were evaluated by two authors. Disagreements between the two evaluators were discussed and resolved by consensus. After removal of duplicates, 292 articles remained at this stage. Next, 260 publications were removed because they did not meet the inclusion criteria. Afterward, four authors independently reviewed the full text of the remaining publications (N=32). The reviewed papers were studied based on the variables shown in Table 1 and the different distributions discussed below.

For the purpose of this review, studies published from December 2019 to August 15, 2020, were reviewed. The survey identified 32 papers that demonstrated digital health applications to fight the COVID-19 pandemic. The distribution by publication month revealed that the publication of studies regarding digital health and COVID-19 began in February 2020, and the distribution of the 32 publications by month is February, 2 (6%); March, 5 (16%); April, 9 (28%); May, 3 (9%); June, 9 (28%); July, 3 (9%); and the first half of August, 1 (3%).

The projects of digital health application for COVID-19 control were deployed at different geographical levels, from international to rural. Six countries carried out six international projects, and the most common collaborations were among European countries, the United States, China, and Australia. The digital health projects at the international level mainly aimed to track real-time transmission and infected cases, define the level of quarantine, and enable peer-to-peer consultation to support care providers in other countries phylogenetically and scientifically. The studies of digital health projects for a given purpose in the 32 studies were most frequently conducted at the country level (n=10, 31%), and the other geographical levels were state (n=4, 13%), region (n=3, 9%), city (n=8, 25%), and rural (n=1, 3%). The United States was the country with the highest number of studies of digital health projects to fight COVID-19 (12/32, 38%), and these 12 studies varied the most in geographical scale, including international (n=3, 25%), state (n=3, 25%), country (n=2, 17%), and city (n=4, 13%) levels. The other studied countries ranked by the number of conducted studies were China (11/32, 34%); the United Kingdom (4/32, 13%); Canada, Spain, and Italy (3/32, 9%); Belgium and France (2/32, 6%); and the Netherlands (1/32, 3%).

To show the applied approaches of digital health for certain methods of COVID-19 control, the results were analyzed, and all the papers were categorized into six domains. These categories, their frequencies and percentages, and their applications for COVID-19 control are presented in Table 2. Some articles mentioned more than one approach to using digital health to control the COVID-19 pandemic.

## Table 2. The frequency of digital health methods and their applications for COVID-19 pandemic control.

<table>
<thead>
<tr>
<th>Domain number</th>
<th>Applied digital health solutions</th>
<th>COVID-19 control approaches</th>
<th>Digital health application projects (N=32), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Digital learning package, mobile apps, and web-based systems</td>
<td>Widespread distribution of information</td>
<td>7 (19)</td>
</tr>
<tr>
<td>2</td>
<td>GISs&lt;sup&gt;a&lt;/sup&gt;, QR&lt;sup&gt;b&lt;/sup&gt; codes, and wearable devices</td>
<td>Real-time tracking of transmission, activity tracking, and quarantine-level analysis</td>
<td>7 (19)</td>
</tr>
<tr>
<td>3</td>
<td>Web-based systems and mobile apps, videoconferencing, and telephone</td>
<td>Telemedicine visit services and virtual venues for meetings</td>
<td>11 (30)</td>
</tr>
<tr>
<td>4</td>
<td>Cloud- and mobile-based systems</td>
<td>Self-care and patient monitoring, training, and diagnosis</td>
<td>7 (19)</td>
</tr>
<tr>
<td>5</td>
<td>Intelligent systems and CDSSs&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Early warning and detection, screening, and triage</td>
<td>4 (10)</td>
</tr>
<tr>
<td>6</td>
<td>Social media</td>
<td>Dynamic burden of the pandemic and analysis of its consequences</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

<sup>a</sup>GISs: geographic information systems.
<sup>b</sup>QR: quick response.
<sup>c</sup>CDSSs: clinical decision support systems.
It has been shown that cell phones can be beneficial for health care [65]; due to their high influence among global populations, these tools are well suited for widespread distribution of information to these populations. Mobile apps are also used for tracking real-time transmission of SARS-CoV-2. Other potentially useful digital health tools are web-based apps and websites; these tools can also distribute information and track transmission. Videoconferencing and telecommunication also appear to be useful barriers to the spread of COVID-19 by enabling social distancing. Moreover, other industries may use teleservices to prevent the dissemination of disease.

Due to time limitations and the different times of onset of the epidemic in different countries, several digital health tools are not included in this paper. These tools have been reported in the news and other resources, and it may be valuable to discuss them as learned lessons for other countries fighting COVID-19. Therefore, we will review the digital health interventions in the different countries based on their available facilities and other requirements.

**China**

In China, multiple approaches are being used to manage the COVID-19 pandemic, ranging from web-based and mobile-based systems to cloud-based systems, CDSSs, and intelligent systems. The total number of cases of COVID-19 in this country showed a slight increase after March 1, 2020, based on the data in [66]. However, this decrease in COVID-19 cases was affected by multiple factors, and the effect of eHealth tools on the decrease should be evaluated. China has widely applied an eHealth app named Health Code to indicate a person’s health status in the past day [67].

China has established a plan to spend approximately US $1.4 trillion on digital infrastructure. This infrastructure upgrade program includes developing 5G networks, industrial internet, data centers, and artificial intelligence [68], which could improve the country’s capability to fight pandemics.

**Italy and Spain**

In contrast to Spain, Italy ranks among the four least advanced European countries in the Digital Economy and Society Index published by the European Commission [69], and approximately half the population of Italy has insufficient digital literacy [70]. The adoption of technology to prevent and manage the COVID-19 pandemic is unremarkable in these two countries. However, a coronavirus-tracking app was developed in Spain [71]. The statistics of total COVID-19 cases showed a dramatic increase after March 1, 2020, in both countries [66]. It appears that these countries should invest more in technologies to manage the pandemic.

**United States**

The US government launched a portal [72] for the public that contains information on how to prevent and manage COVID-19. Moreover, the US Centers for Disease Control and Prevention website [73] contains more detailed medical information on the spreading mechanism, symptoms, prevention, and treatment of COVID-19.

It appears that investigating the infrastructures needed for this technology could have great potential to mitigate these types of crises. In addition to the whole populations that can benefit from digital health technologies, more attention should be paid to interventions for travelers, as they can spread SARS-CoV-2 to other locations and even globally [64].

**Discussion**

**Principal Findings**

The COVID-19 pandemic has spread worldwide, costing lives and bringing upheaval and change to societies and economies. Although the global scientific community is racing to discover effective vaccines and therapeutics, the most essential defense remains public health measures such as personal hygiene and mass physical distancing. To successfully implement these two main measures, digital health and information technologies have emerged to support health systems, and they offer opportunities to reshape current health care systems. The aim of this study was to review the most significant digital health tools applied to fight COVID-19 in the 10 countries that have been most affected by the disease. These tools help governments and people to engage in strategies to control the COVID-19 pandemic through addressing the most urgent needs, including immediate outbreak response and impact mitigation. In China, which is the first country affected by the virus [55] and the most populous country globally, many researchers have worked on multiple aspects of SARS-CoV-2; it is the second most frequent origin country of the included studies. The burden of SARS-CoV-2 could be massive in populous countries; thus, these studies are worthy of investment in these countries. Studies that reported the development of models to predict epidemiological indicators were ignored, as they have not yet yielded any digital tools and require further development [56-59].

Distributing widespread information and tracking real-time transmission were the two most frequent goals of the studies. The former may originate from the importance of prevention in pandemic diseases as well as the simplest task of using information systems. The latter may be a focus in the literature because of the knowledge obtained from the previous experience of epidemics such as influenza and Zika virus [60-62]. Additionally, telemedicine visits for patients may be beneficial for populations because screening and follow-up of patients can be performed while maintaining social distancing in the population [63]. It appears that investigating the infrastructures needed for this technology could have great potential to mitigate these types of crises. In addition to the whole populations that can benefit from digital health technologies, more attention should be paid to interventions for travelers, as they can spread SARS-CoV-2 to other locations and even globally [64].
France and Belgium
The French app StopCovid was developed to trace infected people to control the spread of SARS-CoV-2. Privacy concerns arose regarding adoption of the app. Belgium has announced that a similar app adoption was canceled due to these issues [74].

United Kingdom
The NHS in the United Kingdom works on nine main areas to digitally respond to the pandemic: provide digital channels for citizen guidance and triage; enable remote and collaborative care with systems and data; deliver digital services for NHS Test and Trace; identify and protect vulnerable citizens; support planning with data, analysis, and dashboards; get data and insights to research communities; support clinical trials; provide secure infrastructure and support additional capacity; and plan for recovery, restarting services, and new needs. The government has categorized initiatives in these areas [75].

Iran
Although our study did not include any papers from this country, the Iranian Ministry of Health developed a national screening program website [76] to identify COVID-19 cases in the early stages.

The Netherlands
The Netherlands is one of the leading countries in Europe in digital health care and data. Approximately 90% of the population has digital records, and the Dutch government has invested over 400 million euros (US $482,980,000) in digital health. Hospitals in the Netherlands have signed up for a COVID-19 web-based portal for sharing patient information. Video consultation was provided by more than 8000 health care providers [77].

Germany
The Health Innovation Hub, established by Germany’s Ministry of Health, has published a list of trusted telemedicine applications. The services provided by these apps include remote consultation, risk assessment, and telemedicine services. Before 2018, the country did not allow remote consultations. The German parliament passed the Digital Care Act, which acknowledged that digital health is crucial for fighting the COVID-19 pandemic [78].

Telemedicine systems are highly used in many countries. In European countries, tracking of patients was adopted due to its feasibility in smaller countries; also, home care and self-care receive a relatively large amount of focus in these countries. Intelligent systems, CDSSs, and intelligent triage systems are not well adopted due to the need to supply them with data. These data are being gathered worldwide. Furthermore, analysis of social health data could be interesting, although little research has been done in this regard. Figure 1 shows the extent of the technologies developed for fighting the COVID-19 pandemic in the literature.

Figure 1. Technologies currently being applied to address the COVID-19 pandemic. QR: quick response.
general, it lacks evaluation of the exact outcomes of using these digital health tools; thus, further studies are needed to evaluate the effects and outcomes of using digital health tools. This study could help health policy makers make decisions regarding the investment of these tools to control COVID-19.

Conclusion
This study reviewed the digital health tools to fight COVID-19 that have been reported in the 10 countries in which the disease is most prevalent. Although there is no equal strategy to apply digital health tools across the affected countries for pandemic control, these tools are among the primary policies that governmental and private companies have considered for disease control. The United States has developed the most technologies to fight the pandemic. Furthermore, China, the first country that was affected by COVID-19, has applied a great number of digital tools, such as epidemiological indicators, analysis platforms, drones, robots, mobile apps, training websites and educational media, videoconferencing, smart infection detectors, intelligent patient tracers, and telemedicine systems. Having considered the potential of available information technologies worldwide in the 21st century, particularly in developed countries, it appears that more digital health products, especially intelligent products, remain to be created and applied for the management of viral infections and other health crises.

Conflicts of Interest
None declared.

References
5. NHS Digital. URL: https://digital.nhs.uk/ [accessed 2021-03-06]

https://www.jmir.org/2021/3/e19473


76. New corona screening and care (COVID-19). Iran Ministry of Health and Medical Education. URL: https://salamat.gov.ir/ [accessed 2021-03-06]


Abbreviations
CDSS: clinical decision support system
GIS: geographic information system
mHealth: mobile health
NHS: National Health Service
Digital Health Solutions to Control the COVID-19 Pandemic in Countries With High Disease Prevalence: Literature Review

Please cite as:
R Niakan Kalhori S, Bahaadinbeigy K, Deldar K, Gholamzadeh M, Hajesaeeel-Gohari S, Ayyoubzadeh SM

URL: https://www.jmir.org/2021/3/e19473
doi:10.2196/19473
PMID:33609344
Evidence Synthesis of Digital Interventions to Mitigate the Negative Impact of the COVID-19 Pandemic on Public Mental Health: Rapid Meta-review

Christian Rauschenberg1,2*, MSc; Anita Schick1*, PhD, Dipl-Psych; Dusan Hirjak1, MD; Andreas Seidler4, MD, MPH; Isabell Paetzold3, MSc; Christian Apfelbacher5, PhD, Dr sc hum, MSc, MA; Steffi G Riedel-Heller6, MD, MPH; Ulrich Reininghaus1,7,8, PhD, MSc, Dipl-Psych

1Department of Public Mental Health, Central Institute of Mental Health, Medical Faculty Mannheim, Heidelberg University, Mannheim, Germany
2Department of Psychiatry and Neuropsychology, School of Mental Health and Neuroscience, Maastricht University, Maastricht, Netherlands
3Department of Psychiatry and Psychotherapy, Central Institute of Mental Health, Medical Faculty Mannheim, Heidelberg University, Mannheim, Germany
4Institute and Policlinic of Occupational and Social Medicine, Faculty of Medicine Carl Gustav Carus, Technische Universität Dresden, Dresden, Germany
5Institute of Social Medicine and Health Systems Research, Otto von Guericke University Magdeburg, Magdeburg, Germany
6Institute of Social Medicine, Occupational Health and Public Health, University of Leipzig, Leipzig, Germany
7Centre for Epidemiology and Public Health, Health Service and Population Research Department, Institute of Psychiatry, Psychology & Neuroscience, King’s College London, London, United Kingdom
8ESRC Centre for Society and Mental Health, King’s College London, London, United Kingdom
* these authors contributed equally

Corresponding Author:
Christian Rauschenberg, MSc
Department of Public Mental Health
Central Institute of Mental Health
Medical Faculty Mannheim, Heidelberg University
Mannheim, 68159
Germany
Phone: 49 62117031929
Email: christian.rauschenberg@zi-mannheim.de

Abstract

Background: Accumulating evidence suggests the COVID-19 pandemic has negative effects on public mental health. Digital interventions that have been developed and evaluated in recent years may be used to mitigate the negative consequences of the pandemic. However, evidence-based recommendations on the use of existing telemedicine and internet-based (eHealth) and app-based mobile health (mHealth) interventions are lacking.

Objective: The aim of this study was to investigate the theoretical and empirical base, user perspective, safety, effectiveness, and cost-effectiveness of digital interventions related to public mental health provision (ie, mental health promotion, prevention, and treatment of mental disorders) that may help to reduce the consequences of the COVID-19 pandemic.

Methods: A rapid meta-review was conducted. The MEDLINE, PsycINFO, and CENTRAL databases were searched on May 11, 2020. Study inclusion criteria were broad and considered systematic reviews and meta-analyses that investigated digital tools for health promotion, prevention, or treatment of mental health conditions and determinants likely affected by the COVID-19 pandemic.

Results: Overall, 815 peer-reviewed systematic reviews and meta-analyses were identified, of which 83 met the inclusion criteria. Our findings suggest that there is good evidence on the usability, safety, acceptance/satisfaction, and effectiveness of eHealth interventions. Evidence on mHealth apps is promising, especially if social components (eg, blended care) and strategies to promote adherence are incorporated. Although most digital interventions focus on the prevention or treatment of mental disorders, there is some evidence on mental health promotion. However, evidence on process quality, cost-effectiveness, and long-term effects is very limited.
Conclusions: There is evidence that digital interventions are particularly suited to mitigating psychosocial consequences at the population level. In times of physical distancing, quarantine, and restrictions on social contacts, decision makers should develop digital strategies for continued mental health care and invest time and efforts in the development and implementation of mental health promotion and prevention programs.

(J Med Internet Res 2021;23(3):e23365) doi:10.2196/23365

KEYWORDS

COVID-19; mHealth; eHealth; telemedicine; prevention; mental health promotion; intervention; digital mental health; digital intervention; public mental health

Introduction

Measures to prevent and control infections during the COVID-19 pandemic such as physical distancing, quarantine, and restrictions on social contacts can have a negative impact on public mental health [1]. This includes an increase in depression, anxiety, loneliness, and perceived stress [2] as well as in risk behaviors such as cannabis and alcohol use [3] in the population. In addition to the immediate effects of the infection control measures, further negative consequences for mental health are to be expected due to the more direct, deleterious effects of COVID-19 (eg, illness anxiety, contamination fears) as well as the economic downturn and recession [4]. Recently reported restrictions in access to, and continuity of, care for individuals with mental disorder caused by infection prevention and control measures in some countries are an additional cause for concern [5-6,8].

Digital interventions that do not require face-to-face contact may play an important role in improving public mental health at times of infection prevention and control measures. They can be broadly grouped as telemedicine and internet-based interventions (hereafter eHealth interventions) [7] and app-based mobile health (mHealth) interventions delivered using smartphones or other mobile devices [8]. These interventions provide a unique opportunity for delivering low-threshold, public mental health care tailored to individual needs and contexts in daily life, outside the clinic [9], even under restrictive conditions of the COVID-19 pandemic. As smartphones are mostly in close proximity to users, and accessible whenever and wherever it is convenient, the use of mHealth apps in particular represents a powerful approach that allows for the real-time and real-world delivery of intervention components in individuals’ daily lives.

Digital tools may help to mitigate negative psychosocial consequences most effectively if intervention strategies are not only targeted at vulnerable individuals in a clinically high-risk state or with a mental disorder but also at the population level. More specifically, following the seminal “population strategy” advocated by Rose [10], even a small shift in the population’s mean level of mental health, which is continuously distributed in the population, may lead to a substantial reduction of the prevalence of mental health problems. If applied to the current pandemic, a scalable digital public mental health approach may contribute to lower rates of mental disorders by targeting important determinants and shifting the mean level of mental health in the population.

In order to minimize the negative impact of the COVID-19 pandemic on the mental health of the population, digital interventions can be used in the following areas of public mental health provision: primary prevention strategies, including (1) mental health promotion and literacy at the population level; (2) indicated, selective, or universal prevention targeting high-risk individuals, subpopulations, or the entire population, respectively, as well as secondary and tertiary prevention strategies, including (3) treatment and preventive services for people with mental disorders. Indeed, evidence from ad hoc surveys suggests that digital interventions for improving public mental health are urgently needed to address the psychosocial consequences of the COVID-19 pandemic [1-3,11,12]. For example, findings from the serial cross-sectional survey German COVID-19 Snapshot Monitoring (COSMO Germany [13]) suggest strong concerns about the economy, social inequalities, and the health care system as well as high levels of psychological distress in the adult general population, particularly among young people [14,15]. Another representative survey (Norstatpanel) found that a staggering 38% of youth met the criteria for moderate or severe mental health problems, even after the most restrictive infection control measures had been lifted [16]. Furthermore, the reported social isolation during the COVID-19 pandemic was associated with levels of psychological distress in a dose-response fashion [16]. Recent evidence also suggests a high subjective demand for digital mental health interventions in the general population and people with a mental disorder [17,18], which is matched with a high and rapidly growing number of mHealth apps available in major app stores, with the strongest growth having been noted for mHealth apps [19]. It has further been reported that the demand for mHealth apps has increased globally by 49% during the COVID-19 pandemic [20], with 73% of psychologically distressed and socially isolated youth in the Norstatpanel survey indicating the use of mHealth apps to be helpful in coping with the ongoing COVID-19 pandemic [16].

Taken together, based on the evidence presented, there is an urgent need for, and high potential in, using digital interventions to improve public mental health and mitigate the negative psychosocial impact of the COVID-19 pandemic. However, evidence-based recommendations for the use of digital interventions during public health crises, including this ongoing pandemic, is currently lacking. The present meta-review aimed to synthesize the available evidence on the theoretical and empirical base of interventions, quality assessments from the user perspective (ie, acceptability, usability, satisfaction), safety, effectiveness, and cost-effectiveness of digital interventions in...
the area of public mental health provision (ie, mental health promotion and prevention of and treatment for mental disorder).

**Methods**

**Overview**

A rapid meta-review of systematic reviews on digital public mental health interventions was conducted. For this, PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses [21]) was used as a guideline for reporting findings. In line with the current state of the art in the development and evaluation of complex digital mental health interventions [8], the following criteria to review the available evidence were used: theoretical and evidence base, quality assessments from the user perspective (ie, acceptability, usability, satisfaction), safety, effectiveness, and cost-effectiveness.

**Search Strategy and Selection Criteria**

The MEDLINE, PsycINFO, and CENTRAL databases were searched for systematic reviews and meta-analyses published in the English and German languages from inception to April 2020. An extensive search of bibliographic databases was performed using queries that combined search terms on mental health, public mental health provision, digital eHealth/mHealth interventions (Multimedia Appendix 1), and high-quality reviews (ie, systematic review, meta-analysis) using logical operators. In doing so, database-specific queries were used to ensure semantic equivalence. The queries were launched on May 11, 2020, covering results until April 2020. The results were obtained, and duplicates were removed. References written in English and German were included. No other filters or restrictions were applied.

The search criteria were purposefully broad and considered systematic reviews and meta-analyses that investigated digital tools for health promotion, prevention, or treatment of mental health conditions and determinants likely affected by the COVID-19 pandemic (eg, depression, anxiety, psychosis, substance misuse, self-harm, well-being, quality of life, self-esteem, loneliness). Titles and abstracts were screened for inclusion by 1 reviewer (a research assistant). Studies were included if they were published in a peer-reviewed journal, contained original findings examining the theoretical and evidence base, quality from the user perspective (ie, acceptability, usability, satisfaction), safety, effectiveness, or cost-effectiveness of digital mHealth and eHealth interventions. Due to the rapid meta-review format of our study, conclusions drawn by the authors of the included systematic reviews were reported. The included articles had to be systematic reviews and/or meta-analyses that followed established reporting guidelines (eg, PRISMA [21]). Because of time constraints and the rapid meta-review format of this study, a second reviewer (CR) independently screened a randomly selected subset (40%) of identified studies. The references were categorized as “eligible,” “query,” and “not eligible.” Inclusion and exclusion criteria were applied to references that were queried or eligible. Reviewers were blinded, and potential discrepancies in selection decisions were discussed with another member of the research team. A pilot screening of a randomly selected subset of identified studies (around 5%) was conducted to discuss decisions on categorizing studies at an early stage. As inclusion criteria were purposefully broad, discrepancies between the reviewers (CR and the research assistant) were very low. Full texts of potentially relevant articles were obtained, read, and assessed by 1 reviewer (CR), and data extraction was performed by 3 reviewers (CR and 2 research assistants under the close supervision of CR; see acknowledgments). Reviews and meta-analyses on preprint servers and gray literature were not included. The EndNote reference management software [22] was used to record reviewers’ decisions, including reasons for exclusion. The study selection process was documented using the PRISMA flow diagram (Figure 1).
Results

General Findings

The search strategy of our meta-review on digital interventions yielded 815 peer-reviewed systematic reviews and meta-analyses (Figure 1). Of these, 83 references were included in the meta-review. Overall, 44 of the included reviews summarized findings on eHealth interventions and focused on interventions targeting depression (n=19), anxiety (n=22), problematic substance use (n=11), and eating disorders (n=2). Several reviews included interventions that targeted multiple mental health problems. In total, 16 reviews summarized findings on mHealth interventions and focused on depression (n=2), anxiety (n=1), problematic substance use (n=1), and eating disorder (n=1). Similarly, the majority of included reviews targeted various mental health domain. Furthermore, 23 of the included reviews jointly reported the effects of eHealth and mHealth interventions on various mental health outcomes (Multimedia Appendix 2). A complete summary of included reviews on eHealth, mHealth, and mixed interventions are shown in Multimedia Appendix 2, including findings on their theoretical and empirical base, user perspective, safety, effectiveness, and cost-effectiveness.

Theoretical and Empirical Base

For most eHealth and mHealth interventions in the area of mental health promotion and prevention as well as treatment of mental disorders, the theoretical and empirical base is explicitly mentioned in the description of interventions and are often informed by clinical guidelines and co-designed by service users and mental health professionals [23-26]. This primarily includes evidence-based procedures such as cognitive-behavioral therapy (CBT) or third-wave CBT [23,25,26]. In contrast to digital interventions developed by research groups, prominent mHealth apps available in major app stores do often not provide information on the theoretical or empirical base of their content [8,27-29]. Some mHealth apps may even be harmful and hinder healing processes (eg, asking users to do tasks that are too difficult to complete, presenting means for self-harm as well as lethal means, triggering unwanted distressing memories) [8,27,28].

Quality Assessments From the User Perspective

Evidence from the included systematic reviews suggests moderate to high levels of acceptance, feasibility, and user satisfaction with eHealth and mHealth interventions for mental health promotion and prevention [30,31] as well as for the treatment of mental health problems [32-41]. This applies, in particular, for interventions including social components [32,42], strategies to promote user adherence [33,43], symptom monitoring [44,45], or a blended-care approach [46].

In terms of safety, data sharing and data safety regulations, as well as aspects of eHealth/mHealth and clinical safety of interventions, were often not explicitly reported or systematically investigated in the identified systematic reviews [47-49] (Multimedia Appendix 2). The descriptions of many eHealth interventions do not make explicit reference to prevailing regulations and clinical guidelines [50]. Furthermore, there is evidence that mHealth apps available in major app stores use problematic data sharing and privacy practices (eg,
monetization of sensitive user data through analytics and advertising) [8,27,28].

**Effectiveness of eHealth Interventions**

There was good evidence on the effectiveness of telemedical and other eHealth interventions in the field of mental health promotion and prevention, as well as for the treatment of mental health conditions.

**Mental Health Promotion and Prevention**

There have been a number of systematic reviews that aimed to investigate the effectiveness of telemedical and eHealth interventions for mental health promotion and prevention. These interventions have primarily been shown to improve mental health [34], physical activity [34,35], well-being [36,37], stress [23,38], depression [23,36,38,51,52], anxiety [23,36,38,51,52], and alcohol [24,53-56] and cannabis use [37,58] in the general population in addition to dysfunctional cognition and self-esteem in at-risk populations [59,60]. Importantly, effectiveness has been demonstrated across differing age groups, including adults [24,54,59] and adolescents from the general population [34,52,56,61-63], and effect sizes mostly ranged from small to medium. However, evidence on the use of eHealth interventions for the elderly is scarce, although findings from the identified reviews indicated some evidence on the effectiveness of eHealth interventions for reducing social isolation and increasing social participation of people aged 65 years and older [64], which may be of particular interest in the context of the COVID-19 pandemic.

**Treatment of Mental Health Conditions**

There was also strong evidence on the effectiveness of telemedical and eHealth interventions in the provision of treatment and services for people with mental disorder. This included anxiety disorders [65-68], depression [60,61,65-67,69-73], substance abuse [54,74-76], eating disorders [77], and severe mental illness [78], with overall small to medium effect sizes, not only with regard to the reduction of relevant symptoms but also improvements in dysfunctional cognition [60], self-esteem [60], and quality of life [66]. Some of the identified studies have even reported medium to large effect sizes, not only with regard to the reduction of relevant symptoms but also improvements in dysfunctional cognition [60], self-esteem [60], and quality of life [66].

The effectiveness of telemedicine interventions that use videoconference tools or the telephone has also been well documented in depressive [80-83], anxiety [80,83-85], and psychotic disorders [86], with comparable effects for online group and individual therapy sessions [87,88], compared with conventional (offline) therapy sessions. Superior effectiveness was observed for interventions adopting a blended-care approach combining eHealth with conventional intervention components [46,54,71].

Overall, findings suggest that the evidence on long-term effects and noninferiority compared to conventional therapy and active control conditions remains limited [79,81,82,86,87]. There is also limited evidence on the impact of telemedical and eHealth interventions on underlying processes and mechanisms of change [89].

**Effectiveness of mHealth Interventions**

While there is some initial evidence on the effectiveness of mHealth interventions to improve physical activity [90-95], stress appraisal [96,97], depression [26,96-100], anxiety [25,26,96,97], and alcohol and substance use [55,96,98,101-103], with small to medium effect sizes in all areas of public mental health provision, the amount of research to investigate this issue remains, overall, limited [104-108]. Only a minority of mHealth interventions were found to use more advanced techniques (accelerometer, GPS) to inform the delivery of intervention components [25,89,92]. In addition, a substantial difference was found between mHealth apps available in major app stores, for which there is no or only very limited evidence on their effectiveness [29,108-111], and mHealth interventions developed by research groups. Similar to eHealth interventions, evidence on long-term effects and on underlying processes and mechanisms of action remains very limited.

**Cost-effectiveness**

There is some evidence on the cost-effectiveness of eHealth interventions for depression and anxiety in primary care settings when compared to care as usual and waiting list control conditions [51] as well as for a range of mental disorders when compared to conventional CBT [112,113]. However, only a few systematic reviews have systematically investigated the cost-effectiveness of digital interventions to date, these findings should be interpreted with caution. While there is some evidence on the cost-effectiveness of mHealth interventions (eg, for digital monitoring and feedback in depression) from individual studies [18], evidence summarized at the level of systematic reviews is very limited.

**Discussion**

**Principal Results**

Evidence-based eHealth and mHealth interventions may play a central role in areas of public mental health provision (ie, mental health promotion, as well as prevention of and treatment for mental disorders) to mitigate the negative consequences of the COVID-19 pandemic. To date, however, evidence-based recommendations on existing digital interventions that have been developed and evaluated in recent years are lacking. This meta-review was the first to review the available evidence on the theoretical and empirical base, quality assessments from the user perspective (ie, acceptability, usability, satisfaction), safety, effectiveness, and cost-effectiveness of digital interventions in the area of public mental health provision, that is, mental health promotion at the population level, indicated, selective, or universal prevention targeting high-risk individuals, subpopulations, or the entire population as well as treatment and services for people with mental disorders.

First, there was robust evidence on the effectiveness of telemedical eHealth interventions and initial evidence on the effectiveness of mHealth interventions in relation to mental health outcomes likely affected by the COVID-19 pandemic (eg, anxiety, depression), especially if interventions are informed by clinical guidelines and co-designed by service users and
mental health professionals. Second, effectiveness, acceptability, feasibility, and user satisfaction have been described to be particularly high if digital interventions are embedded in a therapeutic context and include some form of social interaction with a mental health professional (blended-care approach). Third, some of the included systematic reviews and meta-analyses suggest noninferiority of effectiveness for some eHealth interventions as compared to traditional face-to-face therapy, but further replication is needed before firm conclusions can be drawn. Thus, in order to exclude the risk of infection in the current public health crisis, clinicians and other health professionals may consider combining differing types of digital interventions (eg, counseling or psychotherapy using videoconference software augmented by a smartphone-based mHealth app) as this approach may be particularly promising given the current evidence base and reflects a novel digital version of the blended-care approach. However, more research is needed to investigate long-term treatment effects and effects of symptom monitoring on mental health outcomes. Notably, the evidence on the use of digital interventions for the elderly and children is very limited. This is an important finding as these age groups may be particularly challenged by the current pandemic. Fourth, most studies to date do not specifically investigate the additive effects on health-related outcomes when using more advanced techniques (eg, accelerometer, GPS) to further personalize the delivery of intervention components, gamification elements, and the integration of other technologies such as wearables, although it has been described to be potentially beneficial in some of the included reviews [25,89,92,114]. Fifth, the theoretical basis of most digital interventions that have been described in previous reviews were found to be CBTs or third-wave CBTs as they may be particularly amenable to translation into digital intervention components [23,25,26]. Thus, clinicians with an expertise in CBT techniques may find it easier to purposefully incorporate intervention components delivered using digital tools in their daily clinical routines. However, findings suggest that there is a need to further improve the theoretical foundation of digital intervention, particularly mHealth interventions publicly available in major app stores. Sixth, the data available on the process quality and cost-effectiveness of eHealth and mHealth interventions are limited. Seventh, users frequently report concerns about data safety and privacy [115]. While eHealth and mHealth interventions developed and evaluated by research groups generally comply with the General Data Protection Regulation (in European countries) and work in accordance with Good Clinical Practice standards, the contents of many mHealth apps currently available in major app stores do not explicitly refer to existing clinical guidelines and recommendations by learned societies [50,116]. There are a number of reviews that have concluded that mHealth apps have problematic data-sharing and privacy practices [8,27,28] and that there may not only be a lack of quality of offered content but even harmful intervention components. In addition, although not specifically reported in included systematic reviews and meta-analyses, the recent surge in the use of popular and freely available platforms (eg, Zoom, Skype) rather than secured platforms to provide online mental health services may be another cause of concern [117] as these platforms mostly do not comply with national standards for sensitive patient data protection. In order to demonstrate user safety, clinical guidelines should be explicitly taken into account and advice by mental health professionals, learned societies, and IT (information technology) professionals actively incorporated. Overall, apps available in app stores should be used with caution due to risks in data and clinical safety as well as a lack of evidence on their effectiveness.

Limitations

This meta-review has several limitations. Because of time constraints and the rapid meta-review format of this study, the quality of included systematic reviews was not evaluated using established assessment tools (eg, the AMSTAR 2 [A Measurement Tool to Assess Systematic Reviews] checklist [118]). Along similar lines, the conclusions drawn in this meta-review on the quality of evidence are largely based on quality assessments undertaken in the included systematic reviews and meta-analyses. However, if the quality of evidence was not systematically evaluated using a standardized approach, it is indicated in Multimedia Appendix 2. Additionally, only 1 reviewer screened identified articles while a second reviewer independently screened a randomly selected subset (40%) of studies. However, this meta-review was conducted in line with the state of the art of conducting rapid reviews [119]. Furthermore, the World Health Organization has explicitly recommended rapid reviews for evidence synthesis during the ongoing public health crisis, given these are urgently needed for policy makers and the public [120].

In considering the urgent need of continued access to mental health care for vulnerable individuals during the COVID-19 pandemic, and the importance of developing and implementing public mental health prevention and promotion strategies, digital interventions should be provided by public health services and routinely offered when infection control measures are implemented during pandemics. Since there is currently no direct evidence on digital interventions that aim to minimize the psychosocial impact of previous coronavirus and influenza virus outbreaks, digital interventions should be developed and evaluated by research groups in close collaboration with relevant stakeholders to ensure established standards for investigating quality from the user perspective, effectiveness, and cost-effectiveness are met. Importantly, evidence-based digital interventions are scalable and can be rapidly delivered at the population level. This may facilitate delivering personalized care and minimizing the negative impact of the COVID-19 pandemic on public mental health.

Conclusions

Decision makers and stakeholders, including policy makers, technology companies, and public health professionals, should join forces to develop evidence-based strategies for mental health care in the area of public mental health provision, especially in moments of public health crises. As studies from previous pandemics, as well as accumulating evidence from the COVID-19 pandemic, suggest a negative impact on public mental health, the development and implementation of mental health promotion and prevention strategies at the population level may be an important measure to improve public mental health.
health. Digital interventions that incorporate contact with mental health staff in a blended-care approach may be particularly suited to alleviate mental health burden in help-seeking individuals. At times of COVID-19 and physical distancing measures, this may be translated into a digital blended-care approach by combining telemedical with internet-based eHealth or smartphone-based mHealth interventions. Furthermore, efforts should be made to systematically evaluate currently available digital interventions based on established criteria of digital mental health and mental health services research, as demonstrated by recent initiatives (eg, National Health Service Apps Library in the United Kingdom; Platform for Digital Health Applications in Germany; App Evaluation Database provided by the Division of Digital Psychiatry, Beth Israel Deaconess Medical Center, in the United States) [121-123]. This would systematize the search for evidence-based mHealth apps and thus allow clinicians and interested users to make more informed decisions on the quality of currently available digital interventions. There is also a need to carefully examine the role of social inequalities and the related digital divide as well as possible barriers (eg, disproportional access to necessary technologies, educational requirements, language skills, cultural factors, motor or cognitive impairments), which can influence the access to and use of the information platforms of digital mental health interventions.

Acknowledgments

The authors wish to thank research assistants Nina Müller and Viktoria Pöss for helping with data extraction. CR and UR contributed to the conception and design of the study. CR carried out the literature search and data extraction (with the help of Müller and Pöss). CR, AS, IP, and UR contributed to data interpretation and qualitative synthesis, and to the writing of the manuscript. CR and AS wrote the first draft of the manuscript. All authors contributed to critical revision of the manuscript and approved the final version. CR, AR, and UR guarantee the integrity of the work.

UR is supported by a Heisenberg professorship from the German Research Foundation (grant #389624707). The funder had no role in study design, search strategy, synthesis of findings, or writing of the review. The corresponding author had full access to all search items in the review and had final responsibility for the decision to submit for publication.

This work was carried out as part of the COVID-19 Public Health Research Network, an ad hoc consortium of more than 25 scientific societies and organizations that are active in the field of public health. They bring together their expertise in research methods, epidemiology, statistics, social sciences, demography, and medicine. The COVID-19 Public Health Research Network represents thousands of scientists from Germany, Austria, and Switzerland.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The full electronic search strategy for one database.
[DOCX File, 22 KB - jmir_v23i3e23365_app1.docx ]

Multimedia Appendix 2

Complete summary of included reviews on eHealth, mHealth, and mixed interventions. Findings on target populations, intervention components, theoretical and evidence base on process/outcomes, primary outcomes and quality of evidence, secondary outcomes, quality from the user perspective, safety, and cost-effectiveness are shown.
[DOCX File, 82 KB - jmir_v23i3e23365_app2.docx ]

References


22. Endnote X9 ed. Clarivate Analytics. URL: https://endnote.com/ [accessed 2021-03-01]


121. Digital health applications (DiGA). Federal Institute for Drugs and Medical Devices (BfArM), Germany. 2020. URL: https://www.bfarm.de/EN/MedicalDevices/DiGA/_node.html [accessed 2021-03-01]


123. App Evaluation Database. Division of Digital Psychiatry, Beth Israel Deaconess Medical Center. 2020. URL: https://apps.digitalpsych.org [accessed 2021-03-01]

Abbreviations

AMSTAR 2: A Measurement Tool to Assess Systematic Reviews
CBT: cognitive-behavioral therapy
COSMO Germany: German COVID-19 Snapshot Monitoring
IT: information technology
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

©Christian Rauschenberg, Anita Schick, Dusan Hirjak, Andreas Seidler, Isabell Paetzold, Christian Apfelbacher, Steffi G Riedel-Heller, Ulrich Reinig dispenser. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 10.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium,
provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Factors Affecting Public Adoption of COVID-19 Prevention and Treatment Information During an Infodemic: Cross-sectional Survey Study

Yangyang Han1*, BS; Binshan Jiang1*, BS; Rui Guo1, PhD
School of Public Health, Capital Medical University, Beijing, China
*these authors contributed equally

Corresponding Author:
Rui Guo, PhD
School of Public Health
Capital Medical University
No.10 Youanmenwai, Xitoutiao
Beijing
China
Phone: 86 01083911573
Email: guorui@ccmu.edu.cn

Abstract

Background: With the spread of COVID-19, an infodemic is also emerging. In public health emergencies, the use of information to enable disease prevention and treatment is incredibly important. Although both the information adoption model (IAM) and health belief model (HBM) have their own merits, they only focus on information or public influence factors, respectively, to explain the public’s intention to adopt online prevention and treatment information.

Objective: The aim of this study was to fill this gap by using a combination of the IAM and the HBM as the framework for exploring the influencing factors and paths in public health events that affect the public’s adoption of online health information and health behaviors, focusing on both objective and subjective factors.

Methods: We carried out an online survey to collect responses from participants in China (N=501). Structural equation modeling was used to evaluate items, and confirmatory factor analysis was used to calculate construct reliability and validity. The goodness of fit of the model and mediation effects were analyzed.

Results: The overall fitness indices for the model developed in this study indicated an acceptable fit. Adoption intention was predicted by information characteristics ($\beta=.266, P<.001$) and perceived usefulness ($\beta=.565, P<.001$), which jointly explained nearly 67% of the adoption intention variance. Information characteristics ($\beta=.244, P<.001$), perceived drawbacks ($\beta=-.097, P=.002$), perceived benefits ($\beta=.512, P<.001$), and self-efficacy ($\beta=.141, P<.001$) jointly determined perceived usefulness and explained about 81% of the variance of perceived usefulness. However, social influence did not have a statistically significant impact on perceived usefulness, and self-efficacy did not significantly influence adoption intention directly.

Conclusions: By integrating IAM and HBM, this study provided the insight and understanding that perceived usefulness and adoption intention of online health information could be influenced by information characteristics, people’s perceptions of information drawbacks and benefits, and self-efficacy. Moreover, people also exhibited proactive behavior rather than reactive behavior to adopt information. Thus, we should consider these factors when helping the informed public obtain useful information via two approaches: one is to improve the quality of government-based and other official information, and the other is to improve the public’s capacity to obtain information, in order to promote truth and fight rumors. This will, in turn, contribute to saving lives as the pandemic continues to unfold and run its course.

(J Med Internet Res 2021;23(3):e23097) doi:10.2196/23097

KEYWORDS
information adoption; infodemic; China; health information; infodemiology; COVID-19; public health
Introduction

Background

The global outbreak and rapid spread of the COVID-19 pandemic has led the world’s public health and safety systems to face great challenges. As of April 16, 2020, the COVID-19 pandemic has affected at least 211 countries, with 2,362,704 confirmed cases and more than 165,006 deaths globally, while China has confirmed 82,367 cases and the cumulative number of deaths was 3342 [1]. The disease rapidly spread in China because of the massive population migration (ie, Chunyun, also known as the Spring Festival travel rush, which refers to a human migration during this festival) and lack of prevention and control information during the early stage of the pandemic. Moreover, the World Health Organization (WHO) has not only signaled the health risks of COVID-19 but has also labeled the situation as an infodemic, due to the amount of information, both truth and rumors, circulating around this topic [2,3].

Although public health information dissemination represents an exciting combination of broadcasting, sharing, and retrieving relevant health information [4,5], the COVID-19 infodemic did not come as a surprise [6]. The massive growth of health information on the internet was seen to be a real problem [4]. Too much information makes it difficult to find trustworthy sources of information and may harm people’s health. Therefore, the quality of online health information is essential, especially when truth and rumors were still intertwined, which caused the infodemic. However, in the process of fighting COVID-19, the WHO and health authorities worldwide have been working closely with social media platforms, including Facebook, Google, Twitter, and YouTube, to provide evidence-based information to the general public in order to actively counter the rumors that have been circulating [7]. Prevention and treatment information about COVID-19 continues to spread and has an influence on populations.

At the same time, the lack of transparent, timely, and effective risk communication by health authorities regarding this emerging infectious disease in its early stage failed to bring about the appropriate level of public awareness and behavioral responses, such as avoidance of mass gatherings and personal protection in China, Europe, and the United States [8]. Online guidelines providing information for prevention and treatment are inconsistent in adapting to new knowledge, and changing or conflicting information can also confuse the public [9].

Since the beginning of the COVID-19 pandemic, information consumption has increased rapidly and significantly [10]. The new generation of health care consumers consists of an informedpublic, gleaning truth and rumors about health information with both positive and negative effects on themselves [11]. During periods of SARS spread, most people obtained SARS information from television [12]. By the time the Zika virus emerged in 2015-2016, Google Trends showed a significant increase in public searches on the internet related to the Zika virus [13], and the number of searches on video platforms, such as YouTube, had also increased rapidly [14]. Internet-based platforms that people utilized became diversified. During the COVID-19 pandemic, social distancing and stay-at-home restrictions caused the public to be fully exposed to social media; during this time, people actively searched or passively received a large amount of health-related information to prevent and treat diseases. In China, social media platforms, such as WeChat and Douyin (ie, TikTok), played an essential role in obtaining information after the virus began spreading [15]. However, studies have confirmed that over one-quarter of the most viewed YouTube videos about COVID-19 contained rumors, and these reached millions of viewers worldwide [16]. Therefore, determining whether people can use the prevention and treatment information they find on social media is critical in this pandemic.

Moreover, identifying health information from prevention and control measures is a major blind spot for the public. The public are partly responsible for selecting and filtering trustworthy health information [17]. Research shows that more than half of respondents trust almost all information online [18], and people are more likely to believe health rumors because of basic safety needs [19]. As the core part of health behavior theory, behavior intention is the subjective possibility of engaging in certain behavior. Some studies have confirmed that variables in the health belief model (HBM) can materially affect information adoption intention, and this process will affect subsequent health behaviors [20].

Therefore, if concern about identifying trustworthy information is reflected in the global population, we believe that the influencing factors in the subjective and objective aspects of engaging in that behavior may affect information adoption. Motivated by previous studies, this study was based on the information adoption model (IAM) and the HBM. The aim of this study was to explore the influencing factors and paths during public health events that affect the public’s intention to adopt online prevention and treatment information under the infodemic. We aim to provide a basis for decision making and policy suggestions in order to deal with online health information governance in the internet era. Moreover, this study adds to the sparse literature on information adoption.

Research Model and Hypotheses

Information Adoption Model

Sussman and Siegal first proposed the IAM based on the technology acceptance model (TAM) and the theoretical perspective of the elaboration likelihood model (ELM), which regards how information influences people’s decision making as the process of information adoption [21]. From the TAM, a critical aspect of how individuals act on an advocated issue or behavior is the extent to which they believe the information contained within a message is useful [21,22]. From the ELM, this process depends on elaboration likelihood, and two likely antecedents of usefulness have been suggested from this stream of research as well as two key internal validity factors [21]. The ELM explains how individuals adopt information and then change their will and behavior. Moreover, recent literature has also demonstrated that this model can be applied in the context of online information acceptance, argument quality, and source credibility; these are taken as the direct objects of information adoption, and their influence has been repeatedly verified [23,24]. Simultaneously, individuals’ perceived information
usefulness based on information quality and source characteristics plays a crucial intermediary role in information adoption. Health information as a type of information fits into the IAM’s influencing factors. The essence of information adoption is when individuals are persuaded by the received information and then accept the opinions or propositions expressed in the information.

**Health Belief Model**

The HBM has been widely used to explain preventive health behavior [25] and is one of the first and the best-known social cognition models. It focuses on the relationship of health behaviors, practices, and utilization of health services. From its initial design to predict behavioral response to the treatment received by chronic patients [26], it has been validated in different studies. Contemporary research studies have recently focused on the general health behavior of the population [27,28]. The core concept of HBM is people’s perception of disease threat and an assessment of their behavior. The assessment of behavior includes evaluating the effectiveness of behavior, the input and outcome of behavior change, and the obstacle to its implementation [28].

Furthermore, researchers added cues to action, meaning the stimuli or cues that catalyze action. Cues are divided into external cues, such as mass media, and internal cues, such as physical discomfort, that limit people’s beliefs about behavioral health consequences and behavioral effects. The HBM has been widely used in health behavior change [20], which provides scientific theoretical support for understanding the impact of health information propagation on the audience’s health behavior. It has become one of the most comprehensive models to understand health-related behaviors and why people undertake, or do not undertake, actions to prevent or control illnesses [29].

**Integrated Model of IAM and HBM**

Although IAM and HBM are commonly used models, the use of these models independently has not fully explained online health information adoption behavior. IAM focuses on the influence of information characteristics on information adoption without considering the individual’s subjective status quo. However, the information’s influence might change from person to person; the same content can evoke differing notions among receivers [30]. Also, HBM only considers the public’s cognitive information to predict general health behavior without influencing the process. More specifically, this study argues that an individual’s motivation to adopt health information will depend on the individual’s subjective and information-related objective factors. It is also supported by Erkan and Evans’ information acceptance model (IACM), in which a conceptual model was developed based on the integration of IAM and the theory of reasoned action; this model confirmed the influences of both information adoption and attitude toward information on consumers’ purchase intentions and the influence of information usefulness on information adoption [31]. In IACM, information quality, information credibility, and information needs were all found to affect information usefulness [31]. In addition, Ahadzadeh et al combined the TAM and HBM to study health-related internet use [32]. This study demonstrated that individuals who perceived their health to be at risk, or were motivated to use the internet when they believed that the internet was useful for providing health and health management information, would be expected to have a positive attitude toward internet use for health purposes [32].

Our research mainly focused on information adoption behavior during the COVID-19 infodemic; therefore, we developed the IAM-HBM model by considering information characteristics (ie, objective factors) and the public’s health beliefs (ie, subjective factors) about information. Also, the HBM has been criticized for not considering environmental factors, such as social influence (ie, friends, family, and individuals’ internet providers), that can influence health-related behavior [33]. Therefore, we proposed the following path: social influence impacts perceived usefulness of information. Figure 1 shows the conceptual model proposed by this study, which incorporates information characteristics, social influence, perceived drawbacks, perceived benefits, self-efficacy, perceived usefulness, and adoption intention.
**Hypotheses**

*Information characteristics* refer to whether the prevention and treatment information about COVID-19 to which individuals are exposed from the internet is persuasive and to how individuals perceive the credibility of the information source, including the content and source attributes of the information. Sussman and Siegal believed that information characteristics, including quality and source, impacted people’s perceived information usefulness, which then affected information adoption; they also believed that information characteristics impacted individuals’ information adoption directly, which was measured by information adoption intention [21]. Thus, information characteristics are applied to our IAM-HBM model as verified factors in the IAM, impacting individuals’ perceived usefulness of COVID-19 prevention and treatment information. Based on this, we hypothesized the following:

1. **Hypothesis 1a.** Information characteristics are positively associated with the intention to adopt COVID-19 prevention and treatment information.

2. **Hypothesis 1b.** Information characteristics are positively associated with perceived usefulness of COVID-19 prevention and treatment information.

*Social influence* refers to how individuals perceive the influence of those around them when they adopt COVID-19 prevention and control information. Venkatesh et al defined social influence as the degree to which users were affected by people around them using new technologies and systems; this included integrated subjective norms, social factors, and images [34]. The construct of social influence was added to the extended HBM to enhance the prediction ability of the model. Perceived usefulness was mediated by external variables, including social influence [35,36].

*Perceived drawbacks* refer to the difficulties that individuals may encounter when adopting the prevention and treatment information of COVID-19 on the internet. Such difficulties become apparent by the predicted cost of adopting healthy behaviors, including tangible and intangible costs. Tangible cost refers to the cost of perceived usefulness of information, usually measured in monetary terms. Intangible cost refers to the effort required to confirm the usefulness of information, such as time and energy [37,38]. Based on HBM, perceived drawbacks were confirmed as the most powerful single predictor of intended expectations [39]. Yun built an integrated model and verified that perceived drawbacks affect people’s actions in seeking health information through perceived usefulness [40]. If social media users do not need to spend too much money or physical and mental energy, they can reduce the cost of using technology, and their total perceived usefulness will increase when searching for online health information [41].

*Perceived benefits* refer to the benefits that individuals may give themselves if they adopt COVID-19 prevention and treatment information about COVID-19 on the internet. In the research on the HBM, Rosenstock proposed that individuals would weigh the effectiveness of behaviors through cost-benefit analysis when they adopt healthy behaviors. The perception of benefits provided a more preferential action path [41,42]. The positive experiences gained by individuals from acquiring and adopting health information behavior will promote the overall value
perception of this behavior. This will further strengthen the intention of continuing to search for health information [41]. Building on findings by Rosenstock, we explored whether perceived benefits are associated with perceived usefulness. Thus, perceived benefits were applied to this IAM-HBM model as a factor that estimates individuals’ beliefs about the usefulness of COVID-19 prevention and treatment information.

Self-efficacy refers to the level of confidence in an individual’s ability to prevent and treat COVID-19. As an essential part of social cognitive theory, self-efficacy refers to people’s confidence in performing a specific behavior. The higher the expectations, the higher the tendency to make more considerable efforts. This concept has been widely used to understand health behavior change. Self-efficacy also had an impact on health information-seeking behavior [43]. Information on the internet regarding people’s health interventions significantly improved the specific behaviors of self-efficacy, including physical exercise and healthy eating. Physiological and social advantages caused people to have more positive behavior change expectations.

Yun’s integrated model demonstrated that internet self-efficacy affected users’ actions through perceived usefulness when seeking health information on the internet [40]. We gravitate toward the idea that self-efficacy is a determinant of adoption intention.

Based on the discussion above, we hypothesized the following:

5. Hypothesis 5b. Self-efficacy is positively associated with perceived usefulness of COVID-19 prevention and treatment information.

Perceived usefulness refers to an individual’s blanket perception of COVID-19 prevention and treatment information on the internet. It is plausible that adopting such healthy behaviors can meet individuals’ health needs and help them achieve healthy outcomes. Usefulness, utility, and perceived usefulness, which were first applied to TAM by Davis et al, are used to evaluate the utility of information-seeking behavior [22]. As the crucial variable of IAM, perceived usefulness has a significant influence on adoption intention. Thus, perceived usefulness is applied to this IAM-HBM model as a factor that could influence individuals’ COVID-19 prevention and treatment information adoption. In our paper, Hypothesis 6 states that perceived usefulness is positively associated with the intention to adopt COVID-19 prevention and treatment information.

Methods

Data Collection and Participants

Online questionnaires were powered by the survey platform WJX (Changsha Ranxing Information Technology Co), whose web application was embedded into social media platforms from March 24 to April 5, 2020. The electronic version of the questionnaire was uploaded to the WJX web application; respondents (ie, Chinese people in China) could fill in, submit, and share the questionnaire using a Quick Response (QR) code or using a forwarding link issued by the WJX web application. The data were collected using snowball sampling through repetitive one-to-many sharing on social media, a nonprobability sampling method; there were 528 respondents from 30 provinces in China. We gathered data using an online survey because of public space restrictions and because netizens were potentially exposed to the infodemic. After eliminating invalid responses through data filtering, 501 valid questionnaires out of 528 remained (94.9% validity rate). Table 1 shows the demographic characteristics of the sample population.
Table 1. Demographic characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value (N=501), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>216 (43.1)</td>
</tr>
<tr>
<td>Female</td>
<td>285 (56.9)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>18-19</td>
<td>6 (1.2)</td>
</tr>
<tr>
<td>20-29</td>
<td>154 (30.7)</td>
</tr>
<tr>
<td>30-39</td>
<td>122 (24.4)</td>
</tr>
<tr>
<td>40-49</td>
<td>81 (16.2)</td>
</tr>
<tr>
<td>50-59</td>
<td>77 (15.4)</td>
</tr>
<tr>
<td>60-69</td>
<td>51 (10.2)</td>
</tr>
<tr>
<td>70-79</td>
<td>8 (1.5)</td>
</tr>
<tr>
<td>≥80</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Junior high school diploma or below</td>
<td>21 (4.2)</td>
</tr>
<tr>
<td>Senior high school diploma</td>
<td>66 (13.2)</td>
</tr>
<tr>
<td>College graduate</td>
<td>84 (16.8)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>256 (51.1)</td>
</tr>
<tr>
<td>Master’s degree or above</td>
<td>74 (14.8)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>104 (20.8)</td>
</tr>
<tr>
<td>Officer(^a)</td>
<td>50 (10.0)</td>
</tr>
<tr>
<td>Enterprise manager</td>
<td>67 (13.4)</td>
</tr>
<tr>
<td>Office staff or clerk</td>
<td>62 (12.4)</td>
</tr>
<tr>
<td>Professional(^b)</td>
<td>75 (15.0)</td>
</tr>
<tr>
<td>Worker or laborer</td>
<td>24 (4.8)</td>
</tr>
<tr>
<td>Business service</td>
<td>14 (2.8)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>12 (2.4)</td>
</tr>
<tr>
<td>Freelancer</td>
<td>22 (4.4)</td>
</tr>
<tr>
<td>Farmer</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>Retired</td>
<td>63 (12.6)</td>
</tr>
<tr>
<td>No profession(^c)</td>
<td>6 (1.2)</td>
</tr>
</tbody>
</table>

\(^a\)Officer occupations include government officials, cadres, and civil servants.

\(^b\)Professional occupations include doctors, lawyers, journalists, teachers, etc.

\(^c\)No profession includes temporary occupation or unemployed.

Out of the 501 valid responses, 216 (43.1%) were from male participants and the other 285 (56.9%) were from female participants. Further, the majority of respondents were between the ages of 20 and 39 years (276/501, 55.1%). Most of the respondents had earned a bachelor’s degree (256/501, 51.1%), which indicated a high level of education among respondents. In terms of occupation, the largest group was students (104/501, 20.8%), followed by professionals (75/501, 15.0%) and enterprise managers (67/501, 13.4%).

**Quality Control**

We conducted quality control through the survey platform and via the investigators. Once on the platform, respondents were invited to fill in the questionnaire voluntarily. Each Internet Protocol (IP) address, computer, or username could only be used once. Also, there were various filtering rules for invalid answers, such as spending too little time on a questionnaire and trap rules to filter out random answers.
After the surveys were submitted, the respondents were screened by the investigators to retain the valid questionnaires. We excluded the following respondents: those who failed the attention check, where the answers to all the questions were the same or cyclical; those with response times of less than 120 seconds; those under 18 years old; and non-Chinese residents. Also, we checked the consistency between the IP address and the selected region, and questionnaires were eliminated if the IP addresses were not consistent.

**Measures**

The study instrument was modified from those in the relevant existing literature. Measurements and scales were translated into the appropriate Chinese versions to ensure the completeness and accuracy of instruments. After the repeated pretest, the final questionnaire was translated back into English, and the main semantics were not changed, indicating a strong correlation with the original English questionnaire (see Table 2 [21,29,34,44-52]). The instruments were measured using a 5-point Likert scale, ranging from 1 (highly disagree) to 5 (highly agree). All dimensions included three items, except the information characteristics construct, which included five items.
Table 2. Measurement items of the constructs.

<table>
<thead>
<tr>
<th>Construct and variables</th>
<th>Measurement item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information characteristics (IC) [21,45,46]</strong></td>
<td></td>
</tr>
<tr>
<td>IC1</td>
<td>COVID-19 prevention and treatment information on the internet is appropriate for my health demands.</td>
</tr>
<tr>
<td>IC2</td>
<td>COVID-19 prevention and treatment information on the internet is understandable.</td>
</tr>
<tr>
<td>IC3</td>
<td>COVID-19 prevention and treatment information on the internet is shared by most people (eg, by thumb-up or retweet).</td>
</tr>
<tr>
<td>IC4</td>
<td>The argument for COVID-19 prevention and treatment information on the internet is compelling.</td>
</tr>
<tr>
<td>IC5</td>
<td>The publisher of COVID-19 prevention and treatment information on the internet is experienced in the health field.</td>
</tr>
<tr>
<td><strong>Social influence (SI) [44,47]</strong></td>
<td></td>
</tr>
<tr>
<td>SI1</td>
<td>People who are important to me think I should get COVID-19 prevention and treatment information from the internet.</td>
</tr>
<tr>
<td>SI2</td>
<td>My family and friends have obtained COVID-19 prevention and treatment information from the internet.</td>
</tr>
<tr>
<td>SI3</td>
<td>It is prevalent to get COVID-19 prevention and treatment information from the internet.</td>
</tr>
<tr>
<td><strong>Perceived drawbacks (PD) [48,49]</strong></td>
<td></td>
</tr>
<tr>
<td>PD1</td>
<td>It may take me too much time or expense to adopt COVID-19 prevention and treatment information from the internet.</td>
</tr>
<tr>
<td>PD2</td>
<td>Adopting COVID-19 prevention and treatment information from the internet may cause psychological stress.</td>
</tr>
<tr>
<td>PD3</td>
<td>The health risks associated with the adoption of COVID-19 prevention and treatment information from the internet may outweigh the positive health outcomes.</td>
</tr>
<tr>
<td><strong>Perceived benefits (PB) [29]</strong></td>
<td></td>
</tr>
<tr>
<td>PB1</td>
<td>It is important for me to adopt COVID-19 prevention and treatment information to reduce my risk of COVID-19 infection.</td>
</tr>
<tr>
<td>PB2</td>
<td>Adopting COVID-19 prevention and treatment information can help me stay healthy, which is very important to me.</td>
</tr>
<tr>
<td>PB3</td>
<td>The adoption of COVID-19 prevention and treatment information is valuable for me in order to adopt COVID-19 prevention behaviors.</td>
</tr>
<tr>
<td><strong>Self-efficacy (SE) [50]</strong></td>
<td></td>
</tr>
<tr>
<td>SE1</td>
<td>I am confident that I can avoid COVID-19.</td>
</tr>
<tr>
<td>SE2</td>
<td>I can figure out how to avoid COVID-19 infection.</td>
</tr>
<tr>
<td>SE3</td>
<td>Even if I contract COVID-19, I can recover soon.</td>
</tr>
<tr>
<td><strong>Perceived usefulness (PU) [46,51]</strong></td>
<td></td>
</tr>
<tr>
<td>PU1</td>
<td>The COVID-19 prevention and treatment information on the internet is valuable to me in preventing COVID-19.</td>
</tr>
<tr>
<td>PU2</td>
<td>I can make good use of COVID-19 prevention and treatment information on the internet in my life.</td>
</tr>
<tr>
<td>PU3</td>
<td>COVID-19 prevention and treatment information on the internet can improve the health of my family, friends, and myself.</td>
</tr>
<tr>
<td><strong>Adoption intention (AI) [34,52]</strong></td>
<td></td>
</tr>
<tr>
<td>AI1</td>
<td>I will recommend this COVID-19 prevention and treatment information to my family and friends.</td>
</tr>
<tr>
<td>AI2</td>
<td>I will use this COVID-19 prevention and treatment information obtained from the internet in my daily life.</td>
</tr>
<tr>
<td>AI3</td>
<td>I would like to adopt COVID-19 prevention and treatment information, even if it takes my time or money (ie, to buy drugs, protective equipment, etc) to do so.</td>
</tr>
</tbody>
</table>
Ethics Approval and Consent to Participate
This study was approved in writing by the Medical Ethics Committee of Capital Medical University (No. Z2019SY014) and all participants gave informed consent.

Results

Overview
After data collection, the two-stage procedure of structural equation modeling (SEM) was applied to conduct data analysis [41]. The first procedure examined scale validity from the measurement model by confirmatory factor analysis (CFA), while the second procedure interpreted hypotheses testing by the structural model. Both SPSS Statistics for Windows, version 19.0 (IBM Corp), and SPSS Amos, version 24.0 (IBM Corp), were adopted as the tools for analyzing the data.

Measurement Model

Reliability
In this study, questionnaire items had a factor loading of 0.592 and above (see Table 3), which met the evaluation standard that the factor loading for construct measures must exceed 0.5 to be retained [53]. Cronbach $\alpha$ should be at least .70, and high reliability is assumed if it is greater than .80 [54]. The composite reliability (CR) value of greater than 0.70 represented high reliability [53]. All the constructs had both high Cronbach $\alpha$ and CR values, indicating high reliability (see Table 3).

Convergent Validity
Convergent validity measures the correlation of a dimension’s multiple indicators. This study used the average variance extracted (AVE) to estimate the convergent validity [53]. A dimension with an AVE value over 0.50 would be considered as having high convergent validity [55]. As shown in Table 3, all dimensions had AVE values that were higher than the aforementioned cutoff values, which suggest good convergent validity.

In addition, all factor loadings for indicators measuring the same construct were statistically significant (see Table 3), suggesting that all indicators effectively measured their corresponding construct [56] and supported convergent validity.
### Table 3. Reliability and convergent validity.

<table>
<thead>
<tr>
<th>Construct and scale items</th>
<th>Factor loading&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Cronbach α&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Composite reliability coefficient&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Average variance extracted&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information characteristics (IC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC1</td>
<td>0.822</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IC2</td>
<td>0.765</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IC3</td>
<td>0.858</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IC4</td>
<td>0.840</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IC5</td>
<td>0.754</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Social influence (SI)</td>
<td></td>
<td>0.834</td>
<td>0.841</td>
<td>0.642</td>
</tr>
<tr>
<td>SI1</td>
<td>0.702</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>SI2</td>
<td>0.926</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>SI3</td>
<td>0.758</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Perceived drawbacks (PD)</td>
<td></td>
<td>.753</td>
<td>0.756</td>
<td>0.510</td>
</tr>
<tr>
<td>PD1</td>
<td>0.633</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PD2</td>
<td>0.789</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PD3</td>
<td>0.712</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Perceived benefits (PB)</td>
<td></td>
<td>.894</td>
<td>0.897</td>
<td>0.745</td>
</tr>
<tr>
<td>PB1</td>
<td>0.835</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PB2</td>
<td>0.930</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PB3</td>
<td>0.820</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Self-efficacy (SE)</td>
<td></td>
<td>.773</td>
<td>0.788</td>
<td>0.558</td>
</tr>
<tr>
<td>SE1</td>
<td>0.837</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>SE2</td>
<td>0.790</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>SE3</td>
<td>0.592</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Perceived usefulness (PU)</td>
<td></td>
<td>.884</td>
<td>0.885</td>
<td>0.719</td>
</tr>
<tr>
<td>PU1</td>
<td>0.826</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PU2</td>
<td>0.869</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>PU3</td>
<td>0.849</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Adoption intention (AI)</td>
<td></td>
<td>.868</td>
<td>0.875</td>
<td>0.702</td>
</tr>
<tr>
<td>AI1</td>
<td>0.831</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>AI2</td>
<td>0.944</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>AI3</td>
<td>0.723</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

<sup>a</sup>All factor loadings were significant at the P<.001 level.

<sup>b</sup>This value was calculated for each construct and not for individual items.

**Discriminant Validity**

Discriminant validity is achieved if the correlations between different constructs are relatively significant. The chi-square difference test can assess the discriminant validity of every two constructs by calculating the difference of the chi-square statistics for the constrained and unconstrained measurement models [57]. In this study, except for perceived drawbacks, the other six dimensions’ chi-square difference tests were significant at the P=.05 level (see Table 4). Accordingly, the results demonstrated that discriminant validity was successfully achieved for the measurement model.
Table 4. Correlation analysis among constructs to determine discriminant validity.a

<table>
<thead>
<tr>
<th>Construct</th>
<th>ICb</th>
<th>SId</th>
<th>PDd</th>
<th>PBe</th>
<th>SEf</th>
<th>PUG</th>
<th>Allh</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC</td>
<td>0.809</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SI</td>
<td>0.729</td>
<td>0.801</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD</td>
<td>–0.044</td>
<td>–0.040</td>
<td>0.714</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PB</td>
<td>0.741</td>
<td>0.799</td>
<td>–0.068</td>
<td>0.863</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SE</td>
<td>0.437</td>
<td>0.421</td>
<td>0.023</td>
<td>0.512</td>
<td>0.747</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PU</td>
<td>0.773</td>
<td>0.761</td>
<td>–0.152</td>
<td>0.857</td>
<td>0.555</td>
<td>0.848</td>
<td></td>
</tr>
<tr>
<td>AI</td>
<td>0.723</td>
<td>0.664</td>
<td>–0.038</td>
<td>0.741</td>
<td>0.479</td>
<td>0.792</td>
<td>0.838</td>
</tr>
</tbody>
</table>

aDiagonal elements are the square root of average variance extracted of the reflective scales. Off-diagonal elements are correlations between constructs.

Structural Model Analysis

Based on the results of the CFA and modification index of indicator variables, six standard model fit criteria were used to assess the model’s overall goodness of fit: ratio of the chi-square value to the degrees of freedom ($\chi^2$/df), goodness-of-fit index (GFI), comparative fit index (CFI), Tucker-Lewis index (TLI), root mean square residual, and root mean square error of approximation (RMSEA).

As shown in Table 5, comparison of all fit indices with their corresponding recommended values provided evidence of a good model fit: $\chi^2$/df values were between 1.0 and 3.0; GFI, CFI, and TLI were all greater than 0.9; and RMSEA was smaller than 0.08. This demonstrated that the measurement model exhibited a tolerably good fit with the data collected [56].

Table 5. Goodness of fit of the measurement and structural models.

<table>
<thead>
<tr>
<th>Statistical check</th>
<th>Goodness-of-fit criteria</th>
<th>Measurement model</th>
<th>Structural model</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\chi^2$/df</td>
<td>1.0-3.0</td>
<td>2.685</td>
<td>2.677</td>
<td>Good</td>
</tr>
<tr>
<td>Goodness-of-fit index</td>
<td>&gt;0.9</td>
<td>0.908</td>
<td>0.908</td>
<td>Good</td>
</tr>
<tr>
<td>Comparative fit index</td>
<td>&gt;0.9</td>
<td>0.953</td>
<td>0.953</td>
<td>Good</td>
</tr>
<tr>
<td>Tucker-Lewis index</td>
<td>&gt;0.9</td>
<td>0.944</td>
<td>0.944</td>
<td>Good</td>
</tr>
<tr>
<td>Root mean square error of approximation</td>
<td>&lt;0.08</td>
<td>0.058</td>
<td>0.058</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Structure Model

Based on the results of SEM, the fit indices of the structural model are shown in Table 5. Under the same criteria, the structure model fits the observed data as well. Meanwhile, the estimated results of the structural model provided the path coefficients shown in Table 6. Among the eight hypotheses, six paths were supported based on the valid data, significant at the $P=.01$ level, while the remaining two paths were rejected according to SEM (ie, Hypothesis 2 and Hypothesis 5a).

Adoption intention was predicted by information characteristics ($\beta=0.266, P<.001$) and perceived usefulness ($\beta=0.565, P<.001$), which jointly explained 66.8% of the adoption intention variance. Information characteristics ($\beta=0.244, P<.001$), perceived drawbacks ($\beta=0.097, P=0.002$), perceived benefits ($\beta=0.512, P<.001$), and self-efficacy ($\beta=0.141, P<.001$) jointly determined perceived usefulness and explained 81.1% variance of perceived usefulness. In addition, perceived usefulness had the most significant influence on adoption intention. It revealed that perceived usefulness was an important indicator of adoption intention. Perceived benefits had the most significant direct influence on perceived usefulness, followed by information characteristics, while perceived drawbacks had a relatively low path coefficient, which indicated a negative effect at the same
time. Since the rejection of Hypothesis 5a, it means that perceived usefulness had a complete mediating effect on self-efficacy to adoption intention. This result confirmed perceived usefulness as an intermediary variable. Surprisingly, Hypothesis 2 was not supported in this study. The path coefficients supported six of all hypothesized relationships (see Table 6, Figure 2, and Multimedia Appendix 1).

Table 6. Testing results of the hypotheses.

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Path</th>
<th>Standardized path coefficient (β)</th>
<th>P value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypothesis 1a</td>
<td>IC(^a)(\rightarrow) PU(^b)</td>
<td>0.244</td>
<td>&lt;.001</td>
<td>Supported</td>
</tr>
<tr>
<td>Hypothesis 1b</td>
<td>IC(^a)(\rightarrow) AI(^c)</td>
<td>0.266</td>
<td>&lt;.001</td>
<td>Supported</td>
</tr>
<tr>
<td>Hypothesis 2</td>
<td>SI(^d)(\rightarrow) PU</td>
<td>0.115</td>
<td>.07</td>
<td>Rejected</td>
</tr>
<tr>
<td>Hypothesis 3</td>
<td>PD(^e)(\rightarrow) PU</td>
<td>-0.097</td>
<td>.002</td>
<td>Supported</td>
</tr>
<tr>
<td>Hypothesis 4</td>
<td>PB(^f)(\rightarrow) PU</td>
<td>0.512</td>
<td>&lt;.001</td>
<td>Supported</td>
</tr>
<tr>
<td>Hypothesis 5a</td>
<td>SE(^g)(\rightarrow) PU</td>
<td>0.141</td>
<td>&lt;.001</td>
<td>Supported</td>
</tr>
<tr>
<td>Hypothesis 5b</td>
<td>SE(^g)(\rightarrow) AI</td>
<td>0.050</td>
<td>.25</td>
<td>Rejected</td>
</tr>
<tr>
<td>Hypothesis 6</td>
<td>PU(\rightarrow) AI</td>
<td>0.565</td>
<td>&lt;.001</td>
<td>Supported</td>
</tr>
</tbody>
</table>

\(^a\)IC: information characteristics.
\(^b\)PU: perceived usefulness.
\(^c\)AI: adoption intention.
\(^d\)SI: social influence.
\(^e\)PD: perceived drawbacks.
\(^f\)PB: perceived benefits.
\(^g\)SE: self-efficacy.

Figure 2. Structural model results; standardized path coefficients (β) are shown. ***\(P<.001\); **\(P<.01\); ns: not significant (\(P>.05\)).
Analysis of Mediating Effects

To test the indirect effects, bias-corrected bootstrapping with 5000 iterations was implemented to obtain the structural model path significance levels for indirect effects [38]. Bootstrapping, a nonparametric approach, was superior to other approaches in testing mediation models because it does not assume multivariate normality [59,60]. Table 7 shows that perceived usefulness fully mediated the effect of perceived drawbacks, perceived benefits, and self-efficacy on adoption intention, whereas perceived usefulness partially mediated the effect of information characteristics on adoption intention.

Table 7. Mediation effect analysis.

<table>
<thead>
<tr>
<th>Constructs of measurement</th>
<th>Standardized indirect effect</th>
<th>Bias-corrected values</th>
<th>Percentile</th>
<th>Mediating effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>95% CI</td>
<td>P value</td>
<td>95% CI</td>
</tr>
<tr>
<td>IC&lt;sup&gt;a&lt;/sup&gt;→PU&lt;sup&gt;b&lt;/sup&gt;→AI&lt;sup&gt;f&lt;/sup&gt;</td>
<td>0.138</td>
<td>0.069 to 0.218</td>
<td>&lt;.001</td>
<td>0.071 to 0.220</td>
</tr>
<tr>
<td>SI&lt;sup&gt;c&lt;/sup&gt;→PU→AI</td>
<td>0.065</td>
<td>−0.014 to 0.150</td>
<td>.10</td>
<td>−0.020 to 0.145</td>
</tr>
<tr>
<td>PD&lt;sup&gt;c&lt;/sup&gt;→PU→AI</td>
<td>−0.055</td>
<td>−0.094 to −0.023</td>
<td>.002</td>
<td>−0.091 to −0.020</td>
</tr>
<tr>
<td>PB&lt;sup&gt;1&lt;/sup&gt;→PU→AI</td>
<td>0.289</td>
<td>0.183 to 0.426</td>
<td>&lt;.001</td>
<td>0.178 to 0.419</td>
</tr>
<tr>
<td>SE&lt;sup&gt;1&lt;/sup&gt;→PU→AI</td>
<td>0.079</td>
<td>0.026 to 0.152</td>
<td>.002</td>
<td>0.026 to 0.152</td>
</tr>
</tbody>
</table>

<sup>a</sup>IC: information characteristics.
<sup>b</sup>PU: perceived usefulness.
<sup>c</sup>AI: adoption intention.
<sup>d</sup>SI: social influence.
<sup>e</sup>PD: perceived drawbacks.
<sup>f</sup>PB: perceived benefits.
<sup>g</sup>SE: self-efficacy.

Discussion

Principal Findings

This study set out to determine the factors affecting people’s intention of adopting health information on the internet, and the IAM-HBM model was applied. In general, this combined model provided an excellent fit to the data. Our research supports perceived drawbacks, perceived benefits, self-efficacy, perceived usefulness, and information characteristics as factors associated with the intention to adopt online prevention and treatment information to prevent an epidemic in the context of COVID-19.

Evidence-Based Information Plays an Important Role

In the study, information characteristics can strengthen perceived usefulness to adopt health information. In addition, the quality and the source of information influence the perceived usefulness and indirectly impact adoption intention. People are inclined to take in evidence-based information rather than misinformation on the internet [61,62]. Therefore, health communication should include more evidence-based information and should meet the public’s health demand [7]. Swamped by information on the internet, if the information is expressed more reliably or if its publisher is more professional and authoritative, the public will have a more robust perception of the usefulness of the information, thus increasing individuals’ willingness to adopt the information. At the same time, in the face of information overload, especially where some information constituted rumors, the public, who lack professional knowledge, will balance the outcomes of adoption information behavior. Many online repositories full of valuable content are underutilized, becoming “information junkywards” [63], and during the COVID-19 pandemic, an infodemic could be triggered by rumors. As information flow has improved, infodemic prevention and management using facts and evidence can mitigate the next infodemic [64,65].

Improving the Capacity to Obtain Public Information to Fight Mixed Messages

The public’s perceived drawbacks, perceived benefits, and self-efficacy had significant influences on perceived usefulness. Members of the public conduct a cost-benefit analysis before adopting healthy behaviors, in which they weigh the effectiveness of the adoption against the possible cost and risk of time-consuming impediments. As a result, the more benefits and fewer drawbacks one perceives, the more that the health benefits of the adoption behavior outweigh the health risks, resulting in higher perceived usefulness by individuals in considering online health information to prevent COVID-19.

However, only by improving the public’s media literacy and their ability to perceive information can they correctly recognize the obstacles and benefits. At the same time, greater health literacy can improve public health self-efficacy, resulting in increased confidence in adopting healthy behaviors or changing bad behaviors. Many people have limited health literacy [66]; health communication and education are the most cost-effective means to improve health literacy [67]. Therefore, in the release of COVID-19-related health information, attention should be paid to improving public information capacity. For example, officials could actively hold health lectures and disclose health information, and relevant experts could improve the public’s capacity regarding obtaining information.
Simultaneously, with the continuous enrichment of social media, it is difficult for social communication based on social media to achieve full, comprehensive, and balanced transmission of information. We need to avoid falling into information cocoons and confirmation bias [68], and we need to measure the quality of information from an overall perspective.

Government Has Greater Influence Than Family and Friends
Surprisingly, our analysis did not support the hypothesis that social influence is positively associated with perceived usefulness of COVID-19 prevention and treatment information. This finding was counterintuitive, and previous research showed that social networks positively affect people by encouraging them to adopt different health behavior intentions [69].

We think that government press conferences and news-based public opinion during the COVID-19 pandemic in China have weakened social influence on people’s perception and acceptance of health information for the following reasons. First, since the SARS epidemic in 2003, the Chinese government has reformed the news release concept and system. In response to the emergencies, the Chinese government issued a series of policy documents and established the State Council Information Office’s three-level news spokesman system for all central ministries and provincial-level people’s governments [70]. Second, governments at all levels use various channels to publicize, in a timely manner, the prevention and treatment information regarding COVID-19, the latest situation regarding the pandemic, and other public concerns, providing the public with a low threshold and low-cost direct information feedback channel [71]. The government also invited medical experts, such as Dr Zhong Nanshan, Head of the National Team for Control of Novel Coronavirus, to communicate with the public, and this strategy gained public trust [72]. Finally, China’s political system practices high-quality and high-efficiency unified decision making, and they have strict controls over content such as social media [73]. For example, Facebook, Twitter, and YouTube are not allowed in mainland China [74], and information monitoring and timely rumor controls are also available within popular social media platforms, such as WeChat and Sina Weibo [75]. Therefore, the government exerted its full influence during the pandemic to position itself as the primary influence [76].

However, social media is both a source of the infodemic and a public health tool [77]. Therefore, it is necessary to include social media platforms in public information dissemination; rethinking the role of public communication will also be necessary to assume corresponding responsibility during the pandemic. The responsibility is not only to delete information but, as much as possible, to ensure the diversity of the information environment to a sufficient degree; this will enable high-quality public content and thereby increase public participation [64].

Conclusions
In a public health emergency, the online infodemic forces the public to negotiate with prevention and treatment information. By integrating IAM and HBM, this study provided the insight and understanding that perceived usefulness and adoption intention of online health information could be influenced by information characteristics, people’s perceptions of drawbacks and benefits, and self-efficacy. Moreover, people also exhibit proactive behavior rather than reactive behavior. Thus, we should consider these factors to help the informed public obtain useful information via two approaches: one is to control the quality of information and the other is to improve the public’s capacity to obtain information, in order to promote trusted information and to fight misinformation. This will, in turn, contribute to saving lives as the pandemic continues to unfold and run its course.

Limitations
We administered the questionnaire survey during the stage of the pandemic in mainland China when it was under control, which was when the outbreak in China had passed the initial panic stage. People at different stages of the pandemic may have been influenced differently by the influencing factors. Therefore, although we found that social influence had no significant effect on perceived usefulness of information, a more comprehensive future study is suggested to explore whether this is due to social context, stage of the pandemic, or other factors. Moreover, this cross-sectional study was conducted using the WJX web application, and sample populations had a certain amount of experience in filling out online questionnaires and internet use. Therefore, a more comprehensive future study is suggested to include offline and online participants to expand the framework’s application scope.

Acknowledgments
This study was funded by the National Natural Science Foundation of China (No. 71704118).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Path diagram of the information adoption model (IAM)–health belief model (HBM).
[ PNG File, 444 KB - jmir_v23i3e23097_app1.png ]

References
https://www.jmir.org/2021/3/e23097
J Med Internet Res 2021 | vol. 23 | iss. 3 | e23097 | p.709
(page number not for citation purposes)


Abbreviations

AVE: average variance extracted
CFA: confirmatory factor analysis
CFI: comparative fit index
CR: composite reliability
ELM: elaboration likelihood model
GFI: goodness-of-fit index
Antecedents of Individuals’ Concerns Regarding Hospital Hygiene and Surgery Postponement During the COVID-19 Pandemic: Cross-sectional, Web-Based Survey Study

Thomas Ostermann¹, Prof Dr; Julia Gampe¹, BSc; Jan Philipp Röer¹, Prof Dr; Theda Radtke², Prof Dr

¹Department of Psychology and Psychotherapy, Witten/Herdecke University, Witten, Germany
²Health Psychology and Applied Diagnostics, University of Wuppertal, Wuppertal, Germany

Corresponding Author:
Thomas Ostermann, Prof Dr
Department of Psychology and Psychotherapy
Witten/Herdecke University
Alfred-Herrhausen-Str 50
Witten, 58448
Germany
Phone: 49 2302926707
Email: thomas.ostermann@uni-wh.de

Abstract

Background: The COVID-19 pandemic poses a major challenge to people’s everyday lives. In the context of hospitalization, the pandemic is expected to have a strong influence on affective reactions and preventive behaviors. Research is needed to develop evidence-driven strategies for coping with the challenges of the pandemic. Therefore, this survey study investigates the effects that personality traits, risk-taking behaviors, and anxiety have on medical service–related affective reactions and anticipated behaviors during the COVID-19 pandemic.

Objective: The aim of this study was to identify key factors that are associated with individuals’ concerns about hygiene in hospitals and the postponement of surgeries.

Methods: We conducted a cross-sectional, web-based survey of 929 residents in Germany (women: 792/929, 85.3%; age: mean 35.2 years, SD 12.9 years). Hypotheses were tested by conducting a saturated path analysis.

Results: We found that anxiety had a direct effect on people’s concerns about safety ($\beta=-.12$, 95% CI $-0.20$ to $-.05$) and hygiene in hospitals ($\beta=.16$, 95% CI $0.08$ to $0.23$). Risk-taking behaviors and personality traits were not associated with concerns about safety and hygiene in hospitals or anticipated behaviors.

Conclusions: Our findings suggest that distinct interventions and information campaigns are not necessary for individuals with different personality traits or different levels of risk-taking behavior. However, we recommend that health care workers should carefully address anxiety when interacting with patients.

(J Med Internet Res 2021;23(3):e24804) doi:10.2196/24804

KEYWORDS
COVID-19; public health; medical investigations; surgery; hospitalization, medical practices

Introduction

In Germany, the first COVID-19 case was confirmed at the end of January 2020, and COVID-19 incidence rates rose in the following 3 months. In response, the Robert Koch Institute (ie, the German federal government agency and research institute responsible for disease control and prevention) and the Federal Centre for Health Education made the following recommendations to slow the interpersonal transmission of SARS-CoV-2: limit social contact, refrain from traveling unless absolutely necessary, work from home wherever possible, encourage the use of medical masks and gloves, and strengthen hand hygiene practices [1]. At the same time, the European Center for Disease Prevention and Control published a checklist to prepare hospitals for the reception and care of patients with COVID-19. This checklist included items that were related to hand hygiene, personal protective equipment, and the postponement of operations that were unrelated to COVID-19 [2]. However, the implementation of these regulations,
particularly those regarding the use of personal protective equipment during the initial weeks of the pandemic in Germany, was hindered by a lack of adequate medical masks and clothing [3]. Considering the fact that SARS-CoV-2 infection can result in severe illness and death, especially in people aged >65 years and those with defined risk factors (eg, high blood pressure, diabetes, chronic respiratory diseases, and cancer) [4], a lack of personal protective equipment in hospitals and inadequate medical practices can result in affective reactions (eg, worries and concerns) and anticipated behaviors (eg, the denial of important operations) among the general population [5,6].

An example of an affective reaction resulting from a concern about an impending or anticipated threat is worrying about the lack of personal protective equipment in hospitals. Various factors, such as sociodemographic characteristics and personal values, can be used to predict affective reactions [5,7]. Further, affective reactions like concern or worry positively relate to anxiety [8] and negatively relate to risk-taking behaviors [9]. In addition, personality traits (eg, neuroticism) are linked with affective reactions [10]. During the COVID-19 pandemic, it is necessary to investigate the possible antecedents of affective reactions that relate to hospital equipment and medical practices. Such information is necessary for training health care workers to develop psychological skills for helping patients who experience worry, anxiety, and other emotional problems. It is also necessary to investigate how the COVID-19 pandemic affects people’s reactions when they or a person close to them needs to be hospitalized to undergo surgery for treating an illness [11,12]. Studies have shown that the COVID-19 pandemic poses a considerable challenge to routine medical services. For example, a study reported that patients prefer to postpone their operations until after the pandemic has completely passed due to the uncertain environment [12]. However, none of the studies that have been conducted during the pandemic have investigated psychological concepts that might influence individuals’ concerns about hospital hygiene and the postponement of surgeries. Studies on treatment-related decisions have suggested that personality traits, risk-taking behaviors, and anxiety are important factors that affect people’s decisions to avoid visiting a hospital or doctor [13,14].

Based on previous pandemics, it is known that segmenting the population into subgroups (ie, sociodemographic subgroups) is important for designing and delivering messages about health risks and health protection measures [15,16]. However, even though this might be a useful and effective method, these subgroups do not account for several important psychological factors, such as personality traits or anxiety. These factors might be crucial antecedents of affective reactions to public health messages. They might also influence people’s health-related decisions. Specifically, these factors may directly affect anticipated behaviors that relate to people’s decisions to postpone a nonurgent surgery [12,17]. Therefore, this survey study aims to identify the key factors that are associated with hospitalization-related and medical service–related affective reactions and anticipated behaviors during the COVID-19 pandemic.

We hypothesized that individuals with low levels of openness, low levels of agreeableness, high levels of neuroticism, low levels of risk-taking behavior, and high levels of anxiety would experience high levels of negative affective reactions and exhibit high levels of anticipated preventive behaviors in response to hospitalization and medical service provision.

**Methods**

**Survey Summary**

This cross-sectional, web-based survey study took place between March 19 and April 17, 2020. To ensure that our survey was highly visible to potential respondents, it was distributed via social media, email, direct communication methods, and advertisements in various digital communication channels. The recruitment of participants mainly took place at the Department of Psychology of Witten/Herdecke University. All participants were residents of Germany who were aged ≥16 years. All procedures in this study were performed in accordance with the ethical standards of the institutional review board of the Department of Psychology and Psychotherapy of Witten/Herdecke University and those of the American Psychology Association [18,19]. A letter of approval can be obtained from the first author.

**Summary of Survey Instruments**

Prior to the survey, we screened potentially eligible test instruments and scales to assess their suitability for answering the hypotheses. We selected validated scales (ie, whenever possible) for measuring the different survey constructs. We also developed new scales to measure the COVID-19–specific aspects of the survey, as no validated instruments were available at the time of the survey. The development of survey items was based on existing scales from other behavioral domains.

The following survey items, which were answered by using a visual analog scale that ranged from 0 (ie, not at all) to 100 (ie, absolutely), served as dependent variables: affective reactions and anticipated behaviors.

**Affective Reactions**

Affective reactions [20] were measured with two items for assessing concerns about hospital safety, hospital hygiene, and medical practices during the COVID-19 pandemic. After providing a short introduction to place the questions in the context of the COVID-19 pandemic, the following questions were asked: (1) “recently there have been supply bottlenecks of mouthguards, disinfectants or similar for hospitals and medical practices. Do you feel safe in places like this?”; and (2) “how big is your concern that due to supply bottlenecks a proper hygiene cannot be ensured in hospitals or medical practices?”

**Anticipated Behaviors**

Anticipated behaviors were measured with two items for assessing people’s decisions to postpone their own surgery or advise a person close to them against surgery during the pandemic. These items were in line with previous studies [11,12]. After providing a short introduction to place the questions in the context of the COVID-19 pandemic, the
following questions were asked: (1) “assuming you were about to have a non-urgent surgery - how likely would you be to postpone this surgery”; and (2) “suppose a person very close to you was about to have a non-urgent surgery, how likely is it that you would advise against having the surgery?”

The following survey items served as independent variables: personality, risk-taking behaviors, and anxiety.

**Personality**

People’s personalities were measured with the Big Five Inventory (BFI-10, which is the short version of the BFI-44 [21]. The BFI assesses the following five personality traits: openness to experience, conscientiousness, extraversion, agreeableness, and neuroticism (OCEAN). Openness to experience refers to whether people are inventive/curious or consistent/cautious. Conscientiousness refers to whether people are efficient/organized or easygoing/careless. Extraversion refers to whether people are outgoing/energetic or solitary/reserved. Agreeableness refers to whether people are friendly/compassionate or challenging/detached. Neuroticism refers to whether people are sensitive/nervous or secure/confident. Our psychometric analyses indicated that BFI-10 scores sufficiently correlated with BFI-44 scores. Based on the average correlation value ($r=0.83$), 70% of the variance in BFI-44 scores could be explained. After 6-8 weeks, the BFI-10 had an average retest reliability value of 0.75.

**Risk-Taking Behaviors**

Risk-taking behaviors were assessed with the readiness to take risk/search for competition scale of the Hamburger Personality Inventory (HPI), which includes 14 items that are evaluated with a 4-point Likert scale (eg, “Ultimately, I am also unstoppable by massive threats”). HPI item scores are added to calculate a risk-taking score [22]. With a Cronbach $\alpha$ value of .85, the HPI has high content and construct validity. The HPI has a test-retest reliability value of 0.86 after 18 months. Additionally, HPI scores positively correlate with autonomy orientations ($r=0.48$), revolutionary tendencies ($r=0.53$), conflict skills ($r=0.53$), and competitive attitudes ($r=0.60$). These scores also negatively correlate with harm avoidance tendencies ($r=-0.78$).

**Anxiety**

Anxiety was measured with the German version of the Spielberger State-Trait Anxiety Inventory (STAI), which is one of the most commonly used standard tools for measuring anxiety. In research, STAI scores also function as an indicator of the most commonly used standard tools for measuring anxiety. The state anxiety portion of the STAI consists of 20 items that are evaluated on a 4-point Likert scale (eg, “I feel worried”). All item scores are added to calculate a state anxiety score [23]. Higher STAI scores indicate greater anxiety/distress. The STAI has Cronbach $\alpha$ values that range between .90 and .94, which means that it has high content and construct validity.

According to the original publication [23], the test-retest reliability coefficients of the STAI range between 0.65 to 0.75 (ie, within 2 months of completing the STAI). These coefficients remained stable in our psychometric analyses.

To assess whether people’s risk of contracting COVID-19 and information-seeking behaviors (ie, those related to COVID-19) had an impact on their worries and anticipated behaviors, the following constructs were included in our analysis as covariates: risk profile and information-seeking behaviors.

**Risk Profile**

Risk profiles were adapted in accordance with previous studies [4,24]. Our survey included seven dichotomous items (ie, yes=1; no=0) that asked about risk factors for contracting COVID-19 (ie, age of >60 years, chronic lung disease, autoimmune disease, diabetes, kidney or liver diseases, cancer, immune deficiency, and the intake of immunosuppressive remedies). The sum of the item scores was used as a risk profile.

**Information-Seeking Behaviors**

Information-seeking behaviors were adapted in accordance with a previous study [25]. The behaviors we analyzed were in line with another study [26]. Our survey included six dichotomous items (ie, yes=1; no=0) that asked about the sources that people used to obtain information on COVID-19 (ie, television, internet blogs, social media, the website of the German federal government agency that is responsible for disease control and prevention, newspapers, and tabloid press articles). The sum of the item scores was used as an indicator of information-seeking behavior intensity. In addition, age, gender, and educational level (ie, a dichotomous variable that accounted for primary and secondary education) were introduced in the path model as covariates that needed to be controlled.

**Statistical Analysis Strategy**

Participants who fully completed the questionnaires were included in the statistical analysis. Descriptive statistical analyses were performed to describe the sample’s characteristics in terms of the variables that were included in this study. In addition, bivariate correlation values were computed to examine associations among the variables. A saturated path model [27] with manifest variables was used to test whether OCEAN personality traits, anxiety, risk, and risk-taking behaviors were related to worries about hospital safety and hygiene, worries about medical practices, and anticipated behaviors toward nonurgent surgeries (Figure 1). To assess whether people’s risk of contracting COVID-19 and information-seeking behaviors (ie, those related to COVID-19) had an impact on their worries and anticipated behaviors, these variables were included in the analysis.
Figure 1. The hypothesized path model for identifying associations between independent variables (ie, personality traits, risk-taking behaviors, and anxiety) and dependent variables (ie, worries about safety, worries about hygiene, and anticipated behaviors). The model used data from 929 participants. We did not display the control variables (ie, risk profiles, information-seeking behaviors, age, gender, and education) to keep the model overview simple. Dotted lines refer to $P$ values of $\geq 0.01$ and $\leq 0.05$. Bold lines refer to $P$ values of $< 0.001$. Thin lines refer to $P$ values of $\geq 0.05$. We did not display correlations between the control variables and outcomes to keep the model overview simple.

Descriptive Characteristics

Of the 1059 participants who took part in our survey, 929 (87.7%) had complete data sets. Thus, these 929 participants were included in the analyses. As indicated in Table 1, most of the participants (792/929, 85.3%) were female. The mean age of participants was 35.3 years (SD 12.9 years). Of the 929 participants, 890 (95.8%) stated that they were not infected with SARS-CoV-2, and only 7 (0.8%) stated that they were infected with SARS-CoV-2 (ie, at the time of the survey or before the survey). With respect to risk profiles, 683 (73.5%) participants reported that they did not exhibit any of the risk factors for contracting COVID-19, while 112 (12.1%) stated that they had a chronic lung disease. Almost all participants (884/929, 95.2%) subjectively felt restricted due to COVID-19–related regulations and measures. Details on participants’ sociodemographic characteristics are provided in Table 1.

Descriptive statistics and correlations among the variables in the path model are reported in Tables 2 and 3. Worries about proper hospital hygiene and medical practices positively correlated with neuroticism ($r=0.12$) and anxiety ($r=0.21$). Further, all four dependent variables intercorrelated with each other. For example, worries about hygiene and worries about safety significantly correlated with each other ($r=-0.40$; $P=0.001$).
Table 1. The sample’s sociodemographic characteristics.

<table>
<thead>
<tr>
<th>Sociodemographic variables</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>35.3 (12.9)</td>
</tr>
<tr>
<td>Age (years), median (range)</td>
<td>32 (16-82)</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>137 (14.7)</td>
</tr>
<tr>
<td>Female</td>
<td>792 (85.3)</td>
</tr>
<tr>
<td><strong>Educational level, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>No school degree</td>
<td>3 (0.3)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>6 (1.7)</td>
</tr>
<tr>
<td>Secondary modern education</td>
<td>108 (11.6)</td>
</tr>
<tr>
<td>Vocational baccalaureate</td>
<td>75 (8.1)</td>
</tr>
<tr>
<td>General baccalaureate</td>
<td>223 (24)</td>
</tr>
<tr>
<td>Applied science university diploma</td>
<td>116 (12.5)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>181 (19.5)</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>172 (18.5)</td>
</tr>
<tr>
<td>Doctorate degree or higher</td>
<td>34 (3.7)</td>
</tr>
<tr>
<td><strong>COVID-19 status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Not infected</td>
<td>890 (95.8)</td>
</tr>
<tr>
<td>I was under suspicion</td>
<td>17 (1.8)</td>
</tr>
<tr>
<td>I am under suspicion</td>
<td>15 (1.6)</td>
</tr>
<tr>
<td>I was infected</td>
<td>5 (0.5)</td>
</tr>
<tr>
<td>I am infected</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td><strong>Risk profile, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>No risk factors</td>
<td>683 (73.5)</td>
</tr>
<tr>
<td>Aged &gt;60 years</td>
<td>50 (5.4)</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>112 (12.1)</td>
</tr>
<tr>
<td>Autoimmune disease</td>
<td>66 (7.1)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>31 (3.3)</td>
</tr>
<tr>
<td>Cancer</td>
<td>15 (1.6)</td>
</tr>
<tr>
<td>Immunodeficiency</td>
<td>56 (6)</td>
</tr>
<tr>
<td>Intake of immunosuppressants</td>
<td>43 (4.6)</td>
</tr>
<tr>
<td><strong>Information source, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Friends and family</td>
<td>369 (39.7)</td>
</tr>
<tr>
<td>Television</td>
<td>553 (59.5)</td>
</tr>
<tr>
<td>Internet in general</td>
<td>401 (43.2)</td>
</tr>
<tr>
<td>Social media</td>
<td>402 (43.3)</td>
</tr>
<tr>
<td>Dedicated websites</td>
<td>758 (81.6)</td>
</tr>
<tr>
<td>Newspapers</td>
<td>495 (53.3)</td>
</tr>
<tr>
<td>Tabloid press articles</td>
<td>29 (3.1)</td>
</tr>
<tr>
<td><strong>Feeling restricted due to COVID-19–related regulations and measures, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>884 (95.2)</td>
</tr>
<tr>
<td>No</td>
<td>45 (4.8)</td>
</tr>
</tbody>
</table>
Table 2. Bivariate correlations (ie, r values) among variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Conscientiousness</th>
<th>Extraversion</th>
<th>Agreeableness</th>
<th>Neuroticism</th>
<th>RTB</th>
<th>Anxiety</th>
<th>Risk profile</th>
<th>Information profile</th>
<th>Feeling secure</th>
<th>Hygiene</th>
<th>Own surgery</th>
<th>Surgery of a close person</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Openness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>0.03</td>
<td>0.03</td>
<td>0.03</td>
<td>-0.01</td>
<td>0.12</td>
<td>0.01</td>
<td>0.02</td>
<td>-0.07</td>
<td>0.01</td>
<td>0.03</td>
<td>0.01</td>
<td>&lt;-0.01</td>
</tr>
<tr>
<td>P value</td>
<td>.39</td>
<td>.10</td>
<td>.35</td>
<td>.77</td>
<td>&lt;.001</td>
<td>.7</td>
<td>.57</td>
<td>0.05</td>
<td>.78</td>
<td>.38</td>
<td>.73</td>
<td>.91</td>
</tr>
<tr>
<td><strong>Conscientiousness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.15</td>
<td>-0.12</td>
<td>0.12</td>
<td>0.03</td>
<td>-0.08</td>
<td>0.02</td>
<td>-0.11</td>
<td>-0.01</td>
<td>-0.02</td>
<td>&lt;-0.01</td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.38</td>
<td>.02</td>
<td>.59</td>
<td>.25</td>
<td>.51</td>
<td>.09</td>
</tr>
<tr>
<td><strong>Extraversion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.04</td>
<td>-0.19</td>
<td>-0.03</td>
<td>0.01</td>
<td>0.08</td>
<td>-0.09</td>
<td>-0.02</td>
<td>&lt;-0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.75</td>
<td>.90</td>
<td>.13</td>
<td>&lt;.001</td>
<td>.88</td>
<td>.57</td>
<td></td>
</tr>
<tr>
<td><strong>Agreeableness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.12</td>
<td>-0.30</td>
<td>0.22</td>
<td>-0.22</td>
<td>-0.01</td>
<td>&lt;.01</td>
<td>0.13</td>
<td>-0.01</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.23</td>
<td>.41</td>
<td>.84</td>
<td>.02</td>
<td>.07</td>
<td>.47</td>
<td>.95</td>
</tr>
<tr>
<td><strong>Neuroticism</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.32</td>
<td>0.48</td>
<td>0.03</td>
<td>0.03</td>
<td>-0.05</td>
<td>0.13</td>
<td>-0.01</td>
<td>0.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.36</td>
<td>.43</td>
<td>.11</td>
<td>&lt;.001</td>
<td>.69</td>
<td>.79</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RTB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.26</td>
<td>0.04</td>
<td>-0.04</td>
<td>0.04</td>
<td>-0.05</td>
<td>-0.09</td>
<td>-0.06</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>.24</td>
<td>.23</td>
<td>.19</td>
<td>.14</td>
<td>.007</td>
<td>.07</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>0.09</td>
<td>0.07</td>
<td>-0.14</td>
<td>0.21</td>
<td>0.08</td>
<td>0.06</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>.04</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.02</td>
<td>&lt;.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk profile</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>0.06</td>
<td>-0.07</td>
<td>0.12</td>
<td>0.02</td>
<td>0.07</td>
<td></td>
<td>&lt;.001</td>
<td>0.04</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>.03</td>
<td>&lt;.001</td>
<td>.47</td>
<td>.04</td>
<td></td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Information profile</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.01</td>
<td>0.04</td>
<td>-0.01</td>
<td>0.04</td>
<td>-0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.77</td>
<td>.16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Feeling secure</strong> b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td>-0.40</td>
<td>-0.13</td>
<td>-0.13</td>
<td>-0.13</td>
<td>-0.13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hygiene</strong> b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Own surgery</strong> c</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aRTB: risk-taking behavior.
Refers to a worry.

Refers to an anticipated behavior category.

Not applicable.

Significant at a level of $P<.05$.

### Table 3. Mean and SD values of variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Openness</td>
<td>7.60 (2.02)</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>7.15 (1.65)</td>
</tr>
<tr>
<td>Extraversion</td>
<td>6.66 (1.97)</td>
</tr>
<tr>
<td>Agreeableness</td>
<td>6.20 (1.58)</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>6.26 (2.04)</td>
</tr>
<tr>
<td>Risk-taking behavior</td>
<td>31.26 (7.13)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>43.91 (12.23)</td>
</tr>
<tr>
<td>Risk profile</td>
<td>0.40 (0.80)</td>
</tr>
<tr>
<td>Information profile</td>
<td>3.24 (1.36)</td>
</tr>
<tr>
<td>Worries about feeling secure</td>
<td>48.32 (28.23)</td>
</tr>
<tr>
<td>Worries about hygiene</td>
<td>57.33 (30.35)</td>
</tr>
<tr>
<td>Anticipated behavior relating to own surgery</td>
<td>80.46 (28.45)</td>
</tr>
<tr>
<td>Anticipated behavior relating to the surgery of a close person</td>
<td>77.32 (28.93)</td>
</tr>
</tbody>
</table>

### Results From the Path Model

The path model predicted the associations between independent variables (ie, personality, risk-taking behaviors, and anxiety) and dependent variables (ie, feelings about security, worries about hospital hygiene and medical practices, and anticipated behaviors that relate to people’s decisions to postpone their own surgery or advise a person close to them against surgery). Figure 1 presents the parameter estimates of the model (ie, standardized solutions).

The following model-data fit indices were obtained: Chi-square value ($\chi^2=942.94$; $N=929$; $P<.001$), comparative fit index (1.00), Tucker-Lewis Index (1.00), root mean square error of approximation (<.01), and standardized root mean square residual (<.01). These values indicated a moderate model fitness. Table 4 provides the standardized regression coefficients of the path model, which was used to predict affective reactions and anticipated behaviors.
As outlined in Figure 1, the feeling of security with regard to hospitals and medical practices was significantly negatively related to anxiety (β = −.12; P = .001), which is in line with our hypothesis. Further, affective reactions to hospital hygiene and medical practices resulting from a bottleneck of appropriate personal protective equipment for health care workers were significantly positively related to anxiety (β = .16; P < .001) and nonsignificantly negatively related to extraversion (β = −.07; P = .054). Although anticipated behaviors that relate to advising a close person against surgery did not correlate with any of our hypothesized variables, anticipated behaviors that relate to one’s own surgery were negatively associated with neuroticism (β = −.08; P = .04) and risk-taking behaviors (β = −.09; P = .03). Such anticipated behaviors were also positively associated with anxiety (β = .08; P = .03). All of these associations however were not statistically significant after the Bonferroni correction. No other associations between the independent and dependent variables were found. However, women and older participants reported that they experienced higher levels of negative affective reactions and anticipated behaviors compared to men and younger participants, respectively.

Discussion

Principal Findings

To the best of our knowledge, our study is the first to investigate predictors of affective reactions that relate to hospital safety, hospital hygiene, and medical practices during the COVID-19 pandemic. We are also the first to investigate anticipated behaviors that relate to people’s decisions to postpone their surgery or advise a person close to them against surgery during the pandemic. Our findings are in line with those of a German-Austrian survey [30], which found that anxiety was positively related to security actions. Our results suggest that state anxiety is the most influential factor of anticipated health-related behaviors and concerns about safety or hygiene. Apart from state anxiety, none of the other hypothesized predictors (eg, risk-taking behaviors) or personality factors (eg, agreeableness or openness) had any significant association with affective reactions or anticipated behaviors. This is contradictory to the recent findings of Martin [31], who found that agreeableness was related to the perceived severity of the COVID-19 pandemic, and openness was related to low levels of anxiety with regard to contracting COVID-19. Although previous studies have suggested that individuals with high levels of neuroticism exhibit pronounced negative reactions to stressful events [32], our findings show that neuroticism was not associated with anticipated behaviors during the COVID-19 pandemic. In our study, we found that people with high levels of neuroticism were less likely to postpone their own surgery or advise a person close to them against surgery during the pandemic. We are also the first to investigate anticipated behaviors that relate to people’s decisions to postpone their surgery or advise a person close to them against surgery during the COVID-19 pandemic. Further, affective reactions to hospital hygiene and medical practices during the COVID-19 pandemic. We are also the first to investigate anticipated behaviors that relate to people’s decisions to postpone their surgery or advise a person close to them against surgery during the pandemic. Our findings are in line with those of a German-Austrian survey [30], which found that anxiety was positively related to security actions. Our results suggest that state anxiety is the most influential factor of anticipated health-related behaviors and concerns about safety or hygiene. Apart from state anxiety, none of the other hypothesized predictors (eg, risk-taking behaviors) or personality factors (eg, agreeableness or openness) had any significant association with affective reactions or anticipated behaviors. This is contradictory to the recent findings of Martin [31], who found that agreeableness was related to the perceived severity of the COVID-19 pandemic, and openness was related to low levels of anxiety with regard to contracting COVID-19. Although previous studies have suggested that individuals with high levels of neuroticism exhibit pronounced negative reactions to stressful events [32], our findings show that neuroticism was not associated with anticipated behaviors during the COVID-19 pandemic. In our study, we found that people with high levels of neuroticism were less likely to postpone their own surgery. This finding is comparable to that of an early US survey, which found that neuroticism was associated with high levels of concern [33]. The similarities in these results could be explained by the age of our participants. It is possible that our relatively

Table 4. Standardized regression coefficients of the path model, which was used to predict affective reactions and anticipated behaviors.

<table>
<thead>
<tr>
<th>Path predictors</th>
<th>Affective reactions</th>
<th>Anticipated behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Feeling secure, β (95% CI)</td>
<td>Concerns about hygiene, β (95% CI)</td>
</tr>
<tr>
<td>Openness</td>
<td>.01 (−.07 to −.08)</td>
<td>.02 (−.05 to .09)</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>.01 (−.05 to .08)</td>
<td>−.03a (−.09 to .04)</td>
</tr>
<tr>
<td>Extraversion</td>
<td>.03 (−.04 to .10)</td>
<td>−.07a (−.14 to &lt;.01)</td>
</tr>
<tr>
<td>Agreeableness</td>
<td>.05 (−.02 to .12)</td>
<td>−.05a (−.11 to .02)</td>
</tr>
<tr>
<td>Neuroticism</td>
<td>.05 (−.03 to .13)</td>
<td>.01 (−.07 to .09)</td>
</tr>
<tr>
<td>Risk-taking behavior</td>
<td>.01 (−.07 to .08)</td>
<td>&lt;.01 (−.07 to .08)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>−.12c (−.20 to −.05)</td>
<td>.16d (.08 to .23)</td>
</tr>
<tr>
<td>Risk profile</td>
<td>−.06 (−.14 to .01)</td>
<td>.08b (.02 to .14)</td>
</tr>
<tr>
<td>Information-seeking behavior</td>
<td>−.01 (−.09 to .07)</td>
<td>−.01 (−.07 to .05)</td>
</tr>
<tr>
<td>Gender</td>
<td>.09b (0.02 to .17)</td>
<td>−.06a (−.12 to .01)</td>
</tr>
<tr>
<td>Age</td>
<td>−.05 (−.13 to .03)</td>
<td>.10a (.03 to .17)</td>
</tr>
<tr>
<td>Educationf</td>
<td>.03 (−.05 to .11)</td>
<td>−.09b (−.16 to &lt;−.01)</td>
</tr>
</tbody>
</table>

aSignificant at a level of P<.10.
bSignificant at a level of P<.05.
cSignificant at a level of P<.001.
dSignificant at a level of P<.001.

fIn the path model, women were given a value of 1 and men were given a value of 2.

fIn the path model, secondary education was given a value of 1 and tertiary education was given a value of 2.
young participants were not able to accurately imagine a scenario in which they are hospitalized. This might have influenced participants’ responses to our survey. With regard to the relationship between health policy formation and public responses [34], the most important finding of our study was that anxiety was related to both the affective reactions and anticipated behaviors of the participants. Allgleton and Kippax [35], who conducted an analysis on Australian HIV/AIDS policies, argued that suppressed anxiety can be used as a depressive position for eliciting a desired response in the general public [35]. Other studies [36-38] have also found that anxiety is an important predictive factor of taking preventive measures and exhibiting compliant behavioral responses during the 2009 influenza pandemic. Our findings support these empirical results. Health authorities should be aware that anxiety may not only affect individuals’ behaviors but also the behaviors of organizations and systems (eg, splitting and blaming) [39]. In addition, anxiety resulting from the COVID-19 pandemic might also encourage individuals to consult a physician later than necessary (ie, to present their complaints). This has already occurred [40]. Such behavior may result in harms to health, the development of depression [41], or the chronification of disease.

Limitations and Implications for Future Research
Aside from the strengths of our study (eg, its large sample size), several limitations also need to be mentioned. First, due to the dynamic nature of the pandemic, we decided to use a random sample. However, due to our survey dissemination methods, our sample may not be representative of the German population. The generalizability of our results is open to empirical debate, as our sample mostly consisted of middle-aged and well-educated women. Research has shown that compared to men, women are more likely to actively seek health-related information and pay more attention to potential worldwide pandemics [42]. Second, our sample mainly consisted of middle-aged individuals. Therefore, it is reasonable to assume that older people are more likely to postpone surgeries and operations due to the COVID-19 pandemic, as they are more susceptible to the disease than middle-aged people. Older people also have stronger health care needs than middle-aged people [17]. Further research on the COVID-19–related concerns of older individuals is needed. Third, data collection took place during the beginning of the pandemic in Germany. Therefore, it remains unclear whether individuals would have the same affective reactions and anticipated behaviors later into the pandemic. Furthermore, the affective reactions and anticipated behaviors of people from urban areas should be distinguished from those of people from rural areas, as COVID-19 spreads at different rates in different geographical areas [43]. However, during the first phase of the pandemic in Germany, no considerable differences were found in infection and death rates [43]. This finding is also supported by the results of a recent survey study [44], wherein the authors did not find any substantial differences in behavioral intentions between participants from rural and urban regions in China. Fourth, our dependent variables were only measured with one item that used a visual analog scale. This was done to keep the survey concise and specific. Unfortunately, validated measures such as the COVID-19–Induced Anxiety Scale or the Protective Behaviors Towards COVID-19 Scale [45] were not available at the time of our survey. According to Heller et al [46] and Price et al [47], visual analog scales have sufficient psychometric measurement properties. Thus, they can be used when no validated instrument is available. Fifth, although the fitness of our path model was acceptable, it could have been better. However, it should be noted that as the sample size increases and the degrees of freedom remain constant, the Chi-square value increases. This leads to the problem of plausible models being rejected due to a significant Chi-square value. Therefore, too much emphasis should not be placed on the significance of the Chi-square statistic [48]. Furthermore, it should be noted that our data are cross-sectional in nature. As such, causal conclusions cannot be drawn from our data. Future studies should be longitudinal in nature.

Conclusions
Our results provide further insight into affective reactions and anticipated health-related behaviors during the COVID-19 pandemic. Our findings indicate that OCEAN personality traits are not associated with affective reactions and anticipated behaviors. Therefore, specific distinctions do not seem necessary when designing messages about health risks and health protection measures (ie, those related to hospital and medical practices during the COVID-19 pandemic). Even though future research is needed to confirm our results, health care workers should address the issues of patients with anxiety seriously and directly. Clear communication is necessary when providing information on the specific actions that hospitals and medical organizations perform to protect patients and health care workers. This could also help with preventing the cancellation of nonurgent surgeries in hospitals.

Authors’ Contributions
TO, JR, and JG conceptualized this study. TO and TR designed the methodology of this study. JG, JR, and TO designed the survey. TO and TR performed the statistical analysis. TO, JG, and TR prepared the data. TO and TR wrote the initial manuscript draft. TO, JR, JG, and TR reviewed and edited the manuscript. TR created the figures and tables. TO supervised this study. All authors read and approved the published version of the manuscript.

Conflicts of Interest
None declared.

References

https://www.jmir.org/2021/3/e24804

J Med Internet Res 2021 | vol. 23 | iss. 3 | e24804 | p.722

(page number not for citation purposes)

Ostermann et al
1. RKI - Homepage. Robert Koch Institut. URL: https://www.rki.de/EN/Home/homepage_node.html [accessed 2021-02-23]


Abbreviations

**BFI:** Big Five Inventory

**HPI:** Hamburger Personality Inventory

**OCEAN:** openness to experience, conscientiousness, extraversion, agreeableness, and neuroticism

**STAI:** State-Trait Anxiety Inventory
Examining Tweet Content and Engagement of Canadian Public Health Agencies and Decision Makers During COVID-19: Mixed Methods Analysis

Catherine E Slavik¹, MPH; Charlotte Buttle¹; Shelby L Sturrock², MSc; J Connor Darlington³, MSc; Niko Yiannakoulias¹, PhD

¹School of Earth, Environment and Society, McMaster University, Hamilton, ON, Canada
²Division of Epidemiology, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada
³School of Geography and Environmental Management, University of Waterloo, Waterloo, ON, Canada

Corresponding Author:
Niko Yiannakoulias, PhD
School of Earth, Environment and Society
McMaster University
General Science Building
1280 Main Street West, Room 204
Hamilton, ON, L8S 4K1
Canada
Phone: 1 905 525 9140 ext 20118
Email: yiannan@mcmaster.ca

Abstract

Background: Effective communication during a health crisis can ease public concerns and promote the adoption of important risk-mitigating behaviors. Public health agencies and leaders have served as the primary communicators of information related to COVID-19, and a key part of their public outreach has taken place on social media platforms.

Objective: This study examined the content and engagement of COVID-19 tweets authored by Canadian public health agencies and decision makers. We propose ways for public health accounts to adjust their tweeting practices during public health crises to improve risk communication and maximize engagement.

Methods: We retrieved data from tweets by Canadian public health agencies and decision makers from January 1, 2020, to June 30, 2020. The Twitter accounts were categorized as belonging to either a public health agency, regional or local health department, provincial health authority, medical health officer, or minister of health. We analyzed trends in COVID-19 tweet engagement and conducted a content analysis on a stratified random sample of 485 tweets to examine the message functions and risk communication strategies used by each account type.

Results: We analyzed 32,737 tweets authored by 118 Canadian public health Twitter accounts, of which 6982 tweets were related to COVID-19. Medical health officers authored the largest percentage of COVID-19–related tweets (n=1337, 35%) relative to their total number of tweets and averaged the highest number of retweets per COVID-19 tweet (112 retweets per tweet). Public health agencies had the highest frequency of daily tweets about COVID-19 throughout the study period. Compared to tweets containing media and user mentions, hashtags and URLs were used in tweets more frequently by all account types, appearing in 69% (n=4798 tweets) and 68% (n=4781 tweets) of COVID-19–related tweets, respectively. Tweets containing hashtags also received the highest average retweets (47 retweets per tweet). Our content analysis revealed that of the three tweet message functions analyzed (information, action, community), tweets providing information were the most commonly used across most account types, constituting 39% (n=181) of all tweets; however, tweets promoting actions from users received higher than average retweets (55 retweets per tweet). When examining tweets that received one or more retweet (n=359), the difference between mean retweets across the message functions was statistically significant (P<.001). The risk communication strategies that we examined were not widely used by any account type, appearing in only 262 out of 485 tweets. However, when these strategies were used, these tweets received more retweets compared to tweets that did not use any risk communication strategies (P<.001) (61 retweets versus 13 retweets on average).

Conclusions: Public health agencies and decision makers should examine what messaging best meets the needs of their Twitter audiences to maximize sharing of their communications. Public health accounts that do not currently employ risk communication...
strategies in their tweets may be missing an important opportunity to engage with users about the mitigation of health risks related to COVID-19.

(J Med Internet Res 2021;23(3):e24883) doi:10.2196/24883

KEYWORDS
COVID-19; coronavirus; pandemic; public health; Twitter; social media; engagement; risk communication; infodemiology; content analysis

Introduction
Background
On January 25, 2020, the first case of COVID-19 was reported in Canada in a man who had recently traveled to Wuhan, China, where the virus was first identified [1]. By mid-March, in the days after the World Health Organization (WHO) declared COVID-19 to be a pandemic, Canadian public health officials began to issue warnings against all nonessential travel, and soon local community transmission was confirmed to be the primary source of the transmission of cases in the country. By March 22, all Canadian provinces entered a state of emergency, ordered all nonessential businesses to close, and restricted public gatherings [2].

During this time, public health agencies and officials emerged as the de facto leaders and primary decision makers for setting evidence-based public health policies, practices, and norms. Daily updates from medical officers of health and other public health experts would set the course for how each jurisdiction would respond to COVID-19 and outline the public’s role in “flattening the curve.” Some early research suggests that Canadians listened to these messages and followed public health recommendations [3], and also stayed home, particularly in the early weeks of the pandemic, as demonstrated by decreases in the levels of people’s movements tracked through Google’s Community Mobility Reports [4].

Public Health Administration in Canada
The roles and responsibilities of Canadian public health institutions and individuals differ across the country and by levels of government. As a result, it is not always clear where the public should go to access and retrieve information during a health crisis. For example, the federal government’s main role is to communicate national case numbers to all Canadians, coordinate control measures across provinces, and provide updates on national issues such as travel and the delivery of medical supplies. These activities are undertaken mostly by the Public Health Agency of Canada (PHAC), which was established as a separate agency of the federal department of health specifically to improve responses to infectious disease outbreaks after the severe acute respiratory syndrome (SARS) outbreak of 2003 [5].

Conversely, Canadian provinces are responsible for leading the emergency response, whereby ministries of health are tasked with communicating provincial updates on case counts, conducting surveillance and monitoring, providing guidance on infectious disease control measures and policies, and testing and screening practices [6]. Some provinces also operate regional and/or local-level public health units, which communicate information about local public health measures they have set and enforced based on provincial emergency orders. In addition to provincial health ministries, Ontario, British Columbia, and Quebec also have separate provincial-level public health agencies to provide scientific and technical advice on public health matters, conduct specialized data analytics, and provide updates on provincial testing capacity or other expert advice related to infectious disease control. Each of the levels of government described (federal, provincial, and regional/local where they exist) also appoints a medical officer of health to lead public health efforts in their respective jurisdiction, who often holds degrees and training in both medicine and public health.

The diversity in public health responses and responsibilities between institutions and individuals led virtually every Canadian province to take a different approach to crisis communications and information dissemination related to COVID-19. For example, provinces such as British Columbia have put their provincial medical officers of health in the spotlight, while others, including Ontario, have opted to have elected officials such as local premiers or health ministers lead some of the response. Occasionally this has resulted in contradictory messaging from multiple spokespeople, leaving the public confused and unsure whose guidance to follow [7]. This issue is particularly relevant on social media platforms like Twitter, where an abundance of information and misinformation has resulted in an infodemic [8], which can produce uncertainty and anxiety for individuals navigating an information overload [9]. Inconsistencies in health messaging can also erode public trust in the competence and credibility of public health agencies and decision makers [10].

Role of Public Health Agencies on Twitter
One of the ways in which the public has stayed informed on key information and updates on COVID-19 has been through the use of social media applications. Twitter in particular reported its biggest ever annual gain in daily users globally during the pandemic, which was up by 24% year over year during the first 3 months of 2020 [11]. On the one hand, an increase in Twitter users can lead to a more informed public as past research has suggested that a high proportion of users have identified Twitter as a major source of news for them [12]. On the other hand, an increase in Twitter users may also increase exposure to incorrect information or outright misinformation about COVID-19 [13]. Although the mass media have historically played a major role in the flow of information between public officials and the public during crises, the increased use of social media applications like Twitter has allowed members of the public to connect with governmental organizations and individuals more directly, largely...
circumventing the need to follow other unofficial communicators [14].

During a health crisis such as a pandemic, the role of public health agencies and officials as communicators of timely and accurate information is especially crucial in helping the public form accurate perceptions of health risks and adapt their behaviors in ways that are necessary to mitigate risks [15]. In fact, social media platforms like Twitter have enabled users to seek and share information and news updates during past crises to help reduce feelings of uncertainty and cope with threats [16]. Some early studies of the COVID-19 pandemic have highlighted the need for public health officials to utilize more communication channels and exert their influence as risk communicators in a time when the global need for expert information and advice has peaked [17]. Information posted to social media especially at the early stages of any crisis or risk event tends to garner more traction online as users seek out updates. As such, it is critical for risk communicators to establish an early online presence and engage those users from the beginning [18].

One way to assess the online influence of Twitter accounts is to examine the engagement that their tweets receive. This can indicate how much an account’s communications are being seen, studied, and shared. Tweet engagement can be indicated by various measures including the number of retweets (ie, shares of a tweet), likes (ie, number of times a user has seen and acknowledged or agreed with a tweet), or replies (ie, number of times a tweet has been commented on or responded to). Retweets in particular have been identified as an effective measure of engagement as they can indicate both the level of user agreement with a message and also the level of diffusion that message has undergone based on how many shares it has amassed from the original tweeter [19]. Beyond providing confirmation that some information or message has been disseminated to the public, quantifying tweet engagement based on retweets can provide a direct measure of the impact of that tweet on users. Some research has suggested that source credibility plays a role in garnering engagement; health agencies or individuals who appear to provide trustworthy information may be able to leverage their perceived legitimacy to gain more retweets and disseminate their information more broadly [20]. Researchers have also identified engagement strategies that can be used to increase user engagement to tweets. These strategies include the use of hashtags, URLs, user mentions (ie, direct mention of other Twitter user accounts), and media (eg, images or videos) [21].

Prior Work

Our study builds on past research that has examined the use of Twitter specifically by public health departments, agencies, and organizations. Most studies tend to focus on either examining the relationship between tweet features and levels of engagement and/or analyzing the content of the tweets to characterize the tweeting practices of particular accounts. For example, in a study of tweet engagement strategies used by 25 federal health agencies in the United States, it was found that hashtags, URLs, and user mentions were associated with an increased frequency of retweets [22]. In prior content analyses of tweets by state and/or local health departments in the United States, studies classifying the purpose of tweets (eg, whether tweets served to inform users or prompted them to perform some activity) have found that health departments mostly use Twitter to share health information [23-26]. However, other research has suggested that tweets whose function was to promote an action received more retweets than those with other functions [21]. Our work is also guided by research about prior pandemics such as tweeting trends during the H1N1 outbreak [27] and tweets covering Ebola health risks [28-30].

Previous work summarizing best practices in risk communication during broader risk events [31,32], as well as previous public health crises [33-35], underscore the importance of incorporating effective risk communication elements in messaging in order to reduce harm, clarify facts, and address public concerns. Beyond simply providing accurate descriptions of risks about the likelihood and consequences of harms, effective risk communication practices on Twitter may also include the use of messages promoting self-efficacy (ie, an individuals’ beliefs that they have the ability to take action), providing reasseurances, acknowledging concerns and uncertainties surrounding the situation, and indicating coordination of actions between experts. These strategies are viewed as important tools for organizations to augment their credibility and diffuse public fears [36]. Some literature has also noted the importance of applying strategic risk messaging across different outbreak phases by first focusing on information accuracy, then moving to reassurances to reduce uncertainty, and lastly, by emphasizing self-efficacy through individual actions and preventive measures [37].

Study Goal

The goal of our study was to characterize the content and level of engagement of COVID-19 tweets made by Canadian public health agencies and decision makers. Further, we propose recommendations for ways through which health agencies and decision makers could adjust their tweeting practices about COVID-19 and other future health crises to improve risk communication and maximize engagement. Our study seeks to answer four primary research questions (RQs):

- **RQ1**: which types of Canadian public health agencies and decision makers tweeted the most about COVID-19 and when?
- **RQ2**: how much engagement did tweets by Canadian public health agencies and decision makers receive during COVID-19? How did engagement change over time by account type?
- **RQ3**: did tweets containing Twitter engagement strategies receive more retweets than those that did not? How did the use of engagement strategies vary by account type?
- **RQ4**: did tweets from Canadian public health agencies and decision makers that employed a particular message function and risk communication strategy receive more retweets than others? How did the use of risk communication strategies in tweets from Canadian public health agencies and decision makers change over time?
**Methods**

**Data Collection**

A comprehensive list of Canadian public health institutions, agencies, and leaders was compiled after conducting a scoping review of provincial government websites. The resulting list of agencies and decision makers from this initial search was cross-referenced with the “Structural Profile of Public Health in Canada,” a resource published by the National Collaborating Centre for Healthy Public Policy [38] that summarizes how public health is organized federally, provincially, and regionally across Canada. The names of each of these agencies and individuals were then manually searched using the Twitter interface to narrow the list to include only those that had a Twitter account (n=128). This list of agencies and decision makers was then used to pull tweets for the identified key players in Canadian public health communication on Twitter.

Twitter data were downloaded using the Twitter API accessed through R using the rtweet package (The R Foundation) [39]. An R script was created to go through the list of 128 identified Twitter accounts and download the most recent 3200 tweets of each account, which reflects the maximum number of tweets allowed for account-specific searches as imposed by the application programming interface for Twitter. Data were originally collected on May 23 but were recollected every day from June 1 to July 10 using an automated script that iteratively updated the number of interactions with past tweets (such as likes or retweets) and collected new tweets published during the month of June. The Twitter data set contained tweet-level data including the author’s account name, Twitter handle, number of followers at the time of download; the date and time the tweet was published; whether the tweet was an original tweet or a retweet; the tweet’s text, hashtags, user mentions, URLs, favorite and retweet count; and whether the tweet contained media (eg, image).

The Twitter data collected between May 23 and July 10 yielded 303,428 tweets from February 2010 to July 10, 2020. The data were then narrowed down to only include tweets authored between January 1, 2020, and June 30, 2020, resulting in 71,014 tweets. This time period was selected as China first reported COVID-19 for a qualitative content analysis (see Multimedia Appendix 1 for process flow chart). Since public health services and policies are primarily administered at the provincial level in Canada, we wanted our subset of tweets to capture enough geographic variation in the accounts across various provinces. We also wanted our subset of tweets to capture enough variation in tweeting by account type. Therefore, we used a stratified random sample with replacement using proportional weighting to randomly select tweets across various strata based on the number of interactions with past tweets for all tweets in the thread) to avoid double-counting threads that contained multiple tweets, the maximum number of retweets obtained for any single tweet in the thread was used to measure engagement (rather than the average or total number of retweets for all tweets in the thread) to avoid double-counting or high-biased engagement.

Next, accounts were classified based on province, where applicable, or were otherwise identified as a “national” account (eg, PHAC and Canada’s chief medical officer). This was done to select a stratified random sample of 501 tweets about COVID-19 for a qualitative content analysis (see Multimedia Appendix 1 for process flow chart). Since public health services and policies are primarily administered at the provincial level in Canada, we wanted our subset of tweets to capture enough geographic variation in the accounts across various provinces. We also wanted our subset of tweets to capture enough variation in tweeting by account type. Therefore, we used a stratified random sample with replacement using proportional weighting to randomly select tweets across various strata based on the

on whether they contained any of the following keywords: “covid*,” “coronavirus,” “ncov,” “distane*,” “pand*,” “tracing,” “testandtrace,” “curve,” “stayhome,” “handwashing,” “mask,” and “masque.” These keywords were identified by scanning tweets within the sample and noting commonly used words in French- and English-language tweets describing COVID-19. During this scan, it was found that most French-language tweets about COVID-19 used #COVID19 to denote the tweet’s topic relevant to COVID-19, which was a less common practice among English-language tweets. Hence, a larger number of English-language keywords were required to classify whether an English-language tweet was about COVID-19. This selection process resulted in 6982 tweets about COVID-19.

Additionally, we downloaded the publicly available COVID-19 data set from the Government of Canada [1] to plot active case counts over time alongside tweeting trends by public health accounts. The national COVID-19 data set aggregated case counts by the date that the case data were submitted to PHAC rather than the date that the cases were confirmed by the local health authority that collected the data.

**Data Analysis**

To classify the public health accounts by type, each account was categorized as belonging to either an agency or a decision maker. If the Twitter account belonged to an agency, it was classified as being one of 3 types: public health agency (ie, a federal or provincial public health agency, distinct from a health ministry due to its focus on public health), a regional or local health department (ie, a public health department that offers public health programs or services to communities at a scale smaller than the province), or a provincial health authority (ie, provincial health ministries or health authorities). If the account belonged to a decision maker, it was classified as being one of 2 types: medical officer of health (ie, the chief medical health officer of Canada and of each province, and regional or local medical health officers responsible for public health in smaller communities) or provincial minister of health (ie, elected government official who oversees health and public health agencies).

Tweet engagement was measured using retweet count. For tweet threads that contained multiple tweets, the maximum number of retweets obtained for any single tweet in the thread was used to measure engagement (rather than the average or total number of retweets for all tweets in the thread) to avoid double-counting or high-biased engagement.

The national COVID-19 data set aggregated case counts over time alongside tweeting trends by public health accounts. The national COVID-19 data set aggregated case counts by the date that the case data were submitted to PHAC rather than the date that the cases were confirmed by the local health authority that collected the data.

To classify the public health accounts by type, each account was categorized as belonging to either an agency or a decision maker. If the Twitter account belonged to an agency, it was classified as being one of 3 types: public health agency (ie, a federal or provincial public health agency, distinct from a health ministry due to its focus on public health), a regional or local health department (ie, a public health department that offers public health programs or services to communities at a scale smaller than the province), or a provincial health authority (ie, provincial health ministries or health authorities). If the account belonged to a decision maker, it was classified as being one of 2 types: medical officer of health (ie, the chief medical health officer of Canada and of each province, and regional or local medical health officers responsible for public health in smaller communities) or provincial minister of health (ie, elected government official who oversees health and public health agencies).

Tweet engagement was measured using retweet count. For tweet threads that contained multiple tweets, the maximum number of retweets obtained for any single tweet in the thread was used to measure engagement (rather than the average or total number of retweets for all tweets in the thread) to avoid double-counting or high-biased engagement.

Next, accounts were classified based on province, where applicable, or were otherwise identified as a “national” account (eg, PHAC and Canada’s chief medical officer). This was done to select a stratified random sample of 501 tweets about COVID-19 for a qualitative content analysis (see Multimedia Appendix 1 for process flow chart). Since public health services and policies are primarily administered at the provincial level in Canada, we wanted our subset of tweets to capture enough geographic variation in the accounts across various provinces. We also wanted our subset of tweets to capture enough variation in tweeting by account type. Therefore, we used a stratified random sample with replacement using proportional weighting to randomly select tweets across various strata based on the

The Twitter data set contained tweet-level data including the author’s account name, Twitter handle, number of followers at the time of download; the date and time the tweet was published; whether the tweet was an original tweet or a retweet; the tweet’s text, hashtags, user mentions, URLs, favorite and retweet count; and whether the tweet contained media (eg, image).

The Twitter data collected between May 23 and July 10 yielded 303,428 tweets from February 2010 to July 10, 2020. The data were then narrowed down to only include tweets authored between January 1, 2020, and June 30, 2020, resulting in 71,014 tweets. This time period was selected as China first reported COVID-19 for a qualitative content analysis (see Multimedia Appendix 1 for process flow chart). Since public health services and policies are primarily administered at the provincial level in Canada, we wanted our subset of tweets to capture enough geographic variation in the accounts across various provinces. We also wanted our subset of tweets to capture enough variation in tweeting by account type. Therefore, we used a stratified random sample with replacement using proportional weighting to randomly select tweets across various strata based on the

Most tweets in the sample were single standalone tweets within the tweet character limit, but some comprised longer tweet threads. In these cases, tweets were turned into threads using the following procedure. First, all tweets were sorted by publisher and date and time. Next, all tweets that were identified as self-replies (based on the “reply_to_screen_name” variable) were treated as part of a tweet thread. The start of a tweet thread was the tweet that immediately preceded the Chain of tweets that were self-replies. This starting tweet, and all subsequent tweets that were self-replies (based on the “reply_to_screen_name” variable) was the tweet that immediately preceded the chain of tweets that were self-replies. For tweet threads, the maximum number of retweets obtained for any single tweet in the thread was used to measure engagement (rather than the average or total number of retweets for all tweets in the thread) to avoid double-counting or high-biased engagement.

Next, accounts were classified based on province, where applicable, or were otherwise identified as a “national” account (eg, PHAC and Canada’s chief medical officer). This was done to select a stratified random sample of 501 tweets about COVID-19 for a qualitative content analysis (see Multimedia Appendix 1 for process flow chart). Since public health services and policies are primarily administered at the provincial level in Canada, we wanted our subset of tweets to capture enough geographic variation in the accounts across various provinces. We also wanted our subset of tweets to capture enough variation in tweeting by account type. Therefore, we used a stratified random sample with replacement using proportional weighting to randomly select tweets across various strata based on the
number of tweets each stratum contributed to the total sample. These comprised of 8 regional strata, which included British Columbia, Alberta, the Prairies (Saskatchewan and Manitoba), Ontario, Quebec, the Maritimes (Nova Scotia, New Brunswick, Prince Edward Island, and Newfoundland and Labrador), the Territories (Yukon and Northwest Territories), and Canada. No public health Twitter accounts from the Canadian territory of Nunavut were identified. Additionally, we randomly selected tweets across the two broad account types (ie, agencies and decision makers). The resulting stratified random sample of 501 tweets about COVID-19 contained 58 tweets from Canadian national-level accounts, 52 from Alberta, 66 from British Columbia, 50 from the Maritimes, 199 from Ontario, 47 from the Prairies, 17 from Quebec, and 12 from territorial accounts. The sample of 501 tweets about COVID-19 also contained 377 tweets from agencies and 124 tweets from decision makers.

Before beginning the content analysis, 3 researchers (CS, CB, SS) were trained on a set of 50 tweets randomly selected from the overall sample of 6982 COVID-19 tweets. This was done so that the researchers could familiarize themselves with the various variables for coding and troubleshoot any issues with the definitions of the coded variables. To distribute the 501 tweets for the content analysis equally among the three researchers, the French-language tweets (n=27) were first identified and allocated to the researcher with fluency in French. Among the remaining English-language tweets, 50 were randomly selected and allocated to each of the 3 researchers so that these overlapping tweets could be used to calculate the Krippendorff α value for interrater reliability. This resulted in one researcher coding 201 tweets (including the 27 French tweets), and the other two coding 200 tweets each. To integrate the 50 tweets that all 3 researchers had coded into the overall sample, one researcher’s code was randomly selected from the 3 possible codes for each variable, such that the probability of selection was proportional to the frequency of that answer (eg, if two-thirds of coders agreed on a code, there was a 2 in 3 chance of that code being selected).

There were 10 coding variables in total. The first variable, media, captured the presence of media in the tweet and the type of media present (ie, image, video or document), if applicable. The next variable, message function, was coded using 6 nonmutually exclusive coding variables: information, action, or community. “Information” tweets included those whose main purpose was to inform, educate, or update the reader on case counts, disease transmission dynamics, policy changes, and COVID-19 symptoms. “Action” tweets included those whose main purpose was intended to prompt changes in the behaviors or actions of readers, such as encouraging social distancing, hygiene practices, or other harm-reducing behaviors. Finally, tweets were coded as “community” if their main purpose was community-building, identifying community supports and programs, or highlighting stories from or about the local community. Since threaded tweets could contain multiple message purposes, coding was based on the most prominent theme for the entire tweet thread. These variables for message function are consistent with those first proposed by Lovejoy and Saxton [40] for classifying the three main functions of organizations’ Twitter use and have been used in similar research [21,23,25].

The final variable, use of a risk communication strategy, was coded using 6 nonmutually exclusive coding variables: corrective, risk, efficacy, concern, uncertainty, and experts. Tweets were classified as “corrective” if they corrected some incorrect information about COVID-19 or aimed to prevent the spread of misinformation. Tweets were classified as “risk” if they contained information that would help a reader make a judgment about the risk of contracting COVID-19 or experiencing health complications from COVID-19. This included tweets containing information regarding absolute risks, relative risks, as well as the identification of high-risk subpopulations. Tweets were classified as “efficacy” if they referenced an individual’s or community’s ability to execute an action or activity successfully resulting in some tangible benefit to health or a reduction of harm related to COVID-19. Tweets were classified as “concern” if they acknowledged the fears, concerns, worry, or anxiety associated with COVID-19. Tweets were classified as “uncertainty” if they acknowledged uncertainty, confusion, or a lack of available information about COVID-19. Finally, tweets were classified as “experts” if they implicitly or explicitly mentioned some agreement, coordination or collaboration between public health experts or other credible health organizations or individuals. The presence of any one of these 6 variables was used to indicate the use of any risk communication strategy in the tweet and were based in part on best practices in communication identified by Seeger [31] used to improve organizational and individual responses during crisis events (see Multimedia Appendix 2 for dataset of 501 manually coded Tweets).

Statistical Analysis

Each of the 3 coders worked independently through the same randomly selected 50 tweets, where each tweet had 10 variables to be codified. Krippendorff α [41] was used to measure the interrater agreement among coders, which was calculated using the R package irr [42]. Overall, interrater reliability was considered high (α= .829), with all 3 coders reporting total agreement on 453 out of the 500 answers (90.6%). Any codification of unstructured phenomena can have subjective biases, including when there is only one coder. However, the computed level of reliability suggests that there was largely internal agreement amongst the classification of variables within the sample such that results are less likely to be an artifact of internal disagreement or bias.

To assess whether differences in the mean number of retweets per tweet across each message function category were statistically significant, the nonparametric Kruskal-Wallis one-way ANOVA (analysis of variance) test was used since our data were not normally distributed.

We used the nonparametric Mann–Whitney–Wilcoxon Test to assess differences in the mean number of retweets per tweet between tweets containing at least one risk communication strategy and tweets containing no risk communication strategy.
Results

COVID-19 Tweets by Account Type

Our sample comprised 32,737 tweets, which included individual tweets and threads authored by 118 Canadian public health Twitter accounts (agencies and decision makers) between January 1, 2020, to June 30, 2020. Approximately 21% (n=6982) of all tweets contained content about COVID-19. Table 1 summarizes the characteristics of tweets in our sample by account type. Medical officers of health authored the largest percentage of tweets about COVID-19 relative to their total tweets (n=1337, 35%), representing the largest contribution of any account type. Conversely, accounts that belonged to provincial health ministers authored the smallest percentage of their tweets about COVID-19 (n=350, 18%). Accounts corresponding to Canadian medical officers of health also had the highest average number of retweets for COVID-19-related tweets, as well as the largest total follower count (summed across accounts in this category) at 416,611 total users (range 213–206,288 followers).

Table 1. Number of tweets and follower counts by account type, January 1, 2020, to June 30, 2020.

<table>
<thead>
<tr>
<th>Account type</th>
<th>Twitter accounts, n</th>
<th>Total tweets, n</th>
<th>Mean tweets per account</th>
<th>Tweets about COVID-19, n (%)</th>
<th>Mean retweets per tweet about COVID-19</th>
<th>Total follower count, n (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public health agencies</td>
<td>4</td>
<td>2272</td>
<td>568</td>
<td>524 (23)</td>
<td>60</td>
<td>407,546 (10,201-325,112)</td>
</tr>
<tr>
<td>Regional and local health departments</td>
<td>69</td>
<td>19,919</td>
<td>289</td>
<td>3832 (19)</td>
<td>10</td>
<td>406,108 (194-82,347)</td>
</tr>
<tr>
<td>Provincial health authorities</td>
<td>15</td>
<td>4778</td>
<td>319</td>
<td>939 (20)</td>
<td>13</td>
<td>170,387 (23-41,779)</td>
</tr>
<tr>
<td>Medical officers of health</td>
<td>22</td>
<td>3859</td>
<td>175</td>
<td>1337 (35)</td>
<td>112</td>
<td>416,611 (213-206,288)</td>
</tr>
<tr>
<td>Provincial health ministers</td>
<td>8</td>
<td>1909</td>
<td>239</td>
<td>350 (18)</td>
<td>52</td>
<td>134,019 (908-53,325)</td>
</tr>
</tbody>
</table>

*aEquals the number of tweets and/or tweet threads authored by Twitter accounts per type between January 1 and June 30, 2020.

*bCorresponds to the number of followers the accounts had at the end of the study period on June 30, 2020.

Figure 1 displays longitudinal trends in the daily rate of COVID-19 tweets stratified by account type using a 7-day moving average. All account types had an increase in their daily rate of COVID-19–related tweets after January 25 (day 25), when Canada’s first case of COVID-19 was reported (Figure 1). Compared to the other account types, public health agencies authored the highest number of COVID-19–related tweets per account through most of the period studied. An exception to this trend was observed shortly after the WHO declared COVID-19 a pandemic, when the other account types increased their frequency of tweets about the disease. In the time between the WHO’s declaration (day 70) and when Canada’s COVID-19 cases first peaked (day 108), the daily number of COVID-19 tweets per account for regional and local health departments, provincial health authorities, and medical health officers appeared to converge (Figure 1).
Engagement

Figure 2 displays trends in the average number of retweets for COVID-19–related tweets over time by account type. Around day 28, 3 days after the first case of COVID-19 was confirmed in Canada, there was a large spike in the average number of retweets for public health agencies that lasted a few days before returning to baseline. For all account types, the next period of increase in retweets per tweet occurred around the time of the WHO’s pandemic declaration (day 70). However, a few weeks after the pandemic was declared, retweets appeared to trend downward, even before COVID-19 cases peaked in Canada (Figure 2). The maximum daily average in retweets (381 retweets per tweet) was seen on day 80 among accounts belonging to medical officers of health; importantly, this was the day that Canada announced it would be closing its border to most noncitizens and nonpermanent residents. In contrast to other account types, medical officers of health maintained relatively high engagement (average of 50 or more retweets per COVID-19–related tweet) for a sustained period, beginning shortly before the WHO’s pandemic declaration on day 70 and lasting until the second peak in COVID-19 cases in Canada on day 150. For accounts corresponding to provincial health ministers, daily retweets peaked on the same day as they did for medical health officers (day 80) but trended downwards shortly thereafter (Figure 2). Trends in retweets over time were similar for provincial health authorities and regional or local health departments (Figure 2).
Table 2 summarizes the total number of tweets containing each engagement strategy, stratified by account type, as well as the sum and mean number of retweets by Twitter engagement strategy. User mentions were used less frequently than other engagement strategies and received the lowest mean retweets across all accounts. The most frequently used engagement strategies across all account types were hashtags (n=4798) and URLs (n=4781). These two engagement strategies appeared equally as frequently in tweets authored by public health agencies; however, the use of media (e.g., images and videos) was associated with the highest average retweet count (67 retweets per tweet) for this account type. Similar findings were observed for provincial health authorities, which also used URLs most frequently (n=669) and received the highest average retweets on tweets containing media (18 retweets per tweet). Although accounts corresponding to regional and local health departments also incorporated URLs in more tweets than the other strategies (n=2766), they received the highest average retweets for tweets that contained hashtags (13 retweets per tweet). Tweets by regional and local health departments on average received fewer retweets per tweet compared to the other account types. Tweets by medical health officers that contained hashtags on average received the highest number of retweets per tweet compared to any engagement strategy and any account (134 retweets per tweet). Both medical officers of health and provincial health ministers used tweets containing media in fewer than half of their tweets, while the other three account types used media in more than half of their tweets.
Table 2. Summed tweet (n=6982) and retweet frequencies and percentages by engagement strategy and account type, January 1, 2020, to June 30, 2020.

<table>
<thead>
<tr>
<th>Account type and engagement strategy</th>
<th>Number of tweets(^a) containing each engagement strategy, n (%)</th>
<th>Summed retweets for all tweets containing each strategy, n</th>
<th>Mean retweets per tweet containing each strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public health agencies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>350 (67)</td>
<td>23,291</td>
<td>67</td>
</tr>
<tr>
<td>Hashtags</td>
<td>451 (86)</td>
<td>29,418</td>
<td>65</td>
</tr>
<tr>
<td>URLs</td>
<td>451 (86)</td>
<td>24,788</td>
<td>55</td>
</tr>
<tr>
<td>User mentions</td>
<td>139 (27)</td>
<td>2654</td>
<td>19</td>
</tr>
<tr>
<td><strong>Regional and local health departments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>2640 (69)</td>
<td>30,223</td>
<td>11</td>
</tr>
<tr>
<td>Hashtags</td>
<td>2462 (64)</td>
<td>30,824</td>
<td>13</td>
</tr>
<tr>
<td>URLs</td>
<td>2766 (72)</td>
<td>27,136</td>
<td>10</td>
</tr>
<tr>
<td>User mentions</td>
<td>753 (20)</td>
<td>4648</td>
<td>6</td>
</tr>
<tr>
<td><strong>Provincial health authorities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>477 (51)</td>
<td>8555</td>
<td>18</td>
</tr>
<tr>
<td>Hashtags</td>
<td>614 (65)</td>
<td>8333</td>
<td>14</td>
</tr>
<tr>
<td>URLs</td>
<td>669 (71)</td>
<td>6671</td>
<td>10</td>
</tr>
<tr>
<td>User mentions</td>
<td>326 (35)</td>
<td>1644</td>
<td>5</td>
</tr>
<tr>
<td><strong>Medical officers of health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>342 (26)</td>
<td>25,924</td>
<td>76</td>
</tr>
<tr>
<td>Hashtags</td>
<td>1058 (79)</td>
<td>141,841</td>
<td>134</td>
</tr>
<tr>
<td>URLs</td>
<td>681 (51)</td>
<td>61,697</td>
<td>91</td>
</tr>
<tr>
<td>User mentions</td>
<td>396 (30)</td>
<td>15,098</td>
<td>38</td>
</tr>
<tr>
<td><strong>Provincial health ministers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media</td>
<td>157 (45)</td>
<td>5015</td>
<td>32</td>
</tr>
<tr>
<td>Hashtags</td>
<td>213 (61)</td>
<td>14,261</td>
<td>67</td>
</tr>
<tr>
<td>URLs</td>
<td>214 (61)</td>
<td>8134</td>
<td>38</td>
</tr>
<tr>
<td>User mentions</td>
<td>135 (39)</td>
<td>3756</td>
<td>28</td>
</tr>
</tbody>
</table>

\(^a\)Equals the number of tweets and/or tweet threads authored by Twitter accounts per type between January 1 and June 30, 2020.

Content Analysis

During the content analysis of 501 tweets, 16 tweets were identified by the 3 researchers as not being directly related to content about COVID-19, resulting in a data set of 485 tweets about COVID-19. When coding the tweets for message function, 21 tweets were found to not have a classifiable purpose and were omitted from this part of the analysis. Table 3 summarizes the frequency and percentage of tweets identified as information, action, and community for each of the five account types in the sample. More than half of all coded tweets authored by public health agencies were classified as information tweets (n=17, 52%), which received the highest average number of retweets per tweet (56 retweets per tweet) compared to action (43 retweets per tweet) and community tweets (12 retweets per tweet) for these accounts. In our sample, tweets authored by regional and local health departments were most often classified as action tweets (n=101, 47%), and on average these received the highest number of retweets per tweet for this account type (10 retweets per tweet). Tweets corresponding to provincial health authorities, medical health officers, and provincial health ministers were mostly classified as information (n=47, 47%; n=56, 58%; and n=10, 53%, respectively); however, action tweets authored by each of these account types received more retweets per tweet on average compared to their information tweets (12, 259, and 44 retweets per tweet, respectively). The difference in mean retweets across the three message functions was not statistically significant (P=.18). However, when examining only those tweets that received one or more retweet (n=359), the difference between mean retweets across the three message functions was statistically significant (P<.001).
Table 3. Summed tweet (n=464) and retweet frequencies and percentages by message function and account type, January 1, 2020, to June 30, 2020.

<table>
<thead>
<tr>
<th>Account type and message function</th>
<th>Number of tweets(^a) with each message function, n (%)</th>
<th>Summed retweets for all tweets of each function, n</th>
<th>Mean retweets per tweet of each function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public health agencies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information</td>
<td>17 (52)</td>
<td>957</td>
<td>56</td>
</tr>
<tr>
<td>Action</td>
<td>13 (39)</td>
<td>554</td>
<td>43</td>
</tr>
<tr>
<td>Community</td>
<td>3 (9)</td>
<td>36</td>
<td>12</td>
</tr>
<tr>
<td><strong>Regional and local health departments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information</td>
<td>51 (24)</td>
<td>325</td>
<td>6</td>
</tr>
<tr>
<td>Action</td>
<td>101 (47)</td>
<td>1043</td>
<td>10</td>
</tr>
<tr>
<td>Community</td>
<td>64 (30)</td>
<td>223</td>
<td>3</td>
</tr>
<tr>
<td><strong>Provincial health authorities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information</td>
<td>47 (47)</td>
<td>393</td>
<td>7</td>
</tr>
<tr>
<td>Action</td>
<td>33 (33)</td>
<td>388</td>
<td>12</td>
</tr>
<tr>
<td>Community</td>
<td>19 (19)</td>
<td>142</td>
<td>7</td>
</tr>
<tr>
<td><strong>Medical officers of health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information</td>
<td>56 (58)</td>
<td>6172</td>
<td>103</td>
</tr>
<tr>
<td>Action</td>
<td>30 (31)</td>
<td>7765</td>
<td>259</td>
</tr>
<tr>
<td>Community</td>
<td>11 (11)</td>
<td>223</td>
<td>20</td>
</tr>
<tr>
<td><strong>Provincial health ministers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information</td>
<td>10 (53)</td>
<td>293</td>
<td>27</td>
</tr>
<tr>
<td>Action</td>
<td>5 (26)</td>
<td>221</td>
<td>44</td>
</tr>
<tr>
<td>Community</td>
<td>4 (21)</td>
<td>90</td>
<td>23</td>
</tr>
</tbody>
</table>

\(^a\)Equals the number of tweets and/or tweet threads authored by Twitter accounts per type between January 1 and June 30, 2020.

Table 4 summarizes the frequencies and percentages of risk communication strategies used by account type for the stratified random sample of COVID-19 tweets that were coded during the content analysis. Overall, the risk communication strategies that we examined were not very widely used and appeared only in 262 tweets out of our sample of 485 tweets. Since some tweets in our sample contained more than one type of risk communication strategy, as a result, there were 334 strategies used across the 262 tweets. Efficacy statements were the most commonly used strategy (efficacy accounted for more than one-third of the strategies used by each account type), and this strategy appeared in 163 of 262 tweets containing any risk communication strategy. For accounts corresponding to public health agencies, efficacy (n=12, 46%) and risk (n=8, 31%) statements were the most frequently used strategy; however, tweets containing these strategies were not the most retweeted. Instead, a single tweet thread containing corrective information that was authored by PHAC (which addressed misinformation on COVID-19) received the most retweets (134 retweets per tweet). Among regional and local health departments, the second most frequently used risk communication strategy after efficacy was addressing concern about COVID-19; however, their tweets containing corrective information received the most retweets on average (30 retweets per tweet). Provincial health authorities and medical health officers used risk statements at similar frequencies (n=12, 23% and n=24, 22%, respectively); however, tweets containing this strategy had fewer retweets on average among both account types when compared to tweets containing other risk communication strategies. Although medical health officers only authored 4 tweets containing statements that acknowledged the uncertainty around COVID-19, these tweets received the highest number of retweets per tweet compared to the other strategies used by that account type (358 retweets per tweet).
Table 4. Summed risk communication strategies (n=334) and percentages and retweet frequencies by strategy and account type, January 1, 2020, to June 30, 2020.

<table>
<thead>
<tr>
<th>Account type and risk communication strategy</th>
<th>Number of risk communication strategies used by account type, n (%)</th>
<th>Summed retweets for all tweets containing each risk communication strategy, n</th>
<th>Mean retweets per tweet containing each strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public health agencies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective</td>
<td>1 (4)</td>
<td>134</td>
<td>134</td>
</tr>
<tr>
<td>Risk</td>
<td>8 (31)</td>
<td>112</td>
<td>14</td>
</tr>
<tr>
<td>Efficacy</td>
<td>12 (46)</td>
<td>845</td>
<td>70</td>
</tr>
<tr>
<td>Concern</td>
<td>2 (8)</td>
<td>154</td>
<td>77</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>1 (4)</td>
<td>67</td>
<td>67</td>
</tr>
<tr>
<td>Experts</td>
<td>2 (8)</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td><strong>Regional and local health departments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective</td>
<td>4 (3)</td>
<td>119</td>
<td>30</td>
</tr>
<tr>
<td>Risk</td>
<td>5 (4)</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Efficacy</td>
<td>81 (60)</td>
<td>711</td>
<td>9</td>
</tr>
<tr>
<td>Concern</td>
<td>24 (18)</td>
<td>236</td>
<td>10</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>10 (7)</td>
<td>90</td>
<td>9</td>
</tr>
<tr>
<td>Experts</td>
<td>12 (9)</td>
<td>35</td>
<td>3</td>
</tr>
<tr>
<td><strong>Provincial health authorities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Risk</td>
<td>12 (23)</td>
<td>38</td>
<td>3</td>
</tr>
<tr>
<td>Efficacy</td>
<td>18 (34)</td>
<td>129</td>
<td>7</td>
</tr>
<tr>
<td>Concern</td>
<td>10 (19)</td>
<td>220</td>
<td>22</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>3 (6)</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Experts</td>
<td>9 (17)</td>
<td>38</td>
<td>4</td>
</tr>
<tr>
<td><strong>Medical officers of health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective</td>
<td>4 (4)</td>
<td>767</td>
<td>192</td>
</tr>
<tr>
<td>Risk</td>
<td>24 (22)</td>
<td>2709</td>
<td>113</td>
</tr>
<tr>
<td>Efficacy</td>
<td>49 (45)</td>
<td>12,413</td>
<td>253</td>
</tr>
<tr>
<td>Concern</td>
<td>13 (12)</td>
<td>3928</td>
<td>302</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>4 (4)</td>
<td>1433</td>
<td>358</td>
</tr>
<tr>
<td>Experts</td>
<td>15 (14)</td>
<td>1695</td>
<td>113</td>
</tr>
<tr>
<td><strong>Provincial health ministers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrective</td>
<td>0 (0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Risk</td>
<td>2 (20)</td>
<td>123</td>
<td>62</td>
</tr>
<tr>
<td>Efficacy</td>
<td>3 (30)</td>
<td>175</td>
<td>58</td>
</tr>
<tr>
<td>Concern</td>
<td>1 (10)</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>0 (0)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Experts</td>
<td>4 (40)</td>
<td>53</td>
<td>13</td>
</tr>
</tbody>
</table>

*aRisk communication strategies were not mutually exclusive; therefore, a single tweet could contain multiple strategies.

*bEquals the number of tweets and/or tweet threads authored by Twitter accounts per type between January 1 and June 30, 2020.

*cN/A: not applicable.

Figure 3 displays the weekly frequency of COVID-19 tweets containing any risk communication strategy and tweets containing no strategy across all account types for the stratified random sample of COVID-19 tweets that were coded during...
the content analysis. When examining trends across all account types, the use of risk communication strategies appeared to increase in tweets produced after the WHO’s pandemic declaration (week 10) but decreased in the period of time between the first and second peaks of COVID-19 cases in Canada (weeks 15 and 22, respectively). Tweets that did not contain a risk communication strategy were not tweeted as frequently as tweets that did contain a risk communication strategy shortly after the pandemic was declared. The use of any risk communication strategy by all account types appeared to increase again a little after the second peak of COVID-19 cases in Canada after week 22. Tweets using at least one risk communication strategy (n=262) received an average of 61 retweets per tweet, while tweets using no risk communication strategies received an average of 13. This nearly 5-fold difference was statistically significant ($P < .001$).

**Figure 3.** Weekly frequency of COVID-19 tweets containing any risk communication strategy, across all account types, January 1, 2020, to June 30, 2020. WHO: World Health Organization.

**Discussion**

**Principal Results**

**RQ 1 and 2: Tweets and Retweets Over Time by Account Type**

Our study of Canadian public health Twitter accounts revealed that tweeting practices and tweet engagement differed between various agencies and decision makers during the COVID-19 pandemic. Of the five account types that we examined, public health agencies and medical officers of health stood out for their tweeting frequency and the high engagement that their tweets received. These two account types had the largest percentage of tweets about COVID-19 relative to all their total number of tweets, as well as the highest daily rate of COVID-19 tweets. This finding is consistent with their roles as the primary agencies and individuals responsible for implementing and communicating a public health response during health crises in Canada. Our findings showed that these two account types also received the highest average engagement (retweets) during the study period, suggesting that Twitter users also recognize these agencies and individuals as the primary information sources to share with their peers during a public health crisis like COVID-19. These findings are positive in that if public health agencies and medical health officers continue to establish a consistent Twitter presence, attract followers, and engage their Twitter audiences, their communications may continue to be shared widely.

We observed that trends in the daily frequency of tweets by account type over time were generally consistent with changes in public concern and engagement over the course of the pandemic [27]. However, it is interesting to note that during key moments in time where the threats of COVID-19 were increasing, the daily rate of COVID-19 tweets did not always correspond to increased retweet counts, and instead trends in tweeting and retweeting varied by account type. For example, when the first case of COVID-19 was confirmed in Canada on January 25, 2020, public health agencies tweeted the most about COVID-19 and received the most retweets for these tweets compared to all other account types; however, after the WHO declared COVID-19 a pandemic on day 70, the daily rates of COVID-19 tweets for all account types began to increase and nearly converged. Medical officers of health received the most retweets per COVID-19 tweet during this period (day 80). These results suggest that Twitter users may have shifted their engagement from tweets authored by public health agencies to
those by medical health officers; however, this trend was less evident by the time Canada’s COVID-19 cases peaked.

It is also interesting to note that daily rates of COVID-19 tweets authored by public health agencies seemed to peak around the same time that key moments related to COVID-19 took place in Canada (ie, after Canada’s first case, just before the first peak in COVID-19 cases, and shortly after the second peak in COVID-19 cases), which suggests that trends in case counts may have at least partially informed this account type’s tweeting practices. This trend was not seen for medical officers of health, whose daily rates of COVID-19 tweets trended downward after the WHO declared COVID-19 a pandemic, despite subsequent peaks in Canadian COVID-19 cases. This is important because increasing COVID-19 case counts partially inform the public about their risk of contracting COVID-19 and thus may lead to increased information seeking. As a result, more public health accounts should respond to increasing case numbers with increased daily tweeting about COVID-19, not less. Unfortunately, information seeking cannot be indicated by engagement metrics such as retweet counts; therefore, our results do not reflect which tweets were most seen or read by Twitter users. However, other research has noted that frequently updated social media feeds are perceived by audiences as more relevant during crises and should be updated enough so as to be noticed by users, regardless of whether they receive engagement [20].

Despite having lower daily COVID-19 tweet rates compared to public health agencies, medical officers of health and provincial health ministers received the highest daily retweets per tweet on day 80, 10 days after the WHO declared COVID-19 a pandemic. This finding was somewhat surprising given that past research has identified health agencies (especially at the federal level) as being able to garner more retweets than other public health accounts during past pandemics, largely due to their recognition and influence over online information sharing [33]. This finding may reflect a Twitter audience shift from governmental institutions to individuals, consistent with some research that has identified a spokesperson effect during public health crises, whereby people seek out a leading voice that is credible and relatable as their primary source of information [43].

One reason that medical officers of health may have been able to maintain a higher average retweet count for the remainder of the study period is that Twitter users may have perceived their content as more medically or scientifically relevant during the pandemic, which other studies have found can lead to more retweets [14,44], likely because expert accounts are perceived as highly authoritative and trustworthy information sources. Perhaps unsurprisingly, Twitter accounts corresponding to provincial health ministers had the lowest percentage of tweets about COVID-19, and the number of retweets that their tweets received decreased significantly after peaking on day 80. Given that provincial health ministers are elected public officials, often with little to no expertise in public health, our findings suggest that these individuals likely delegated responsibilities around COVID-19 communications to other accounts more focused on public health. These results are also consistent with prior research that found that the public may be more likely to distrust information from governments or elected officials and more likely to share information from sources perceived as more trusted or more “expert” (eg, physicians and medical researchers) [45].

**RQ3: Use of Engagement Strategies**

The frequent use of hashtags and URLs in the majority of COVID-19 tweets that we analyzed is consistent with other studies examining engagement to tweets authored by health agencies [22], and suggests that many Canadian public health agencies and decision makers are aware of and incorporate common Twitter engagement strategies in their tweeting practices. However, the use of these metrics was not always associated with higher engagement, suggesting that there is no single strategy to garner engagement. Hence, each account type may need to tailor their approach. Although user mentions were among the least used engagement metric, and received the lowest average retweets per tweet, the value of these types of tweets extends beyond engagement. In fact, user mentions are viewed as a way to establish dialogue between a tweeter and their audience, build relationships between users, and improve transparency and trust in tweeting institutions [46]. Other studies have also noted that organizations that do not fully utilize Twitter engagement strategies may be missing important opportunities to craft more interactive and engaging communications during a crisis [47].

**RQ4: Tweet Message Functions and Use of Risk Communication Strategies**

In our content analysis of a stratified random sample of tweets by Canadian public health agencies and decision makers, we found that of the three message functions that we examined, information tweets were most common across all account types, except regional and local public health departments, which used action tweets more frequently. This finding was consistent with other studies that have found tweets conveying information to be the most frequently tweeted by health organizations during other pandemics [26,48]; however, action tweets were most frequently produced in a study by Wahbeh et al [49] of physicians’ tweets on COVID-19. Despite information tweets being the most frequently used by the accounts in our sample, action tweets received on average more retweets per tweet for all account types except for public health agencies, which received on average more retweets for information tweets. Other research has also found that action tweets receive the most engagement compared to tweets with other message functions [21]. Our findings suggest that users may seek out and engage with different messages from different account types, relying more on public health agencies for information about COVID-19 and relying on the other accounts for instructions on actions and preventative measures they should be taking. During regular non-crisis periods, community tweets can help a public health agency build an online community and initiate a sense of togetherness [25]; however, the lack of engagement that these tweets received in our study suggest that the public’s need for information and direct actions during the COVID-19 pandemic may require public health agencies and decision makers to shift away from community-type tweets during a crisis to meet the needs of their audiences.
Furthermore, the results of our content analysis demonstrated that the risk communication strategies that we examined were not very widely used by any account type, appearing in just over half of the tweets that we analyzed. For example, our study found very few tweets provided corrective information that could be used to tackle misinformation about COVID-19, which is consistent with work by Guidry et al [28] that found only 1% of tweets by health organizations in their sample addressed misinformation on Ebola. These findings suggest that a lack of corrective tweets could represent a missed opportunity for public health agencies and officials to combat misinformation spread during a pandemic. It is also worth noting that risk tweets containing statements that would aid users in making a judgment about their risk of contracting COVID-19 or the harms associated with COVID-19 only appeared in approximately 11% of the tweets in our sample (n=51). In fact, only one category of the risk communication strategies that we examined (efficacy) appeared in at least one-third of the tweets authored by all account types, a frequency that was similar to the percentage of tweets containing efficacy statements about the Zika virus in a study of tweets authored by US public health agencies [33]. On the other hand, tweets that acknowledged concerns about COVID-19 tended to receive among the highest retweets per tweet in our study, which is consistent with risk communication literature identifying concern as an important strategy that aids the public in developing faith in communicators that demonstrate compassion [31].

Despite the overall lack of risk communication strategies employed in the tweets in our sample, our findings demonstrate that including one or more strategies was associated with more engagement on average compared to tweets that did not contain any risk communication strategies (61 retweets per tweet versus 13 retweets per tweet, respectively). We also found that risk communication strategies tended to be used at key moments during the COVID-19 pandemic. The use of risk communication strategies appeared to peak in the weeks just after the WHO declared COVID-19 a pandemic and trended slightly upward after each of the two peaks of COVID-19 cases in Canada. This finding is consistent with other studies that have found that risk communication becomes less prevalent over the course of a crisis [50], since this information is considered most valuable at the beginning of a crisis when uncertainty is high [35]. However, given that our understanding of COVID-19 transmission and health impacts is still developing, a lack of sustained risk communication in tweets by Canadian public health agencies and decision makers could be problematic if it leads to inaccurate perceptions of personal health risks or indifference toward public health measures.

With so much discussion of the pandemic online, supplying information users with high-quality, consistent messaging on the health risks associated with COVID-19 is critical for improving health literacy in the population [51]. Therefore, while the use of these risk communication strategies at key moments could be viewed as promising, more risk communication overall should be undertaken by all public health Twitter accounts to ensure that their audience continuously receives relevant, accurate, and up-to-date information on potential health risks related to COVID-19.

**Strengths, Limitations, and Future Work**

One methodological advantage that sets our study apart from others is the use of tweet threads, in addition to individual tweets, as the unit of analysis, rather than analyzing each tweet from a thread on its own. Analyzing threads allowed for a more accurate examination of tweeting practices by recreating the message as it would have been viewed originally on a Twitter user. This was a major strength of our content analysis as it allowed for the entire message to be coded and analyzed, rather than a small segment of it. Since threads are commonly used to craft messages that would otherwise be impossible to fit within a tweet’s character limit, analyzing them individually would have provided an incomplete picture.

This research has several limitations related, in large part, to its reliance on Twitter data. First, we analyzed the tweets of public health agencies and decision makers in Canada who had tweeted between January 1 and June 30, 2020; however, there are numerous other authoritative health-related Twitter accounts and other official government accounts that tweeted about COVID-19 during this period (eg, physicians, health nongovernmental organizations, etc), which the public may have also engaged with. Moreover, not all members of the public use Twitter; therefore, engagement as measured by counts of retweets does not offer insights into which public health agencies or decision makers the broader Canadian public may consider most important. Additionally, our results may not reflect today or tomorrow’s Twitter landscape, and therefore only indicate tweeting practices at a snapshot in time. However, our study can offer a glimpse into trends on information sharing during the first 6 months of the COVID-19 pandemic based on what Canadian public health agencies and decision makers were tweeting and how Twitter users engaged with this content. Our study’s findings can be useful to those public health accounts that we included in our analysis as well as to other health organizations or individuals that may be looking for ways to better utilize Twitter to engage with users seeking health information on this platform.

The findings from our study could be improved through additional analysis of content authored by public health accounts on other social media platforms (eg, Instagram, Facebook, etc) or additional refinement of the categories we used for classifying the Twitter accounts and tweet content. For example, future work examining public health communications in Canada could build on our work by contrasting tweeting practices by province or other geographic elements, which could uncover more trends in information sharing and engagement given the region-specific administration of Canada’s public health policies. In addition, future work in this area could explore patterns in retweeted tweets and perform a network analysis to examine the Twitter interactions between various public health accounts.

**Conclusions**

This study analyzed tweets by Canadian public health agencies and decision makers between January 1, 2020, and June 30, 2020, to examine their tweeting practices during the early stages of the pandemic. We also aimed to identify ways that tweets could be improved to effectively communicate risk and maximize engagement on this platform. Using a mixed methods approach, we found that including one or more strategies was associated with more engagement, which is consistent with other research. However, our study also revealed a lack of risk communication strategies, particularly in terms of corrective messaging. This highlights the need for public health agencies to focus on developing and implementing risk communication strategies that address public concerns and provide accurate information to prevent the spread of misinformation.

Our findings suggest that Canadian public health agencies and decision makers could benefit from adopting a more strategic approach to risk communication on Twitter. By incorporating a variety of strategies, such as providing accurate information, addressing public concerns, and demonstrating compassion, they can enhance public engagement and foster a sense of trust and faith in their messaging. This is particularly important during public health crises, where timely and accurate information can make a significant difference in public health outcomes.

In conclusion, our study provides insights into the tweeting practices of Canadian public health agencies and decision makers during the early stages of the COVID-19 pandemic. By identifying strengths, limitations, and future work, we hope to contribute to the ongoing discourse on effective risk communication strategies in public health. Further research could explore how these findings can be applied in other contexts and how various social media platforms can be used to optimize health communication efforts.
approach, we conducted Twitter analytics and a qualitative content analysis to characterize the level of engagement that COVID-19 tweets authored by Canadian public health accounts received, as well as the purpose of their tweets and their use of key risk communication strategies. Our research findings suggest that while public health agencies authored more daily COVID-19–related tweets than other account types, engagement tended to be higher for tweets authored by medical health officers, particularly during key moments of the pandemic. Overall, most account types appeared to focus on disseminating information, with the exception of regional and local health departments, which tended to promote more action from users. Our results also point to the need for public health agencies and decision makers to monitor Twitter analytics in order to understand their audience and leverage whatever Twitter engagement strategies help maximize shares of their communications.

During the beginning of any crisis, the use of risk communication strategies by organizations and officials leading the response is critical to help inform the public about an often highly uncertain and rapidly evolving situation, address concerns, and instill trust in those leaders. Our study found that risk communication strategies were not widely used in tweets by any account type, even though these strategies were associated with more engagement. These findings suggest that Canadian public health agencies and decision makers may be missing an important opportunity to engage with information users about the mitigation of health risks related to COVID-19. Finally, our study builds on other literature that has explored differences in engagement to communications authored by individuals and institutions, and suggests that any medical officer of health or other expert individual currently not on Twitter should consider the platform as a means to disseminate information that Twitter users appear to be interested in sharing.

Acknowledgments
This project is supported in part by funding from the Canadian Social Sciences and Humanities Research Council (grant: 435-2020-0257).

Conflicts of Interest
None declared.

Multimedia Appendix 1
Flow chart of Tweet exclusion process.
[ PNG File , 77 KB - jmir_v23i3e24883_app1.png ]

Multimedia Appendix 2
Dataset of manually coded Tweets (n=501) from content analysis.
[ XLSX File (Microsoft Excel File) , 55 KB - jmir_v23i3e24883_app2.xlsx ]

References

https://www.jmir.org/2021/3/e24883
J Med Internet Res 2021 | vol. 23 | iss. 3 | e24883 | p.740

(page number not for citation purposes)


Abbreviations

ANOVA: analysis of variance
PHAC: Public Health Agency of Canada
RQ: research question
SARS: severe acute respiratory syndrome
WHO: World Health Organization
Viewpoint

Clinical Trial Data Sharing for COVID-19–Related Research

Louis Dron\(^1\), MSc; Alison Dillman\(^2\), MPH; Michael J Zoratti\(^1\), MSc; Jonas Haggstrom\(^3\), PhD; Edward J Mills\(^1\), FRCP Edin; Jay J H Park\(^4\), MSc

\(^1\)Cytel Canada Inc., Vancouver, BC, Canada
\(^2\)School of Public Health, Faculty of Medicine, Imperial College London, London, United Kingdom
\(^3\)International COVID-19 Data Alliance, London, United Kingdom
\(^4\)Department of Experimental Medicine, University of British Columbia, Vancouver, BC, Canada

Corresponding Author:
Jay J H Park, MSc
Department of Experimental Medicine, University of British Columbia
802-777 West Broadway
Vancouver, BC, V5Z 1J5
Canada
Phone: 1 (604) 294 3823
Email: jayhpark1@alumni.ubc.ca

Abstract

This paper aims to provide a perspective on data sharing practices in the context of the COVID-19 pandemic. The scientific community has made several important inroads in the fight against COVID-19, and there are over 2500 clinical trials registered globally. Within the context of the rapidly changing pandemic, we are seeing a large number of trials conducted without results being made available. It is likely that a plethora of trials have stopped early, not for statistical reasons but due to lack of feasibility. Trials stopped early for feasibility are, by definition, statistically underpowered and thereby prone to inconclusive findings. Statistical power is not necessarily linear with the total sample size, and even small reductions in patient numbers or events can have a substantial impact on the research outcomes. Given the profusion of clinical trials investigating identical or similar treatments across different geographical and clinical contexts, one must also consider that the likelihood of a substantial number of false-positive and false-negative trials, emerging with the increasing overall number of trials, adds to public perceptions of uncertainty. This issue is complicated further by the evolving nature of the pandemic, wherein baseline assumptions on control group risk factors used to develop sample size calculations are far more challenging than those in the case of well-documented diseases. The standard answer to these challenges during nonpandemic settings is to assess each trial for statistical power and risk-of-bias and then pool the reported aggregated results using meta-analytic approaches. This solution simply will not suffice for COVID-19. Even with random-effects meta-analysis models, it will be difficult to adjust for the heterogeneity of different trials with aggregated reported data alone, especially given the absence of common data standards and outcome measures. To date, several groups have proposed structures and partnerships for data sharing. As COVID-19 has forced reconsideration of policies, processes, and interests, this is the time to advance scientific cooperation and shift the clinical research enterprise toward a data-sharing culture to maximize our response in the service of public health.

(J Med Internet Res 2021;23(3):e26718) doi:10.2196/26718

KEYWORDS

COVID-19; data-sharing; clinical trials; data; research; privacy; security; registry; feasibility; challenge; recruitment; error; bias; assessment; interoperability; dataset; intervention; cooperation

The scientific community has made several important inroads in the fight against COVID-19. The pandemic has mobilized the global research community at an unparalleled scale [1-3]. From the start of the COVID-19 pandemic to date, 2516 clinical trials have been registered globally [4]. Most are within hospitalized patient contexts, with other trials focusing on outpatient treatment or prophylaxis, whether through vaccination or pre- or posttreatment prophylaxis. Of the 2516 registered clinical trials, records indicate that 1278 (50.79%) trials are still actively enrolling patients, 26 (1.03%) have suspended recruitment, 43 (1.70%) have terminated, and 67 (2.66%) have withdrawn [4]. However, it is important to note that the status of 28.22% (710/2516) of these trials have not been updated in their respective registries since they were first posted, whereas only 1.83% (46/2516) of the trials that are past their expected completion dates have reported results linked to their respective
registries [4]. According to a living systematic review on randomized clinical trials for COVID-19 published in The BMJ, only 85 trials have been published as of October 21, 2020, despite the large number of trials that have been registered and reported as complete [5]. Of these 85 published trials, 54 (64%) trials reported information on planned sample size, and 25 (46%) did not meet their recruitment targets [5]. In fact, they recruited approximately half of their planned recruitment (median 52.3%; IQR 31.7%-80.6%) [5]. A summary of these findings is provided in Figure 1.

Figure 1. Summary of registered clinical trial status for COVID-19-related research.

During this time, we have seen a large number of trials conducted without results being made available. It is likely that a plethora of COVID-19 trials have stopped early, not for statistical reasons but due to lack of feasibility [4]. Reasons for studies becoming nonfeasible are extensive, ranging from unwillingness to participate due to quarantine, challenges in telemedicine solutions for trials [6], and emergency changes to staff resourcing [7]. Furthermore, there are likely feasibility challenges in the recruitment dependent on the patient context. Trials range from patients in intensive care to healthy volunteers in vaccine and treatment prophylaxis trials. As such, contributions of recruitment competition and patient hesitancy to the lack of feasibility are heavily treatment-context driven. Accordingly, many clinical trials during the COVID-19 pandemic have faced a multitude of challenges related to consenting and recruiting new participants given the proliferation of trials that are competing for recruiting eligible participants into their own respective trials [8,9].

Trials stopped early for feasibility are, by definition, statistically underpowered and thereby prone to inconclusive findings. Statistical power is not necessarily linear with the total sample size, and even small reductions in patient numbers or events can have a substantial impact on the research outcomes. Given the profusion of clinical trials investigating identical or similar treatments across different geographical and clinical contexts, one must also consider that the likelihood of the substantial numbers of false-positive and false-negative trials, emerging with the increasing overall number of trials, adds to public perceptions of uncertainty. Complicating this issue is the evolving nature of the pandemic, where baseline assumptions on control group risk factors used to develop sample size calculations are far more challenging than those in the case of well-documented diseases.

The standard answer to address these challenges during nonpandemic settings is to rigorously assess each trial for statistical power and risk-of-bias and then pool the reported aggregated results using meta-analytic statistical approaches.
This solution simply will not suffice for COVID-19. Even with random-effects meta-analysis models, it will be difficult to adjust for heterogeneity of different trials with aggregated reported data alone, especially given the absence of common data standards and outcome measures. Common data standards are a key feature of system interoperability and facilitate synthesis methodologies to be rapidly scaled, such as meta-analyses. To date, several groups have proposed structures and partnerships for data sharing in the context of COVID-19, some of which are integrated with prespecified statistical analysis methodologies [10,11]. Given the substantial under-recruitment reported to date, vast numbers of trials will be underpowered. This lack of power may be due to design challenges, or a consequence of termination prior to reaching the recruitment target. As such, integration of different trial datasets for individual participant-level data (IPD) meta-analyses may be the only solution in determining what works and is safe for COVID-19. In an IPD meta-analysis, rather than measuring aggregate study-level outputs, data can be taken from either all or a proportion of participants within individual studies. In doing so, more nuanced comparisons between patient groups is possible. For example, participants across two trials may have, on average, significant differences in demographics to one another, yet substantial proportions of patients across both trials may have sufficient similarity for a valid analysis. Meta-analyses integrating IPD have a number of potential methodological advantages, particularly when subpopulations of interest demonstrate promising treatment signals. In particular, IPD meta-analyses allow for more effective subgroup analyses and better statistical power for detecting treatment interaction effects [12] in cases wherein differences between populations are marked. These methods are endorsed by the Cochrane collaboration—a useful tool, especially when treatment effects are influenced by the follow-up duration. As COVID-19 research evolves to longer-term outcomes (sometimes referred to as “long-COVID”) [13], these analytical advantages are likely to develop further. The key to the process of evidence synthesis is the appropriate selection of trials with comparable patient populations and design features, such as outcome definitions [14]. In the absence of unified data structures and data sharing agreements, this process may either be time consuming or entirely nonfeasible, depending on data heterogeneity.

To serve the public who are waiting for the medical research community to efficiently make medical discoveries, the COVID-19 pandemic has (arguably) mandated sharing IPD into a public health obligation. Although the International Committee of Journal Editors has previously discussed the importance of data sharing of clinical trials, this discussion has largely been limited to published clinical trials [15]. The data sharing mandate for the COVID-19 pandemic should be extended to all clinical trials, including those trials that will not be published because they ended early for feasibility reasons. Other informal data sharing platforms for ongoing trials are available, such as clinical trial registries, which can provide information on outcome measures and broad design features [4].

Sharing of IPD has historically proven to be challenging, as investigators and sponsors have held tight to their data for academic, regulatory, and commercial reasons. However, the health and economic consequences of the pandemic thus far signal a need to mandate data sharing, expedite systems to apportion credit for data sharing, and preserve commercial interests. The need to share and collaborate openly supersedes our personal career or organizational goals. This sentiment has been shared among the research community, and many organizations (such as the Wellcome trust [16]) have quickly identified the need to share data more rapidly than has historically been the case.

The International COVID-19 Data Alliance (ICODA) provides an example of recent improvements in data sharing within the context of a global pandemic [17,18]. Convened by Health Data Research UK, ICODA is an international health data-led research response that seeks to provide a platform to enable researchers to access global data to derive insights about COVID-19 to advance the development of therapeutics [17,18]. The organization recognizes the urgent need to enable access to data that can be linked with other data in a safe and secure way.

As the processes for addressing personal privacy, data security, and data standardization have become sufficiently more sophisticated in recent years, barriers previously considered to be insurmountable have been minimized [10,19]. Investigators that have launched clinical trials can utilize existing global clinical research data sharing platforms such as Vivli [19], TransCelerate Biopharma [20], and ICODA [17,18], to collectively and securely curate and analyze their findings. Taken together, data from different trials can answer meaningful public health questions while avoiding the risk of becoming inconclusive in isolation. Investigators are keen for data; as represented by Vivli [11], as of December 2020, over 200 requests for trial-level data have been made in 2020, although no publications utilizing COVID-19 data are available from this group at present. Challenges in execution of these methods and strategies are multifaceted, involving researcher awareness of resource availability, technical capacity for analysis, and access agreements from data providers. To this end, we applaud the efforts of groups mentioned above in reaching out to researchers for proposals and taking strides toward simplifying the often challenging process of providing patient-level data. Successful analysis and subsequent publications utilizing these methods may provide an informative case study to promote further researcher contribution.

Particularly in the context of a pandemic, researchers, policymakers, and the general public are finding challenges in navigating the multitudes of data available daily. In tandem, high-profile instances of retractions owing to poor data screening [21] have led many to reach “data fatigue” [22]. Here, data synthesis exercises that utilize the aforementioned statistical efficiencies of patient-level data provide an avenue through which data fatigue may be minimized and succinct summaries that may otherwise be unachievable, as well as improve awareness of therapeutic trends in COVID-19.

We hope that the COVID-19 pandemic is a historic turning point of a sharing culture in the medical research community. The need for rapid and robust clinical research for the discovery of effective and safe therapeutics and vaccines has never been
higher. Strengthening our public health response to COVID-19 will require larger collated patient-level datasets to facilitate the scientific precision required for answers on COVID-19 medical interventions. As COVID-19 has forced reconsideration of policies, processes, and interests, this is the time to advance scientific cooperation and shift the clinical research enterprise toward a data-sharing culture that can maximize our response in the service of public health.

Conflicts of Interest
None declared.

References


Abbreviations

ICODA: International COVID-19 Data Alliance
IPD: individual participant-level data

©Louis Dron, Alison Dillman, Michael J Zoratti, Jonas Hagstrom, Edward J Mills, Jay J H Park. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 12.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
A Self-Assessment Web-Based App to Assess Trends of the COVID-19 Pandemic in France: Observational Study

Fabrice Denis1*, MD, PhD; Arnaud Fontanet2*, MD, PhD; Yann-Mael Le Douarin3*, MD; Florian Le Goff4*, MSc; Stephan Jeanneau5*, MSc; François-Xavier Lescure6, MD, PhD

1Institut Inter-régional de Cancérologie Jean Bernard, Le Mans, France
2Emerging Diseases Epidemiology Unit, Institut Pasteur, Paris, France
3French Society of Digital Health, Paris, France
4Kelindi, Lille, France
5Adobis Group, Grenoble, France
6AP-HP, Infectious and Tropical Diseases Department, Bichat-Claude Bernard University Hospital, Paris, France

*these authors contributed equally

Corresponding Author:
Fabrice Denis, MD, PhD
Institut Inter-régional de Cancérologie Jean Bernard
9 rue Beauverger
Le Mans, 72000
France
Phone: 33 684190480
Email: f.denis@cjb72.org

Abstract

Background: We developed a self-assessment and participatory web-based triage app to assess the trends of the COVID-19 pandemic in France in March 2020.

Objective: We compared daily large-scale RT–PCR test results to monitor recent reports of anosmia through a web-based app to assess the dynamics of emergency department visits, hospitalizations, and intensive care unit (ICU) admissions among individuals with COVID-19 in France.

Methods: Between March 21 and November 18, 2020, users of the maladiecoronavirus.fr self-triage app were asked questions about COVID-19 symptoms. Data on daily hospitalizations, large-scale positive results on RT–PCR tests, emergency department visits, and ICU admission of individuals with COVID-19 were compared to data on daily reports of anosmia on the app.

Results: As of November 18, 2020, recent anosmia was reported 575,214 times from among approximately 13,000,000 responses. Daily anosmia reports during peak engagement with the app on September 16, 2020, were spatially correlated with the peak in daily COVID-19–related hospitalizations in November 2020 (Spearman rank correlation coefficient $\rho=0.77; P<.001$). This peak in daily anosmia reports was observed primarily among young adults (age range 18–40 years), being observed 49 days before the peak of hospitalizations that corresponded to the first wave of infections among the young population, followed by a peak in hospitalizations among older individuals (aged ≥50 years) in November 2020. The reduction in the daily reports of anosmia associated with the peaks in the number of cases preceded the reduction in daily hospitalizations by 10 and 9 days during the first and the second waves of infection, respectively, although the reduction in the positivity rates on RT–PCR tests preceded the reduction in daily hospitalizations by only 2 days during the second wave of infections.

Conclusions: Data on daily reports of anosmia collected through a nationwide, web-based self-assessment app can be a relevant tool to anticipate surges in outbreaks, hospitalizations, and ICU admission during the COVID-19 pandemic.

Trial Registration: ClinicalTrials.gov NCT04331171; https://clinicaltrials.gov/ct2/show/NCT04331171

(J Med Internet Res 2021;23(3):e26182) doi:10.2196/26182

KEYWORDS
app; big data; COVID-19; diagnosis; diagnostic test; digital health; France; mobile phone; observational; participatory app; self-assessment; surveillance; trend; web-based app
Introduction

Apps involving patient-reported outcomes have been shown to improve outcomes including survival benefit [1-3]. We developed and launched a self-assessment and participatory web-based surveillance app for COVID-19, called “maladiecoronavirus.fr,” during the growth phase of the COVID-19 pandemic in March 2020 in France. This self-triage tool was aimed at directing symptomatic patients with COVID-19 to emergency care or to general practitioners after the analysis of symptoms and comorbidities. We previously reported that data from this web-based app could be a relevant tool to reduce the burden on emergency call centers [4]. Interestingly, this web-based app was useful in monitoring COVID-19 spread during the initial wave of infections in March 2020 in France, with spatial correlations among the number of hospitalizations, users reporting fever and cough, and users reporting anosmia [5]. The ability to detect an early rise and decline in COVID-19 incidence would also be extremely useful in anticipating a patient’s course of hospitalization to avoid overcrowding at emergency departments and saturation of the intensive care unit (ICU) and to anticipate the availability of hospital beds dedicated to patients with COVID-19.

In France, nationwide RT–PCR test results are available on a daily basis and are used to estimate the effective reproduction number. However, variability in testing indications and access to tests have led to speculations regarding the practicality and validity of large-scale RT–PCR test results and concomitantly the monitoring of trends of the pandemic. Our web-based app may be a useful alternative. In this study, we compared the results of large-scale RT–PCR tests on a daily basis to daily reports of anosmia from among the users of the app to predict the dynamics of emergency department visits, hospitalizations, and ICU admission of individuals testing positive for COVID-19 during the outbreak in France.

Methods

Users of maladiecoronavirus.fr in France were recruited through nationwide media campaigns, including social media, radio, and magazine campaigns, during March 17–29, 2020. Participants were recruited through the maladiecoronavirus.fr website as previously described [5]. Data including sociodemographic characteristics, zip code, and comorbidities were anonymously obtained. The participants were asked about the following symptoms potentially associated with COVID-19: fever (body temperature of >37.7°C), unusual cough, shortness of breath, sore throat, muscle aches, diarrhea, anorexia, and asthenia. Anosmia was included in this list of potential symptoms on March 21, 2020. After recording the symptoms of the participants, a notification was sent to them recommending them to either stay at home and use the website again in case of evolving symptomatology (self-monitoring) or to contact a general practitioner or an emergency number if they reported experiencing dyspnea or severe anorexia. Questionnaires responses were excluded from the analysis if they did not include a zip code or if the duration of completion was inconsistent (<30 seconds). The study was approved by the French Health Data Hub, which reviews the ethical conduct of research with human subjects and the confidentiality and safety of their data. The web-based app was not considered a medical device by regulatory authorities because no tracking was performed, and the data were anonymized. The app did not monitor the adherence of the participants to the self-triage recommendations and did not inquire participants about their test results. Participants did not need to create an account or log into the app to access it. The app did not identify duplicate responses and did not make follow-up inquiries with the participants.

Data on daily large-scale positive outcomes on diagnostic RT–PCR tests, emergency department visits, hospitalizations, and ICU admissions among individuals with COVID-19 were obtained from Santé publique France, the Oscour network, and the French Ministry of Health. Big data were analyzed by Data Chain (Adobis Group). We did not ask app users for daily reports, but we assessed daily overall reports of anosmia among the users. We compared these daily reports of anosmia on the app, daily positive RT–PCR tests results, daily emergency department visits, daily conventional hospitalization, and daily ICU admissions among individuals with COVID-19 in order to determine which source of data best predicts the peaks and declines in hospitalization and ICU admission.

Age stratification was performed to assess the predictability of subsequent hospitalization. Spearman rank correlation analysis was performed for statistical analysis.

Results

Between March 17 and November 18, 2020, a total of 13,000,343 completed questionnaires were included, of which 7,507,332 were excluded owing to the unavailability of the zip code or an inconsistent completion duration, and recent anosmia was reported 575,214 times. The number of assessed questionnaires represents the number of assessments and not the number of individuals.

Data on daily reports of anosmia on the website and daily hospitalizations during the outbreak were well correlated (p=0.75; P<.001) (Figure 1). During the first wave of infections in March 2020, the peak in daily reports of anosmia (113,234 connections) was reached on March 22, 2020, and that of daily hospitalizations (4281 patients) was reached 10 days later on April 1, 2020.
Before and during the second wave of infections towards the end of October 2020, a total of 3 early peaks of daily reports of anosmia on the website occurred on July 21, 2020 (n=417); September 16, 2020 (n=905); and October 26, 2020 (n=805); and the peak in daily hospitalizations was reached on November 4, 2020 (n=3681), having occurred 49 days after the highest peak in the daily reports of anosmia. Daily hospitalizations decreased after November 4, 2020; this occurred 9 days after the last peak in daily reports of anosmia. Data on the median age of users of the web-based app are shown in Figure 2. The median age of the participants was 40 years (IQR 27-56) during the first peak of connections (first wave of the pandemic in March 2020); 32 years during the second peak of connections on July 22, 2020; 30 years during the third peak of connections on September 16, 2020; and 37 years during the fourth peak of connections on October 26, 2020 (second wave of the pandemic). Participants aged ≥45 years were more numerous during the last peak of connections in October 2020 than in the third peak in September 2020 (n=190/2088, 9.1% vs n=402/1668, 24.1%, respectively) (Figures 2A and 2B).

The number of ICU admissions peaked (n=450) on November 4, 2020, 9 days after the last peak of daily reports of anosmia. Daily numbers of emergency department visits peaks (n=787) on November 2, 2020, a total of 7 days after the last peak of daily reports of anosmia. The number of positive outcomes on daily RT–PCR tests peaked (n=69,564) on November 2, 2020, a total of 7 days after the last peak of daily reports of anosmia and only 2 days before the peak of hospitalization occurred (Figures 3A, 3B, 3C, and 3D).

A large-scale curfew, followed by a general lockdown, was initiated on October 23, 2020. Contamination in RT–PCR tests reduced on November 2, 2020, a total of 15 days after lockdown enforcement, and daily reports of anosmia decreased from October 27, 2020, a total of 4 days after lockdown enforcement. Large-scale positive outcomes on daily RT–PCR tests and daily reports of anosmia during the third peak of connections on September 16, 2020, were spatially correlated at the county level with the peak in daily COVID-19–related hospitalizations in November 2020 (p=0.77 for both; P<.001) (Figure 4).
Figure 2. Age of users reporting anosmia on the web-based self-triage app maladiecoronavirus.fr during the COVID-19 outbreak in France. (2A) Median age of the users of the app. *Peak of hospitalizations during the first wave of the pandemic. **Peak of hospitalizations during the second wave of the pandemic. Four peaks of daily reports of anosmia were recorded from the web-based app: the first peak of reports of anosmia (+; median age=40 years), second peak of reports of anosmia (++; median age=32 years), third peak of reports of anosmia (+++; median age=30 years), and fourth peak of reports of anosmia (++++; median age=37 years). (2B) Histograms of the number of reports of anosmia based on the age of the users during third and fourth peaks of connections. Users of aged >45 years were more numerous in the October 2020 outbreak than in the September 2020 outbreak peak of during the second wave of hospitalizations (n=190/2088, 9.1% vs n=402/1668, 24.1% respectively).
Figure 3. Trends of the COVID-19 pandemic during the second wave of infections in France from August 10 to November 18, 2020: (3A) comparison between the number of daily reports of anosmia and positive outcomes on daily RT–PCR tests; (3B) comparison between the number of daily reports of anosmia and the number of emergency department visits; (3C) comparison between the number of daily reports of anosmia and the number of daily hospitalizations; and (3D) comparison between the number of daily reports of anosmia and the number of daily admissions to the intensive care unit.
Figure 4. Maps displaying the correlation between daily reports of anosmia with COVID-19–related hospitalizations during the second wave of the pandemic in France. The cumulative number of (4A) daily reports of anosmia during September 15-17, 2020; (4B) positive outcomes on large-scale RT–PCR tests on September 16, 2020; and (4C) daily hospitalizations of individuals with COVID-19 in France during November 3-5, 2020.

Discussion

Our results suggest that the peak of daily reports of anosmia determined from our web-based self-triage app based on symptoms reported by individuals suspected with COVID-19 in September 2020 was spatiotemporally correlated with the daily peak of hospitalizations during the second wave of the pandemic in November 2020 in France. During this period, an early first peak of daily reports of anosmia occurred among young adults on July 21, 2020, and the highest peak occurred on September 16, 2020, occurring 49 days before the peak of daily hospitalizations in November 2020. A reduction in the number of daily reports of anosmia by users of the web-based app also preceded the reduction in the number of daily hospitalizations by 10 and 9 days during the first and the second waves of the pandemic, respectively, in France.

During the first peak of hospitalizations in March 2020, we initially observed that the peak of daily reports of anosmia on our web-based app occurred 10 days before the peak in daily hospitalizations, which is similar to the mean 11-day period between infection and hospitalization among individuals experiencing severe forms of the disease as reported previously [6]. We did not assess the dynamics of RT–PCR tests in the population in March 2020 because RT–PCR tests were not performed on a large scale but were rather performed only for hospitalized individuals with COVID-19 at that time. The magnitude of connections to the web-based app was high in March 2020 because it occurred during the outset of media campaigns of the web-based app. No media campaigns occurred before the second wave of the pandemic in October 2020, which explains why the magnitude of the connections was lower than that during the first wave of the pandemic.

The second peak of daily reports of anosmia occurred in July 2020 without a subsequent increase in the number of hospitalizations. This may be explained by the young age of the infected users (median age 32 years), who were at a low risk of severe disease, and the summer season during which transmission to older individuals was limited by the elevated outdoor temperature and reduced indoor transmission. However, the reduction in the number of hospitalizations after the first wave of the pandemic decreased simultaneously, suggesting the initiation of a new outbreak in July 2020.

During the second wave of the pandemic in October 2020, the reduction in the positive outcomes on daily RT–PCR tests occurred only 2 days before the peaks in daily hospitalizations and ICU admission, suggesting a decreased potential of RT–PCR data to predict the precedence of the reduction in the number of hospitalizations when compared with the number of daily reports of anosmia. This issue was probably also associated with the delays in getting tested and in obtaining the results. Moreover, the analytic sensitivity of RT–PCR testing is high, and the long duration of the RNA-positive tail suggests that most infected individuals are being identified after the infectious period has passed. This may overestimate incidence of the disease and explain the lack of an association of daily testing with the peak in hospitalizations and ICU admission [7]. This overestimation is also associated with the high proportion of asymptomatic individuals identified through contact tracing investigations and self-testing of suspected individuals. The risk of saturation of biological laboratories and the lack of reactions on RT–PCR testing may also lead to the discordance of data from individuals testing positive from the actual dynamic of the outbreak, leading to the decreased potential of RT–PCR test data in predicting the hospitalization rate.

The potential of the web-based app as a predictor of the hospitalization rate is based on the high specificity of anosmia as a diagnostic feature of COVID-19, occurring few days before symptom exacerbation among hospitalized patients with COVID-19 [6].

We recorded a high peak of daily reports of anosmia on September 16, 2020, which was 49 days before the maximum peak of daily hospitalizations in November 2020, with a low median age of users (9.1% [n=190/2088] of whom were aged ≥45 years); this was followed by a second peak of hospitalizations among older individuals on October 26, 2020 (24.1% [n=402/1668] of whom were aged >45 years). The
anticipation of the peak in hospitalizations in these 49 days is probably specific to the summer period and subsequently to a relatively large first wave of infections among young adults—which occurred in mid-July 2020 without a significant increase in the hospitalization rate—and at a higher scale toward the end of summer vacations and during the back-to-school period after which many clusters of infection were observed at schools and universities. As young, internet-savvy users developed anosmia, they extensively used the app, but only few of them had severe COVID-19 and few required subsequent hospitalization. The September 2020 peak in daily reports of anosmia was probably followed by progressive disease transmission to older patients in October 2020, with a subsequent domino effect during low-temperature periods and increased indoor transmission. This may have triggered a second wave of infections among older users (who are at an increased risk of severe COVID-19) in October 2020, followed by a large wave of hospitalizations in November 2020. Since this app is used less extensively by older patients (in whom anosmia is less frequent), the magnitude of the daily reports of anosmia was lower in October 2020 than in September 2020, but the hospitalization rate increased. Thus, this app does not predict the magnitude of hospitalization after a peak in the reports of anosmia, unless focusing on older individuals.

During the first and the second wave of the pandemic in France, a reduction in the daily reports of anosmia preceded the reduction in the number of daily hospitalizations and ICU admissions by 10 and 9 days, respectively, in March and October 2020 but not in July or September 2020. This was not observed in July 2020 after a low hospitalization rate was reported among older individuals. However, daily hospitalizations stopped increasing in September 2020 a few days after the reduction in reports of anosmia in September 2020.

Although this tool does not accurately anticipate an increase in the magnitude of hospitalization, it seems to accurately predict the reduction in the hospitalization rate. The anticipation of the reduction in emergency department visits individuals reporting anosmia (by 7 days), hospitalizations (by 9 days), and ICU admissions (by 9 days) is thus crucial for anticipating the surge during the pandemic and in managing the requirements of beds in the ICU and dedicated COVID-19 wards.

We recorded more than 13,000,000 responses between March 17 and November 18, 2020, and 575,214 daily reports of anosmia from among an unknown number of users. As user data were anonymized, duplicate responses may have been obtained and were not assessable. However, the anonymous nature of the data collected from the app and the lack of tracking favored its extensive utilization in the French population, which was not observed with tracking applications.

As revealed from RT–PCR data, the infection rates decreased 15 days after large-scale curfew and lockdown measures were enforced, whereas daily reports of anosmia began decreasing 4 days later. This observation, along with spatiotemporal data obtained from reports of anosmia, can help the authorities nationwide to harness the value of emergency department visits, hospitalizations, and ICU admissions and to obtain early estimates of the outcomes of lockdown measures. Studies have assessed the generalizability of this tool in many countries in Europe (eg, UK and Germany) and in the United States [8-11].

Acknowledgments
We thank the app users for their participation in this study, as well as Magali Balavoine, MSc (Weprom, Angers, France). No participant was compensated for their contribution. We also thank the Caisse Primaire d’Assurance Maladie de Sarthe (Thibault Lhermitte) and the French Ministry of Health (Dr Yann-Mael le Douarin), Docaposte (Denis Weiss, Denis De Amorim, Regis Senegou), and DernierCri. Weprom designed and conducted the study; collected, managed, analyzed, and interpreted the data; prepared, reviewed, and approved the manuscript; and approved the submission of this manuscript for publication. Weprom, FD, Docaposte, Kelindi, DernierCri, and provided administrative, technical, and material support.

Authors’ Contributions
FD had complete access to all the study data and was responsible for the integrity of the data and the accuracy of the data analysis. FD conceptualized and designed the study. All authors acquired, analyzed, and interpreted the data, drafted and critically revised the manuscript for important intellectual content. FD performed the statistical analyses. FD, AF, and FXL supervised the study.

Conflicts of Interest
FD reports receiving a personal fee from AstraZeneca, Ipsen, Sivan Innovation, Kelindi, Pfizer, Chugai, and Roche. FD and FLG are the cofounders of Kelindi. SJ is the founder of Adobis Group. Outside of this work, AF receives fees from Gilead and MSD for educational seminars. FXL does not report any conflict of interest.

References

https://www.jmir.org/2021/3/e26182


Abbreviations

ICU: intensive care unit

©Fabrice Denis, Arnaud Fontanet, Yann-Mael Le Douarin, Florian Le Goff, Stephan Jeanneau, François-Xavier Lescure. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 12.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Effectiveness of Interactive Tools in Online Health Care Communities: Social Exchange Theory Perspective

Dixuan Ren¹, PhD; Baolong Ma¹, Prof Dr
School of Management and Economics, Beijing Institute of Technology, Beijing, China

Abstract

Background: Although the COVID-19 pandemic will have a negative effect on China’s economy in the short term, it also represents a major opportunity for internet-based medical treatment in the medium and long term. Compared with normal times, internet-based medical platforms including the Haodf website were visited by 1.11 billion people, the number of new registered users of all platforms increased by 10, and the number of new users’ daily consultations increased by 9 during the pandemic. The continuous participation of physicians is a major factor in the success of the platform, and economic return is an important reason for physicians to provide internet-based services. However, no study has provided the effectiveness of interactive tools in online health care communities to influence physicians’ returns.

Objective: The effect of internet-based effort on the benefits and effectiveness of interactive effort tools in internet-based health care areas remains unclear. Thus, the goals of this study are to examine the effect of doctors’ internet-based service quality on their economic returns during COVID-19 social restrictions, to examine the effect of mutual help groups on doctors’ economic returns during COVID-19 social restrictions, and to explore the moderating effect of disease privacy on doctors’ efforts and economic returns during COVID-19 social restrictions.

Methods: On the basis of the social exchange theory, this study establishes an internet-based effort exchange model for doctors. We used a crawler to download information automatically from Haodf website. From March 5 to 7, 2020, which occurred during the COVID-19 pandemic in China, cross-sectional information of 2530 doctors were collected.

Results: Hierarchical linear regression showed that disease privacy ($\beta=.481; P<.001$), reputation ($\beta=.584; P<.001$), and service quality ($\beta=.560; P<.001$) had a significant positive effect on the economic returns of the physicians. The influence of mutual help groups on earnings increases with an increase in the degree of disease privacy ($\beta=.189; P<.001$), indicating that mutual help groups have a stronger effect on earnings when patients ask questions about diseases regarding which they desire privacy.

Conclusions: For platform operators, the results of this study can help the platform understand how to improve doctors’ economic returns, especially regarding helping a specific doctor group improve its income to retain good doctors. For physicians on the platform, this study will help doctors spend their limited energy and time on tools that can improve internet-based consultation incomes. Patients who receive internet-based health care services extract information about a doctor based on the doctor’s internet-based efforts to understand the doctor’s level of professionalism and personality to choose the doctor they like the most. The data used in this study may be biased or not representative of all medical platforms, as they were collected from a single website.

(J Med Internet Res 2021;23(3):e21892) doi:10.2196/21892

KEYWORDS

efforts; income; privacy disease; platform; social exchange

https://www.jmir.org/2021/3/e21892
**Introduction**

**Background**

Since December 2019, the highly contagious novel coronavirus pneumonia (COVID-19) has been spreading within and beyond China [1]. The first case in China was identified in Wuhan City, Hubei Province, in early December [2]. To contain the outbreak, Wuhan imposed a quarantine from 10 AM on January 23, 2020, onward [3]. Most cities in Hubei Province were also quarantined, restricting people from traveling out of their own cities. People in proximity can easily transmit COVID-19; thus, social (ie, physical) distancing is an important measure to reduce its spread [4]. By February 2020, China had introduced travel bans and quarantine measures, closed public services, and canceled social events to contain COVID-19. COVID-19 also endangers people undergoing in-person care at hospitals as patients with different diseases gather in hospitals; therefore, the government stopped offline care to avoid spreading COVID-19 between doctors and patients [5]. However, medical consultations with patients who do not have COVID-19 remained a challenge during the pandemic.

The obvious answer to this challenge is online health care community (OHC), in which doctors can provide primary care for patients via internet-based platforms. This method can effectively prevent COVID-19 infections, which are deadly and highly transmissible [6,7]. Moreover, patients who do not have emergent diseases can receive doctor consultations. China Medical and Health Service System Planning (2015-2020) promulgated by the State Council notes that it is necessary to actively use the internet, cloud computing, and other information technologies to transform the existing health service model to benefit Chinese health service needs. Undoubtedly, the OHC will usher in unprecedented development opportunities as the government actively guides and supports the management of COVID-19 pandemic [8]. Compared with traditional offline health care, the OHC can prevent COVID-19 infections and operate outside of typical health care restrictions regarding time and space, as patients can communicate with doctors and obtain health information anytime and anywhere [6]. Therefore, the use of internet-based platforms to offer primary patient care provides a new and beneficial method to effectively allocate medical resources, improve doctor-patient relationships, and reduce medical costs and patient waiting time.

The prosperity of the OHC cannot be achieved without the continued participation and efforts of doctors, particularly high-status doctors who have always been a scarce medical resource. In the short term, doctors may want to gain reputation; however, in the long term, they still want to earn money [9]. Performance output is closely related to a person’s effort at work [10]. The OHC provides convenience for patients and should consider the economic returns of doctors to encourage doctors to actively participate, change their methods, and reasonably allocate their own energy and time both online and offline. An effort has been defined as the accumulated amount of time invested, energy spent, or activity by which work is accomplished [10-12] and is composed of three factors: direction (working smart), level (working hard), and persistence (in terms of the amount of time spent working and continuing to try to achieve a goal in the face of failure). Doctors’ efforts aim for patients to perceive the professional ability and attitude of service doctors, then patients feel satisfaction and hope for gaining further internet-based services, and the doctors’ webpages are visited frequently, ultimately increasing the economic return of the doctors. The OHC mainly relies on the exchange of health knowledge and information between doctors and patients [13]. Therefore, the relationship between doctors’ internet-based efforts and their economic returns is of great significance for OHC development. Whether health care workers can modify their traditional health care methods and actively participate in and adapt to the new health care model of the OHC remains to be determined. This study primarily reviews existing studies from the perspective of social exchange theory and the relationship between effort and earnings.

**Literature Review**

**Social Exchanges Between Patients and Doctors**

Social exchange theory describes the relationship among people from the perspective of benefits and costs. Individual behavior typically tries to maximize benefits by paying as little as possible [14], finding the optimal solution between costs and benefits. The participation of doctors in the OHC can be considered as a social exchange behavior that is described by social exchange theory [15] rather than a purely economic exchange. Social exchange theory advocates the use of economic methods to analyze noneconomic social behaviors and has been widely used to understand the dynamic exchange processes in social relationships [16]. On the basis of a systematic review of the literature on social exchange theory, 2 critical features of social exchange have been clarified: (1) dynamic interaction behaviors (ie, repeated exchange actions) and (2) the power in structural relationships (ie, the power to maintain the interdependent relationship among the exchangers in a social exchange) [17].

**Relationship Between Efforts and Earnings**

For service areas, efforts can enhance consumers’ perceptions of the quality of products. Employees’ work efforts influence customer satisfaction, and customers perceive that the harder employees work, the more satisfied they will be of the services they receive [18]. Efforts in the health consultation market are perceived as an exchange of resources in which doctors actively demonstrate their ability to attract more attention and obtain more consultation [18,19]: the harder employees work, the better their performance will be. There is a positive correlation between employee effort and job performance, and work effort level is one of the determinants of job performance [20,21]. Individuals or organizations with a strong sense of reciprocity are more willing to share knowledge and believe that knowledge sharing will yield certain personal rewards [22,23]. In the OHC market, there is a strong link between doctors’ internet-based efforts and their internet-based rewards.

**Research Model**

The professional capital used by doctors to participate in knowledge exchange describes the attitudes of interaction between the doctors and patients during social exchanges as well as the doctors’ professional commitment (eg, enthusiasm,
responsibility, and morality) [24]. The professional capital of doctors can be directly observed by patients through doctors’ effort behavior, which is shown in a series of dynamic interactive therapeutic behaviors because the interaction behavior of doctors is guaranteed by their ability to act independently and a set of rules of commitment [25]. As previously mentioned, studies have shown that effort has a positive effect on performance. The OHC is a typical information asymmetry market, and doctors know their professional abilities better than patients [9]. As recipients, patients interpret doctors’ efforts and adjust their purchasing behavior accordingly. Patients who receive a doctor’s effort are typically more likely to buy health care products than patients who do not receive it. On the basis of social exchange theory, doctors should provide information about their medical ability to users through effort behaviors to improve their earnings: the more doctors work, the more benefits they can obtain. The internet-based efforts of doctors can influence patient selection based on the social exchange function and affect the internet-based economic return and offline referrals of doctors. Patients believe that doctors who make more efforts possess higher service quality and therefore have a higher probability of being selected; thus, doctors gain higher economic returns when they put forth more effort.

Person efforts have not been considered in previous studies on the OHC market. There is a strong link between effort and performance, in which the OHC platform only supplies 2 interactive tools of effort between physicians and patients. However, effectiveness of interactive effort tools in internet-based health care areas remain unclear. Thus, we aim to (1) examine the effect of doctors’ internet-based service quality on their economic returns during COVID-19 social restrictions, (2) examine the effect of mutual help groups built on their economic returns during COVID-19 social restrictions, and (3) explore the moderating effect of disease privacy on individual efforts and economic returns during COVID-19 social restrictions.

On the basis of social exchange theory, doctors’ participation in the OHC is a process in which professional capital participates in social exchange for economic returns. The research model is illustrated in Figure 1.

Figure 1. Exchange model describing doctors’ efforts and returns.

Methods

Study Design

In the OHC, patients can assess the value of doctors through the distribution and frequency of interactions with doctors (eg, the doctors’ replies and the mutual help groups) to describe doctors’ ability and willingness to work [26]. In this study, the benefit of internet-based consultation refers to the financial return that doctors obtain after performing certain tasks that expend time and energy. In combination with social exchange theory and the scenario investigated in this study, this study identifies two effort tools of doctor-patient interaction: quality of service and mutual help groups.

Interaction between sellers and consumers increases sellers’ trust and promotes consumers’ behavioral intentions [27]. Positive interactions that allow patients to feel the doctor’s efforts and service attitudes online can help overcome distrust between doctors and patients.

OHCs are a collection of virtual discussion groups in which members can share feelings, knowledge, and experience about the health topics of their interests [28]. Doctors provide communication opportunities for patients with similar diseases. Patients can find valuable resources through a doctor’s effort in a series of interactions in OHCs. Exchange behaviors are used to bridge doctors’ efforts and patients’ rewards.

Different disease types have different psychological characteristics, cognitive needs, and patient involvement [29]. Privacy diseases refer to diseases that patients are reluctant to disclose to others, as disclosure of relevant information about these diseases will lead to a series of consequences, such as patients’ mental stress, love discrimination, disease discrimination, work pressure, and social stigma [16]. Thus,
OHCs provide a channel for privacy patients to acquire medical knowledge. Internet-based doctors’ efforts (eg, the quality of service and mutual help groups) can effectively eliminate patients’ concerns; thus, the positive effect on economic returns is stronger.

Thus, we hypothesize the following:

- Hypothesis 1 (H1): The service quality of physicians in OHCs is positively associated with the economic returns of doctors.
- Hypothesis 2 (H2): Mutual help groups in OHCs are positively associated with the internet-based economic returns of doctors.
- Hypothesis 3 (H3): The degree of disease privacy positively regulates the effect of physicians’ service quality on revenue from internet-based consultations.
- Hypothesis 4 (H4): The degree of disease privacy positively regulates the influence of mutual help groups on the revenue of internet-based consultations.

**Data Collection**

This study collected data from haodf website for analysis. Haodf website is a typical internet-based health consulting service platform in China that has a long history of establishment, mature operation, high user coverage, high doctor activity, and high-quality hospital. Therefore, Haodf website was investigated in this study. By March 20, 2020, 591,832 doctors from 9614 hospitals had registered on the haodf website. Thus, haodf is a representative internet-based health advisory platform.

We used a crawler to download information automatically from Haodf website. From March 5, 2020, data collection lasted for 2 days and involved 2530 doctors. We collected the service quality, groups, status, and other relevant information for each doctor in the data set.

**Measures**

Physician engagement in OHCs is typically a form of social exchange with patients, which is characterized by structural power and dynamic interactions [15]. Income is important for social exchange. The product of the number of doctors’ services and the unit price of consultation was used to determine the internet-based economic rewards.

Social exchange is a two-way transaction: “there must be both pay and return” [30]. Doctors can use two tools to show their efforts on the Haodf website: the doctors’ quality of service and the mutual help group. The Haodf website provides patients with the ability to consult doctors [31]. This study uses the number of doctors who respond to user inquiries on the platforms as a variable of doctors’ service quality. We assessed mutual help groups using the number of groups in which patients who consulted a doctor was assigned to different topic groups based on their disease characteristics. Communication in the same topic group occurred between the patients and doctors or patients with similar diseases. Doctors could provide service information and advice to the group. Disease privacy refers to a patient’s reluctance to tell others or disclose that they have a disease [9]. Hepatitis B is highly contagious, and the disclosure of disease-related information may cause discrimination. Therefore, hepatitis B was investigated in this study as a disease with a high degree of privacy.

On the basis of the research model and hypotheses, the economic returns of internet-based care are affected by the internet-based efforts of doctors (quality of service and mutual help groups) and the degree of disease privacy. In addition, economic returns may be affected by other factors. First, the professional title of doctors affects doctors’ internet-based economic returns. High-status doctors have higher priorities and privileges. For example, patients are always more willing to see the chief physician regardless of the doctors’ professional level. Second, doctors’ profits are affected by their reputation. Reputation in the internet-based market is primarily described through evaluation and feedback. Sellers with a better reputation have higher price premiums [32]. Finally, customers are more willing to visit century-old stores because they assume that stores with a longer operation time can deliver good service quality to customers. Similarly, if the doctor’s home page has been operational longer and updated recently, the doctor’s service quality is more likely to be recognized by patients. Therefore, city level, hospital level, doctor title, reputation, and internet-based service life was considered as control variables in this study.

Variables measured in this study are shown in Table 1.
Table 1. Measurement of variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dependent variables</strong></td>
<td></td>
</tr>
<tr>
<td>Internet-based economic rewards</td>
<td>The product of the number of doctors’ services and the unit price of consultation.</td>
</tr>
<tr>
<td><strong>Independent variables</strong></td>
<td></td>
</tr>
<tr>
<td>Doctors’ quality of service</td>
<td>Sum up the number of doctors’ answers from the patient consultation area of the doctor’s home page.</td>
</tr>
<tr>
<td>Mutual help groups</td>
<td>Grab the count directly from the topic page of the doctor’s personal home page.</td>
</tr>
<tr>
<td><strong>Moderator variables</strong></td>
<td></td>
</tr>
<tr>
<td>Privacy disease</td>
<td>Hepatitis B</td>
</tr>
<tr>
<td><strong>Control variables</strong></td>
<td></td>
</tr>
<tr>
<td>Hospital level</td>
<td>On the basis of the classification of 3 levels, 1 is the tertiary hospital, 2 is a secondary hospital, and 3 is the class-1 hospital. The higher the number, the higher the hospital’s level.</td>
</tr>
<tr>
<td>Status</td>
<td>There are 5 grades: the chief physician is fifth grade, the associate chief physician is fourth grade, the attending physician is third grade, the resident physician is second grade, and other doctors are first grade. The higher the number, the higher the doctor’s rank.</td>
</tr>
<tr>
<td>Reputation</td>
<td>As the value range of these 3 indicators, including votes, letter of thanks, and gifts, vary, they are averaged after standardization to measure the reputation of doctors.</td>
</tr>
<tr>
<td>Longevity</td>
<td>The number of years between the time the doctor’s home page was created and the time the data were collected.</td>
</tr>
</tbody>
</table>

Statistical Results

Quantitative survey data were analyzed using SPSS (version 25.0; IBM Corporation). Table 2 shows the descriptive statistical results for all the variables. Associate chief physicians and chief physicians account for approximately half of all online doctors [33]. As shown in Table 2, the mean of doctor status was 4.52, indicating that the status of online doctors was above that of associated chief physicians. The average hospital rating was 2.99, indicating that the hospital where the online doctor worked offline was above level 2. Reputation is the average of the 3 indicators standardized (thank you letters, votes, and gifts); thus, its mean is 0. The average age of the doctor’s home page was 8.46 years, the average number of online responses per doctor was 10,436.90, and the average number of mutual help groups built per doctor was 63.13.

Table 2. Results for descriptive statistics.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Value, mean (SD)</th>
<th>Minimum value</th>
<th>Maximum value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Returns</td>
<td>14,974.64 (32,179.683)</td>
<td>0</td>
<td>270,660</td>
</tr>
<tr>
<td>Quality</td>
<td>10,436.90 (10,427.042)</td>
<td>946</td>
<td>78,331</td>
</tr>
<tr>
<td>Groups</td>
<td>63.13 (152.230)</td>
<td>0</td>
<td>1651</td>
</tr>
<tr>
<td>Privacy</td>
<td>0.20 (0.399)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Hospital</td>
<td>2.99 (0.140)</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Status</td>
<td>4.52 (0.721)</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Reputation</td>
<td>0.15 (0.965)</td>
<td>–0.78</td>
<td>4.83</td>
</tr>
<tr>
<td>Reputation 1</td>
<td>120.20 (126.967)</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Reputation 2</td>
<td>260.82 (254.238)</td>
<td>7</td>
<td>1421</td>
</tr>
<tr>
<td>Reputation 3</td>
<td>380.23 (466.302)</td>
<td>11</td>
<td>2785</td>
</tr>
<tr>
<td>Longevity</td>
<td>8.46 (2.419)</td>
<td>1.76</td>
<td>11.04</td>
</tr>
</tbody>
</table>

Results

To ensure that multicollinearity does not confound the regression results, this study first examined the variance inflation factors (VIFs) among variables. As all VIFs are lower than 5, no serious multicollinearity exists among the independent variables [34,35].

In this study, hierarchical regression analysis was used to examine the effect of the quality of service and mutual help groups on online economic rewards as well as the moderating effect of disease privacy. Considering the research design, the hierarchical regression analysis method is more suitable for this study because this study conducts a separate analysis of the variables of each layer to determine the differences among them. The purpose of the hierarchical regression analysis method is
to investigate the contribution of the variable to the regression equation when the contributions of other variables are excluded.

The regression results of the hierarchical regression analysis in this study are presented in Table 3.

**Table 3.** Regression analysis.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Dependent variable: internet-based economic returns, nonstandardized coefficients (SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Model 1</td>
</tr>
<tr>
<td><strong>Control variables</strong></td>
<td></td>
</tr>
<tr>
<td>Privacy</td>
<td>0.481(^{a}) (0.127)</td>
</tr>
<tr>
<td>Hospital</td>
<td>−0.072 (0.362)</td>
</tr>
<tr>
<td>Status</td>
<td>0.087 (0.079)</td>
</tr>
<tr>
<td>Reputation</td>
<td>0.584(^{a}) (0.054)</td>
</tr>
<tr>
<td>Longevity</td>
<td>−0.019 (0.024)</td>
</tr>
<tr>
<td><strong>Independent variables</strong></td>
<td></td>
</tr>
<tr>
<td>Quality</td>
<td>N/A(^{c})</td>
</tr>
<tr>
<td>Groups</td>
<td>N/A</td>
</tr>
<tr>
<td>Quality x privacy</td>
<td>N/A</td>
</tr>
<tr>
<td>Groups x privacy</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(^{a}\)P<.001.  
\(^{b}\)P<.01.  
\(^{c}\)N/A: not applicable.

Model 1 only contains control variables, and the results show that the degree of disease privacy (\(P<.001\)) and reputation (\(P<.001\)) have a significant positive effect; thus, doctors who provide medical services for patients with a high degree of disease privacy can obtain more economic returns. Channels between online and offline have substitutes and synergies [36,37]. Patients with nonprivacy diseases can go to hospitals without any concern, providing an alternative to internet-based medical services. However, patients with privacy diseases do not wish to go to hospitals for treatment and tend to use internet-based medical services. Therefore, OHCs tend to have patients with privacy diseases [9]. The internet-based reputation of doctors has a positive effect on doctors’ internet-based incomes. A good reputation indicates that patients recognize the quality of service and indicates a lower risk of service quality. At a significance level of \(P<.05\), the hospital level (\(P=.84\)), doctors’ status (\(P=.27\)), and longevity (\(P=.42\)) were not significant predictors of internet-based economic returns. Model 1 explained 37% of the variation in dependent variables.

Model 2 added the influence of doctors’ service quality and mutual help groups on the revenue of doctors’ internet-based consultation based on model 1. According to the results shown in Table 3, H1 doctors’ service quality had a positive effect on internet-based economic returns, and thus H1 was supported (\(P<.001\)). The H2 mutual help group did not have a positive effect on internet-based consultation income (\(P=.27\)). The degree of interaction and the level of 2-way communication between the service provider and the patient are critical to the customer’s ultimate perception of the service provider’s service results [38]. Thus, doctors’ replies are vital to patients as a result of these answers, which can alleviate distress. Model 2 explained 50.8% of the variation in the dependent variable. Compared with model 1, adding 2 tools of effort improved the explanatory ability of the model.

Finally, we analyzed the effects of the 2 interaction terms, which are the interaction terms between doctors’ service quality and disease privacy, the interaction terms between mutual help group and disease privacy. The results indicate that H3 is not supported (\(P=.16\)); however, H4 is supported (\(P<.001\)). Privacy diseases can lead to social stigmatization, and these stigmatizations can have many negative effects on patients [39]. Although patients with privacy diseases are not willing to visit hospitals, they must receive doctors’ care, the concern of other people, and health care information to recover. Model 3 explained 58% of the variation in the dependent variable, which indicates that compared with model 2, the 2 interaction terms increased the explanatory power of the model. The interaction between mutual help groups and disease privacy is shown in Figure 2. When the degree of disease privacy increases, the influence of mutual help group on earnings changes from a negative correlation to a positive correlation, indicating that when patients consult low disease privacy, the more mutual help group, the lower the incomes; however, when patients consult high disease privacy, the more mutual help group, the higher the incomes.
Discussion

Principal Findings

The COVID-19 pandemic has significantly disrupted normal medical activities worldwide. To help decrease the spread of COVID-19, online health care platforms have been rapidly used by governments and users [40,41]. Currently, the Haodf website primarily provides 2 internet-based effort tools for doctors to interact with patients (doctors’ quality of service and mutual help groups). In this study, we sought to examine the effect of these tools on the economic returns of doctors’ internet-based consultations, and these mechanisms are adjusted by the degree of disease privacy. The primary findings of this study are summarized below.

Effect of Doctors’ Internet-Based Service Quality on Their Economic Return

Doctors’ internet-based service quality has a positive effect on the revenue of doctors’ internet-based consultation, which indicates that the high doctors service quality to patients’ consultation, the more economic return they obtain. In traditional Chinese culture, patients often judge the professional ability and service quality of doctors based on the hospital’s grade and the doctor’s status. Status is a sociological concept that focuses on rights or discrimination due to differences in social class rather than performance [42]. Patients have also become accustomed to long waiting times for outpatient registration, as Beijing has converged on the best resources in China. This situation causes many problems, including poor hospital environments and short communication between doctors and patients. Owing to COVID-19–related stay-at-home restrictions, in-person communication among patients is less frequent [43,44]. Doctors put patients with the same disease into a virtual group that provides convenient communication among its members. However, patients are not willing to participate in group discussions too much, as the members in the virtual community feel strange and lack trust in each other. Thus, mutual help groups do not affect the revenue of internet-based consultations.

The Moderating Effect of Disease Privacy

Disease privacy positively regulates the influence of mutual help groups on the revenue of internet-based consultation, which indicates that when the degree of disease privacy increases, mutual help groups increase the benefits of doctors’ internet-based consultation. Patients with nonprivacy diseases easily communicate in person with others without any concerns. These patients can also communicate offline with patients who have similar diseases without the fear of discrimination or unfair treatment [45]; thus, they do not have strong intentions to find companions to communicate about their diseases in a virtual group. Patients with nonprivacy diseases in a virtual community were unfamiliar with each other, had a strong sense of strangeness, and could not trust each other. When patients have not joined a virtual community on their own [6], doctors’ efforts would not be recognized by patients; therefore, the economic return would not increase. Conversely, patients with privacy diseases are reluctant to go to hospitals for consultation because of the risk to their privacy; thus, they have few opportunities to meet people who have a similar disease. In this situation, patients may not receive efficient or timely medical treatment because of a lack of medical knowledge and communication.
with doctors. In virtual communities, doctors build a bridge between patients with privacy diseases and others in the outside world, and members in the mutual help group do not know each other; thus, users do not need to worry about disclosure of their disease status. Patients with privacy diseases were more willing to communicate with members of the group. Thus, doctors’ efforts to build mutual help groups can be recognized by patients, which leads to improved economic returns.

**Limitations**
This study has produced some beneficial results; however, there are still certain limitations that must be addressed in future studies. First, data were taken from one OHC, the Good Doctor website, which is the most acceptable web-based consultation platform [33,46]; thus, the universality of the results is questionable. Future studies will consider collecting physician data from different types of OHCs and empirically testing the model’s findings. Second, in this study, only two tools (doctors’ service quality and mutual help groups) provided by a single health consultation platform to describe the interaction efforts between doctors and patients were included, which may lead to an insignificant influence of the tools on the doctors’ economic returns. In the future, the interactive efforts of other health consultation websites should be considered. Third, only one type of privacy disease was investigated (hepatitis B). Patients with different diseases have different degrees of involvement in information processing, and the degree of influence of information on patients’ choices is also different [47-49]. Although the representativeness of this disease was considered in the selection of this study, further studies should consider diseases with different privacy levels, as different diseases that need privacy may have different service requirements.

**Conclusions**
In the face of the COVID-19 pandemic, internet-based medical treatment has become a new choice for people seeking medical treatment because of its unique features, including a lack of geographical restrictions, no in-person contact, and prevention of infection. Governments have rapidly used alternative methods for health care delivery, including web-based consultation, when people are restricted from their normal activities [5,8]. Many internet consultation platforms, including Haodf website, have seen a surge in visits during the epidemic. The prosperity of the platform depends on the continuous participation and efforts of doctors, and obtaining satisfactory economic returns is an important motivation for doctors’ continuous participation. Therefore, it is of great significance for platforms, doctors, and patients to study internet-based consultation income.

This study expands and enriches the application and connotations of individual efforts. Individual effort has been focused on traditional industries and has never been used in online health care services. Online health services differ from traditional offline industries. This study expanded the application scope of efforts from the traditional offline industry to online health services and further identified 2 types of effort tools (doctors’ replies and mutual help groups) based on the characteristics of the internet-based health market. These 2 effort tools are unique variables in the field of eHealth and have not been covered in previous studies in the field of electronic commerce. In addition, the degree of disease privacy is a unique variable in the field of OHCs, which has not been mentioned in previous studies in the field of electronic services, including electronic government and electronic commerce. This study identified that the uncertainty of privacy disclosure and the uncertainty of service quality may increase when the degree of disease privacy improves; thus, doctors must put in more efforts online to improve their services. Concurrently, this study also clearly distinguished the different influence mechanisms of the degree of disease privacy on the doctors’ service quality and the mutual help groups. Doctors who built many mutual help groups could obtain higher incomes when serving patients with privacy diseases.

**Acknowledgments**
This research was supported by research funds of the National Natural Science Foundation of China (grant number: 71972012).

**Conflicts of Interest**
None declared.

**References**


https://www.jmir.org/2021/3/e21892 J Med Internet Res 2021 | vol. 23 | iss. 3 | e21892 | p.765 (page number not for citation purposes)


Abbreviations

OHC: online health care community

VIF: variance inflation factor
information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Artificial Intelligence–Aided Precision Medicine for COVID-19: Strategic Areas of Research and Development

Enrico Santus¹,², PhD; Nicola Marino²,³, BSc; Davide Cirillo²,⁴, PhD; Emmanuele Chersoni⁵, PhD; Arnau Montagud⁴, PhD; Antonella Santuccione Chadha²,⁶, MD; Alfonso Valencia⁴,⁷, PhD; Kevin Hughes⁸, MD; Charlotte Lindvall⁹,¹⁰, MD, PhD

¹Division of Decision Science and Advanced Analytics, Bayer Pharmaceuticals, Whippany, NJ, United States
²The Women's Brain Project, Zurich, Switzerland
³Department of Medical and Surgical Sciences, Università degli Studi di Foggia, Foggia, Italy
⁴Barcelona Supercomputing Center, Barcelona, Spain
⁵Department of Chinese and Bilingual Studies, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)
⁶Biogen International GmbH, Baar, Switzerland
⁷Institució Catalana de Recerca i Estudis Avançats, Barcelona, Spain
⁸Massachusetts General Hospital, Boston, MA, United States
⁹Dana-Farber Cancer Institute, Boston, MA, United States
¹⁰Harvard Medical School, Boston, MA, United States

Corresponding Author:
Davide Cirillo, PhD
Barcelona Supercomputing Center
c/Jordi Girona, 29
Barcelona
Spain
Phone: 34 934137971
Email: davide.cirillo@bsc.es

Abstract

Artificial intelligence (AI) technologies can play a key role in preventing, detecting, and monitoring epidemics. In this paper, we provide an overview of the recently published literature on the COVID-19 pandemic in four strategic areas: (1) triage, diagnosis, and risk prediction; (2) drug repurposing and development; (3) pharmacogenomics and vaccines; and (4) mining of the medical literature. We highlight how AI-powered health care can enable public health systems to efficiently handle future outbreaks and improve patient outcomes.

(J Med Internet Res 2021;23(3):e22453) doi:10.2196/22453

KEYWORDS
COVID-19; SARS-CoV-2; artificial intelligence; personalized medicine; precision medicine; prevention; monitoring; epidemic; literature; public health; pandemic

Introduction

The ongoing COVID-19 pandemic has highlighted the fragility of the health care system during unexpected events, testing the endurance of even the top-performing ones [1]. As noted by several scholars, embracing artificial intelligence (AI) for health care optimization and outcome improvement is not an option anymore [2]. Concerning the ongoing COVID-19 pandemic, several studies have highlighted that the timely inclusion of AI-powered technologies would have accelerated the identification of and effective response to COVID-19 outbreaks worldwide. An example is the widely reported algorithm from the Canadian company BlueDot, based on natural language processing (NLP) and machine learning, which forecasted the emerging risk of a virus spread in Hubei province in late December 2019, by screening news reports and airline ticketing [3].

Awareness of the benefits of employing AI to support and manage the COVID-19 crisis and its aftermath is increasing, particularly in the medical and research community. Notable examples of early AI-powered contributions include the discovery of relevant SARS-CoV-2 target proteins by...
DeepMind’s AlphaFold [4] and the design by Infervision of a computer vision algorithm for the detection of coronavirus pneumonia based on lung images [5].

Benefits do, however, come with technical challenges and related risks that still need to be properly assessed. For example, the absence of transparency and interpretability in AI models obscures the fact that the efficacy of these technologies is not equal across population groups. COVID-19 incidence and outcomes vary according to a large number of individual factors, including age, sex, ethnicity, health status, drug utilization, and others [6]. Sensitizing AI technologies to the diversity of the patient population and ensuring data security [7] is imperative to avoid biased decisions [8-10]. Therefore, a crucial step to obtain robust, trustworthy, and intelligible applications that account for demographic equity is to assess potential biases in the resources used to train AI models for precision medicine [11].

As of today, AI systems are, regrettably, rarely endowed with robustness to class imbalances, such as sex and gender groups [12]. In this regard, sex differences in COVID-19 cases, as well as sex-specific risk factors and socioeconomic burden, have been recently highlighted in a case study by the European Commission [13]. Dataset multidimensionality that can fairly represent the population constitutes one of the main challenges for biobanking and cohort design efforts that collect different axes of health data [14]. In this regard, fair and broad data collection systems are of primary importance. Two essential international references for COVID-19 genomic and medical data are the EMBL-EBI COVID-19 Data Portal [15] and the NIH National COVID Cohort Collaborative (N3C) [16]. The COVID-19 Host Genetics Initiative [17] is an international collaborative undertaking to share resources to investigate the genetic determinants of COVID-19 susceptibility, severity, and outcomes [18]. The Coronavirus Pandemic Epidemiology (COPE) consortium aims to involve experts in the development of a personalized COVID-19 Symptom Tracker mobile app that works as a real-time data capture platform [6], which garnered over 2.8 million users in a few days. Moreover, COVID-19 sex-disaggregated data are collected by Global Health 50/50 [19], an initiative housed at University College London, advocating for gender equity.

Other ethical concerns include life-or-death decisions through risk prediction models, which may help optimize resource allocation in times of scarcity. The application of nonoptimal models may incur the risk of worsening biases and exacerbating disparities for people with serious illnesses and different treatment priorities, potentially causing the reduction in the use of services rather than achieving the best patient care [20]. Nevertheless, the power of prediction models is impressive, and it may play a key role in the future if properly exploited. For instance, a study from Cambridge University [21] shows how the use of secure AI operating on anonymized COVID-19 data can accurately predict the patient journey, allowing an optimal allocation of resources and enabling well-informed and personalized healthcare decision-making. This is a particularly important point, especially considering the difficulty in managing the increasing need for intensive care units (ICUs) during the COVID-19 pandemic peak [22,23].

The way the AI systems will be exploited is probably the most delicate topic in this adoption process, particularly if we refer to the decisional independence of the medical staff. As humans, in fact, clinicians are also affected by numerous cognitive biases, including the confirmation bias, which may lead them to give excessive importance to the evidence supporting automated prediction (eg, risk prediction, diagnosis, and treatment suggestion) and ignore evidence that refutes it [8,24].

Despite the abovementioned concerns, there are numerous success stories in the adoption of risk prediction models. For example, Duke University adopted a system called Sepsis Watch that identifies in advance the inflammation leading to sepsis—one of the leading causes of hospital deaths. Within two years from the tool introduction, the number of sepsis-induced patients drastically decreased [25], thanks to three key elements: (1) adaptation of the predictive model to a highly specific context; (2) scalability through integration with hospital workflows; and (3) the adopted user experience-based approach, which places clinicians and health care professionals at the center of the software development process, adhering with the human-in-the-loop paradigm [26,27].

The COVID-19 crisis is accelerating anticipated changes towards a stronger collaboration between computer science and medicine. In particular, the crisis has exposed the need for increased scrutiny of the relationship between AI and patients as well as healthcare personnel under the lens of human and emotional needs, as demonstrated by the surge of mental health consequences of the pandemic [28] and the growing development of AI-based mental health apps and related digital tools [29]. Such aspects, together with others related to general data access and the use of AI for disease outcome prediction, are fueling the current debate about the convergence of AI and medicine [30,31] and the actionable realization of AI-powered innovations to bridge the gap between technological research and medical practice, including applications in medical triage and advice, diagnostics and risk-adjusted paneling, population health management, and digital devices integration [32]. Concerning this aspect, it is important to mention the recent publication of guidelines for the rigorous and transparent adoption of AI in the clinical practice: CONSORT-AI (Consolidated Standards of Reporting Trials–Artificial Intelligence) [33] and SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence) [34].

Translating patient data to successful therapies is the major objective of implementing AI for health [35], especially in times of a pandemic crisis, with the ultimate goal of achieving a successful bench-to-bedside model for better clinical decision-making [36,37]. In this work, we review some major examples of what AI has achieved during the COVID-19 pandemic and the challenges that this technology and the medical community are currently facing in four main strategic areas of research and development (Figure 1): (1) triage, diagnosis, and risk prediction; (2) drug repurposing and development; (3) pharmacogenomics and vaccines; (4) mining of the medical literature.
Figure 1. Main strategic areas of research and development for the realization of artificial intelligence (AI) to fight COVID-19: (1) triage, diagnosis, and risk prediction; (2) drug repurposing and development; (3) pharmacogenomics and vaccines; and (4) mining of the medical literature. The text within the four panels enlists the advantages and actionable solutions exhibited by the AI-aided precision medicine approaches surveyed in this work.

Triage, Diagnosis, and Risk Prediction

AI has been applied to determine treatment priorities in patients with COVID-19 or triage and to better allocate limited resources. A group of researchers at the General Hospital of the People’s Liberation Army (PLAGH), Beijing, China, has developed an online triage tool model [38] to manage suspected COVID-19 pneumonia in adult patients with fever [39]. Using clinical symptoms, routine laboratory tests, and other clinical information available at admission (eg, clinical features), they trained a model based on logistic regression with the least absolute shrinkage and selection operator (LASSO), obtaining an area under the receiver operating characteristic curve (AUROC) of 0.841 (100% sensitivity and 72.7% specificity). Based on data from two hospitals in Wenzhou, Zhejiang, China, another study group recently used an entropy-based feature selection approach: they modeled combinations of clinical features that could identify initial presentation patients who are at a higher risk of developing severe illness, with an accuracy of 80% [40]. Their results show that mildly elevated alanine aminotransferase levels, the presence of myalgias (body aches), and an elevated hemoglobin level (red blood cells), in this order, are predictive of the later development of acute respiratory distress syndrome.

A thorough study on risk prediction was carried out at the University of Cambridge based on the development of a proof of concept system to model the full patient journey through risk prediction models [21]. By identifying the risk of mortality and ICU/ventilator need, the system aims at enabling doctors to answer questions such as: Which patients are most likely to need ventilators within a week? How many free ICU beds in the hospital are we likely to have in a week from now? Which of two patients will get more benefits from going on a ventilator today? The predictive models showed accuracies ranging from 77% for ventilator need to 83% for ICU admission and 87% for mortality.

Risk prediction models are not new to the AI-aided health care approach. They have already been successfully utilized for tasks such as predicting the risk of developing cancer [41,42] and identifying which patients are likely to benefit from heart-related procedures [43]. However, the COVID-19 crisis has accelerated the utilization of such models. In a recent study, Wynants and collaborators [44] screened 14,217 published titles about the pandemic from PubMed and Embase (Ovid, arXiv, medRxiv, and bioRxiv), finding over 107 studies describing 145 prediction models. Among them, 4 models aimed to identify people at risk and 50, to predict the mortality risk, progression to severe disease, ICU admission, ventilation, intubation, or length of hospital stay. These models not only provide interesting results but also inform about the most valuable predictors, such as age, body temperature, lymphocyte count, and lung imaging features. Despite this, these models cannot be directly applied in the clinical setting without further validation, in order to guarantee data and experiment transparency and robustness, together with decision interpretability and model generalizability.

The remaining 91 models from this study were dedicated to the diagnosis of COVID-19, 60 of which exploited medical imaging. This number clearly shows that diagnosis is another important field for the application of AI techniques [45], with digital pathology exhibiting high effectiveness. In particular, convolutional neural networks (CNNs) have been supporting radiologists in their expert decisions [46]. In a recent study, a CNN was trained to automatically learn patterns related to COVID-19 (ie, ground-glass opacities, multifocal patchy
consolidation, and/or interstitial changes with a predominantly peripheral distribution), achieving an AUROC of 0.996 (98.2% sensitivity and 92.2% specificity) and outperforming the reverse-transcription polymerase chain reaction, which also suffers from a significant time lag. In addition to accuracy, these approaches put the speed of the diagnosis on the table: CNNs can analyze up to 500 images in a few seconds, whereas radiologists would need to complete the task several days later.

Although chest computed tomography (CT) scans represent a commonly exploited source of information to train AI to rule out SARS-CoV-2 infection, the rapid detection of patients with COVID-19 can greatly benefit from learning approaches that utilize heterogeneous types of data. In this regard, it is crucial to consider the importance of training CNNs in a correct gender balance in medical imaging datasets to avoid producing distorted classifications for assisted diagnosis [12]. Moreover, it is crucial to rely on high-quality benchmarking and robust validation strategies to assess the generalization of the model to other datasets and populations [47,48].

Indeed, AI can exploit multidimensional data, including the series of epidemiological, clinical, biological, and radiological criteria defined by the World Health Organization [49]. In a collaboration between researchers at hospitals in China and in the USA, CNN and other machine learning methods (eg, support vector machine, random forest, and neural networks) have been used to model and integrate CT scans and clinical information for diagnostic purposes [45]. The joint model that uses both information sources achieved a 0.92 AUROC (84.3% sensitivity and 82.8% specificity), outperforming the individual models. Moreover, the models allowed the identification of age, viral exposure, fever, cough, cough with sputum, and white blood cell counts as the main features associated with SARS-CoV-2 infection status.

Recently, the National Institute of Biomedical Imaging and Bioengineering has launched the Medical Imaging and Data Resource Center with the goal of coupling AI and medical imaging for COVID-19 early detection and personalized therapies [50].

AI has also been utilized to identify patients at higher risk of mortality. Researchers at the Tongji Hospital, Wuhan, China, have screened electronic health records of 375 discharged patients to use clinical measurements as features and have trained a gradient-boosted decision tree model to predict mortality risk [51]. The accuracy of the system was 93%. Its utilization would make it possible for physicians to immediately identify critical cases and act accordingly. The model was also able to detect three key clinical features, that is, lactic dehydrogenase, lymphocyte count, and high-sensitivity C-reactive protein.

**Drug Repurposing and Development**

Although triage, diagnosis, and risk prediction are three of the most relevant tasks that AI has helped with during the peaks of the pandemic, other objectives are currently being addressed for long-term solutions. Among them are target selection for drug repurposing [52] and approaches for drug development, including de novo drug design [53].

Drug repurposing comprises identifying existing drugs that could effectively act on proteins targeted by the virus. Recently, 332 high-confidence SARS-CoV-2 protein–human protein interactions have been experimentally identified, as well as 69 ligands, comprising drugs approved by the USA Food and Drug Administration (FDA) and compounds in preclinical and clinical trials, which specifically target these interactions [54]. Understanding which proteins and pathways in the host the virus targets during infection is crucial for the development of AI systems for drug repurposing.

For instance, algorithms modeling the interaction between drugs and proteins have helped identify baricitinib, which was previously used for the treatment of arthritis, as a useful drug against COVID-19 [55]. This drug inhibits the proteins that help the virus penetrate the host cell. Thanks to approaches that exploit the computational identification of relations between existing drugs and target molecules, research published by a team of Korean and American scientists has allowed the identification of FDA-approved antivirals that could potentially target the key proteins for COVID-19 [56].

The molecular processes of virus-host interactions have been recently reconstructed in an international effort coordinated by domain experts, called the COVID-19 Disease Map project [57]. The project aims to maintain an open-access resource for continuous, curated integration of data and knowledge bases to support computational analysis and disease modeling. It represents a milestone of paramount importance for the development of AI systems for SARS-CoV-2 and their comparison with models of other coronaviruses. Moreover, by providing information about the intermolecular wiring of virus-host interactions, the project enables network-based AI modeling for COVID-19 drug repurposing, which has recently shown promising results by using network diffusion and network proximity [58]. Moreover, deep neural networks largely employed in NLP, such as the Transformer architecture, have also been proposed for COVID-19 drug repurposing [56].

In the field of drug development, that is, the pharmacotherapeutic course of a newly identified lead compound, computational models have been proven extremely successful in facilitating a quicker, cheaper, and more effective development of new drugs [59]. For instance, AI can map multidimensional characteristics of proteins to considerably speed up the research process in comparison to traditional methodologies such as x-ray crystallography. In this regard, AI is crucial in optimizing drug discovery pipelines and improving drug development outcomes, with estimated costs of US $2.6 billion [59].

Structural modeling and chemoinformatics methods for COVID-19 (eg, docking-based binding conformation studies of small molecules to target human or viral proteins) can greatly benefit from AI solutions. For instance, AI-based approaches have been used to infer structural similarities among molecules, such as algorithms that can model the graphical structure of chemical compounds through graph convolutional networks or other approaches [60]. AI systems can also leverage knowledge
Pharmacogenomics and Vaccines

Pharmacogenomics, which is the study of the role of genomic characteristics of an individual in drug response, represents a key gateway to personalized medicine [62-64]. Although the translation of genomic information into clinical practice is recognized as one of the most challenging aspects of the future of medicine [65], the information about the genetic makeup of individual patients has the potential to guide clinical decision support and to facilitate biomedical research in many different areas. For instance, genomics can inform drug discovery by providing simultaneous insights into the disease mechanisms and potential targets for treating individual patients [66].

Pharmacogenomics approaches to COVID-19 are still in their infancy. Indeed, although the SARS-CoV-2 genome was published in draft on January 10, 2020 [67], and real-time tracking of the pathogen evolution is now available [68], much less genomic information is currently available about the host. Several studies focus on genetic variations associated with susceptibility to infection and clinical manifestations, including human leukocyte antigen (HLA) variants in the UK Biobank population-based cohort [69] and angiotensin-converting enzyme 2 (ACE2) variants in the Italian population [70]. Retrospective and prospective studies focusing on COVID-19 disease susceptibility and severity have been collected by the COVID-19 Host Genetics Initiative [17,18].

Despite the absence of direct evidence of pharmacogenomics data in COVID-19 patients, the related literature for COVID-19 therapies, including hydroxychloroquine, ribavirin, and baricitinib, has been recently surveyed [71]. Potential actionable genetic markers have been reported, namely, several genetic variants that can alter the pharmacokinetics of drugs that may affect the response to COVID-19 treatments. Importantly, as age, race, gender, and comorbidities have been associated with COVID-19 risk [72], these factors are deemed warranted to assess their role in the variation of treatment responses and need further investigation.

Population genetics is also needed to better understand the association between genetic variability and COVID-19. The importance and complexity of population genetic information, such as genome-wide association studies (GWAS), for drug discovery are exemplified by a study showing that 8% of drugs approved by the FDA target molecules with genetic support, whereas only 2% of phase-1 drugs are genetically supported [73]. Despite such low rates, GWAS can help identify therapeutics that can be repurposed to treat individuals affected by diseases that are mechanistically related to those for which the drugs were developed [74]. Insights from GWAS can also inform about better patient management and therapy, such as the case of variants in six genes on chromosome 3, namely SLC6A20, LZTFL1, CCR9, FYCO1, XCR6, and XCR1, which have been recently associated with severe COVID-19 cases with respiratory failure [75].

Understanding population genetic heterogeneity is crucial for vaccine design, in particular, as it concerns the individual variability of the major histocompatibility complex (MHC-I and MHC-II) proteins, encoded by the HLA gene, which present SARS-CoV-2 epitopes to the immune system. Such individual variability, coupled with the importance of cellular immunity in the severity of the response to the infection, makes the identification of actionable targets for COVID-19 vaccines a challenging endeavor. AI models for COVID-19 vaccine development focus on the prediction of potential epitopes by using a variety of techniques, such as deep docking [76], long short-term memory networks [77], extreme gradient boosting [78], as well as approaches that account for different HLA alleles by combining several existing machine learning tools [79]. A recent survey of AI-based approaches to COVID-19 vaccine design [80] suggests that the most popular candidate is the SARS-CoV-2 spike protein, which initiates the interaction with the host through the attachment to the ACE2 receptor [81].

Mining of the Medical Literature

The staggering rate of publications about COVID-19, both in the form of preprints and peer-reviewed articles, is posing unprecedented challenges to knowledge acquisition and the information quality assessment process. A large part of content is produced by humans for humans, in the form of free text, where crucial pieces of information end up being buried. Because free text is not intelligible by machines, human intervention must identify the relevant pieces of information from the publications and turn it into a tabular form. Recent developments in NLP techniques have helped the automation of this process through machine learning and, in particular, deep learning algorithms [82,83]. Symptoms, patient demographics, clinical data, algorithms, performance, and limitations are identifiable in the texts by properly trained models, which can obtain comparable accuracy to humans at a much faster rate, making it finally possible to monitor the enormous volume of the literature produced [84]. The resulting structured data can be exploited to enrich knowledge graphs (KGs) [85-87], which provide a means to represent and formalize information [85,88], analytical, relational, and inferential investigations and fill the knowledge gaps in the community. Moreover, to rationalize the immense quantity of information on COVID-19, new algorithms
can generate low-dimensional representations of the KGs, allowing researchers for clustering and classification [85,89].

We list here representative KG efforts that have been directed at the fight against COVID-19 (see Textbox 1).

**Textbox 1. Knowledge graph resources for COVID-19.**

<table>
<thead>
<tr>
<th>Project names and references:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• KG-Covid-19 Knowledge Graph Hub [90]</td>
</tr>
<tr>
<td>• COVID-19 Community Project [91]</td>
</tr>
<tr>
<td>• COVID-KG [92]</td>
</tr>
<tr>
<td>• CovidGraph [93]</td>
</tr>
<tr>
<td>• COVID-19 Miner [94]</td>
</tr>
<tr>
<td>• COVID-19 Biomedical Knowledge Miner [95]</td>
</tr>
<tr>
<td>• COVID-19 Taxila [96]</td>
</tr>
</tbody>
</table>

The KG-Covid-19 Knowledge Graph Hub project is the first Knowledge Graph Hub (KG-Hub) [90] dedicated to COVID-19. KG-Hub is a software to download and transform data to a central location for building KGs from different combinations of data sources. The Covid-19 KG-Hub downloads and transforms data from more than 50 different COVID-19 databases of drugs, genes, proteins, ontologies, diseases, phenotypes, and publications and generates a KG that can be used for machine learning.

The COVID-19 Community Project [91] is a community-based KG that links heterogeneous datasets about COVID-19, in three main areas: the host, the virus, and the cellular environment. These KGs use several publicly available datasets, such as the CORD-19 dataset, a set of over 51,000 scholarly articles about coronaviruses [97].

Other notable databases used in KGs are the COVID-19 Data Portal (see Introduction) and The COVID-19 Drug and Gene Set Library [98]. One of the tools that use these is the COVID-KG [92], which embeds entities in the KG, such as papers, authors, or journals [99].

CovidGraph [93] is a collaboration of researchers to build a research and communication platform that encompasses over 40,000 publications, case statistics, genes and functions, molecular data, and much more. The output is a KG in which entity relationships can be found and new pieces of literature can be discovered. Another tool that uses the CORD-19 dataset is COVID-19 Miner [94], which provides access to a database of interactions among genes or proteins, chemicals, and biological processes related to SARS-CoV-2, which are automatically extracted using NLP from the CORD-19 dataset and manuscripts updated daily from the preprint servers medRxiv and bioRxiv [100].

Furthermore, COVID-19 Biomedical Knowledge Miner [85,95] is an intent to lay the foundation for a comprehensive and interactive KG in the context of COVID-19 that connects the causes and effects and enables users to completely explore the information contained therein. Data are supplied from papers available in PubMed and preprints available from platforms such as bioRxiv, chemRxiv, medRxiv, PrePrints, and Research Square. Lastly, COVID-19 Taxila [96] is an AI and NLP system that uses thousands of COVID-19–related publications, clinical trials, and other relevant sources to enable users to search and analyze the COVID-19 literature. Publications and data are automatically updated.

**Discussion**

The COVID-19 pandemic has caused some of the most significant challenges that national health care systems have had to face in recent human history. These systems include not only hospitals but also a multitude of clinicians, retirement and nursing homes, families, and communities. Government lockdown policies undertaken to reduce hospital strain has impacted the society as a whole and has also had social and economic consequences, which have been more severe for minorities and vulnerable groups [101]. Moreover, this pandemic is taking place in the age of social media and Web 2.0, which contain plenty of misinformation and fake news, and with no way for the average internet user to check the reliability of the sources. Nevertheless, the COVID-19 crisis has also shown the promise of technology in facilitating a better understanding of a complex disease and its impact on public health.

Here, we illustrated examples of how AI can advance research and clinical medicine and prepare governments for future similar crises. AI shows promise to deliver models for outbreak analytics and detection, prevention, early intervention, and decision-making. We highlighted the unparalleled opportunity for AI to fill the gap between translational research and clinical medicine. Finally, in addition to the medical applications of AI, it is worth mentioning the potential of NLP for monitoring the quality of the information available to the public and fighting fake news [102-104].

Thanks to the availability of big data and high-performance computing, the fight against the novel coronavirus can leverage the support of AI, as demonstrated by initiatives such as the COVID-19 High Performance Computing Consortium [105]. This technology allows us to address, at a much higher speed and a comparable performance, complex tasks that cannot be executed by humans—who can now focus on more intelligence-demanding activities such as emotional intelligence and human-to-human bonding [106].
Although AI is traditionally trained on large datasets for identifying population-level patterns (ie, common characteristics among people belonging to some clinical classes), recent efforts have promoted the utilization of this technology in conjunction with the principles of precision medicine, to substitute the “average patient” [42] with a real individual, based on geographical and socioeconomic signature as well as genetic, epigenetic, and other molecular profiles [107]. Under this paradigm, AI is meant to empower clinicians to tailor interventions [108] (whether preventive or therapeutic) to the nuanced—and often unique—features of every human being [109]. To this end, multidimensional datasets, such as the variety of data modalities that are currently collected and modeled for COVID-19 [110-112], capture individual genetic, biochemical, physiological, environmental, and behavioral variations [113] that may interfere with the progression, development, and treatment of a disease. Thanks to the drop in price of sequencing the human genome (from billions to hundreds of dollars in 30 years [114]), it is now possible to exploit AI to study phenotypic, genotypic, and environmental correlations among diseases [115]. With this approach, AI can predict the risk of an individual to develop a disease and estimate the likelihood of success for a treatment. In the case of COVID-19, this could lead to a better allocation of resources and an improved match between treatments and patients, consequently improving outcomes for preventive and therapeutic interventions. Therefore, AI-aided precision medicine connects some of the key benefits for a sustainable and effective health care system: efficiency, efficacy, and safety assessment [30].

AI is recognized as a necessity to achieve precision medicine in COVID-19. The current crisis has highlighted that a huge amount of work is still needed to exploit AI-based solutions to their full potential in order to transform health care. AI implementation in the clinical setting is still far from completion [115]. The highly fragmented and diverse health care systems, absence of a protocol for documenting patient data, ethical constraints (such as privacy), and limitations of AI itself (eg, bias and non-interpretability) still represent serious challenges to extensive AI adoption [116].

Acknowledgments

We are deeply thankful to the Women’s Brain Project (WBP) (www.womensbrainproject.com), an international organization advocating for women’s brain and mental health through scientific research, debate, and public engagement. The authors would like to thank Maria Teresa Ferretti and Shahnaz Radjy for the helpful comments. DC, AM, and AV have received funding from the European Commission’s Horizon 2020 Program H2020-SC1-DTH-2018-1, “IPC-individualizedPaediatricCure” (ref. 826121), and H2020-ICT-2018-2, “INFORE-Interactive Extreme-Scale Analytics and Forecasting” (ref. 825070).

Authors’ Contributions

ES and NM conceived the study with the contribution of ASC, EC, and DC. ES and NM directed the content selection and design, assisted by EC, DC, and AM. AV, KH, and CL supervised the project. The corresponding author had the final responsibility for the decision to submit the manuscript for publication. All authors have contributed to the writing and editing of the manuscript and have read and approved the final manuscript.

Conflicts of Interest

ASC and ES are currently employees at Biogen International GmbH, HQ, Switzerland, and Bayer Pharmaceuticals, USA, respectively. The other authors declare no competing interests. KH is a founder and owns equity of CRA Health (formerly Hughes RiskApps), is co-creator of Ask2Me.Org, which is licensed for commercial use by the Dana-Farber Cancer Institute, and receives honoraria from Myriad Genetics.

References


38. Suspected COVID-19 pneumonia Diagnosis Aid System. URL: https://intensivecare.shinyapps.io/COVID19/ [accessed 2021-02-19]


90. KG-Covid-19 Knowledge Graph Hub. GitHub. URL: https://github.com/Knowledge-Graph-Hub/kg-covid-19 [accessed 2021-02-22]


92. COVID-KG. GitHub. URL: https://github.com/GillesVandewiele/COVID-KG/ [accessed 2021-02-22]

93. COVID-19 Knowledge Graph. CovidGraph. URL: https://covidgraph.org/ [accessed 2021-02-22]


95. COVID-19 Biomedical Knowledge Miner. Biomedical Knowledge Miner (Bik>Met). URL: https://bikmi.covid19-knowledgegmage.com/ [accessed 2021-02-22]


98. The COVID-19 Drug and Gene Set Library. Ma'ayan Laboratory, Computational Systems Biology. URL: https://amp.pharm.mssm.edu/covid19/ [accessed 2021-02-22]


106. Fogel AL, Kvedar JC. Artificial intelligence powers digital medicine. NPJ Digit Med 2018;1:5 [FREE Full text] [doi: 10.1038/s41746-017-0012-2] [Medline: 31304291]


Abbreviations

ACE2: angiotensin-converting enzyme 2
AI: artificial intelligence
AUROC: area under the receiver operating characteristic curve
CNN: convolutional neural network
CONSORT-AI: Consolidated Standards of Reporting Trials–Artificial Intelligence
CT: computed tomography
FDA: Food and Drug Administration
GWAS: genome-wide association studies
HLA: human leukocyte antigen
ICU: intensive care unit
KG: knowledge graph
LASSO: least absolute shrinkage and selection operator
NLP: natural language processing
SPIRIT-AI: Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence

©Enrico Santus, Nicola Marino, Davide Cirillo, Emmanuele Chersoni, Arnau Montagud, Antonella Santuccione Chadha, Alfonso Valencia, Kevin Hughes, Charlotte Lindvall. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 12.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.
Benchmarking Triage Capability of Symptom Checkers Against That of Medical Laypersons: Survey Study

Malte L Schmieding¹,², MD; Rudolf Mörgeli¹, MD; Maike A L Schmieding³; Markus A Feufel⁴*, Dipl-Ing (FH), MSc, PhD; Felix Balzer¹,²*, MSc, PhD, MD

¹Department of Anesthesiology and Operative Intensive Care, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany
²Institute of Medical Informatics, Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany
³Department of Biology, Chemistry, and Pharmacy, Institute of Pharmacy, Freie Universität Berlin, Berlin, Germany
⁴Department of Psychology and Ergonomics (IPA), Division of Ergonomics, Technische Universität Berlin, Berlin, Germany

*these authors contributed equally

Corresponding Author:
Felix Balzer, MSc, PhD, MD
Institute of Medical Informatics
Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin
Charitéplatz 1
Berlin, 10117
Germany
Phone: 49 30 450 5704
Email: felix.balzer@charite.de

Abstract

Background: Symptom checkers (SCs) are tools developed to provide clinical decision support to laypersons. Apart from suggesting probable diagnoses, they commonly advise when users should seek care (triage advice). SCs have become increasingly popular despite prior studies rating their performance as mediocre. To date, it is unclear whether SCs can triage better than those who might choose to use them.

Objective: This study aims to compare triage accuracy between SCs and their potential users (ie, laypersons).

Methods: On Amazon Mechanical Turk, we recruited 91 adults from the United States who had no professional medical background. In a web-based survey, the participants evaluated 45 fictitious clinical case vignettes. Data for 15 SCs that had processed the same vignettes were obtained from a previous study. As main outcome measures, we assessed the accuracy of the triage assessments made by participants and SCs for each of the three triage levels (ie, emergency care, nonemergency care, self-care) and overall, the proportion of participants outperforming each SC in terms of accuracy, and the risk aversion of participants and SCs by comparing the proportion of cases that were overtriaged.

Results: The mean overall triage accuracy was similar for participants (60.9%, SD 6.8%; 95% CI 59.5%-62.3%) and SCs (58%, SD 12.8%). Most participants outperformed all but 5 SCs. On average, SCs more reliably detected emergencies (80.6%, SD 17.9%) than laypersons did (67.5%, SD 16.4%; 95% CI 64.1%-70.8%). Although both SCs and participants struggled with cases requiring self-care (the least urgent triage category), SCs more often wrongly classified these cases as emergencies (43/174, 24.7%) compared with laypersons (56/1365, 4.10%).

Conclusions: Most SCs had no greater triage capability than an average layperson, although the triage accuracy of the five best SCs was superior to the accuracy of most participants. SCs might improve early detection of emergencies but might also needlessly increase resource utilization in health care. Laypersons sometimes require support in deciding when to rely on self-care but it is in that very situation where SCs perform the worst. Further research is needed to determine how to best combine the strengths of humans and SCs.

(J Med Internet Res 2021;23(3):e24475) doi:10.2196/24475
**Introduction**

**Use of Symptom Checkers**

Patients obtain health-related information from health care professionals, but more frequently, information for patients is provided in print; on the web; and, most recently, via smartphone apps. Patients not only use these resources to supplement information received from health care professionals but also as a decision-support tool to advise them on whether and where to seek adequate health care, especially as health care pathways grow more complex. Symptom checkers (SCs) are tools developed to provide support to laypersons. Users can enter their complaints and, with some SCs, demographic or health-related information (eg, age, sex, and past medical history) to obtain advice on the urgency of their complaints (triage advice) and the most likely diagnosis. The demand for this type of support is evident; in the United States, 1 in 3 people reported resorting to the internet for self-diagnosis [1], and a study from 2019 found that half of the patients involved in that study had investigated their symptoms with an online search engine before going to an emergency department [2].

**Evidence on SCs**

Despite their popularity, there is no established framework to evaluate the performance of SCs [3,4]. The use of case vignettes, based on real or fictitious patients, has been a common approach for rating SCs [5-9]. The 2 most recent non–industry-funded audit studies using this methodology rated SC triage capability as unreliable, with an average of only 49% and 58% of appraisals deemed correct [10,11]. In line with these findings, a 2020 literature review concluded that most investigated SCs offered limited benefits [12].

A study showing that laypersons are just as capable of predicting criminal recidivism as a complex commercial algorithm [13] inspired us to compare the triage capability of SCs with that of participants with little or no medical training: are SCs merely a more complicated means of pointing out what an untrained individual could just as easily deduce? Is there an advantage to consulting SCs instead of relying on one’s own judgment?

In addition to advising the individual user, SCs are also said to have the potential to reduce the burden on health care services. Unfortunately, not only has this potential benefit not materialized yet [3] but also there is evidence of the opposite effect, as overly risk-averse SCs promote more visits to emergency care services [14]. To address this issue, we also analyzed whether SCs were more risk averse than our participants. Although SCs can also provide diagnostic suggestions, we considered triage advice to be more relevant for assessing the impact of SC on use of health care resources and patient safety.

The purpose of this study is to benchmark the triage capability of SCs against that of their potential users, that is, laypersons.

**Methods**

**Ethics Approval and Consent to Participate**

This study was approved by the Ethics Committee of the Department of Psychology and Ergonomics (Institut für Psychologie und Arbeitswissenschaft) at Technische Universität Berlin (tracking number: FEU_03_20180615). Participants volunteered to participate in the survey, and informed consent was required.

**Data Collection**

This investigation builds on a prior study by Semigran et al [11], who evaluated SC triage performance based on case vignettes. We used their results on the performance of SCs as well as their case vignettes. Data were collected to determine the triage ability of medical laypersons, which was then used as a benchmark for comparing laypersons’ performance with that of SCs.

**Participants**

All participants were US residents, at least 18 years of age, and had no professional medical background. Our investigation was limited to US residents, as the triage level definitions and the gold standard solutions assigned to the case vignettes by Semigran et al [11] might only be applicable to the US health care environment and might not apply to other health care systems with different service provider options.

**Survey**

We created an online survey with UNIPARK (QuestBack GmbH) [15] containing questions on demographics (age, sex, US residency, and highest level of completed formal education), past online searching behavior for medical information, 45 randomly ordered clinical case vignettes, and 5 attention checks (see Procedure for further details). We used the 45 case vignettes compiled and adjusted by Semigran et al [11], which are between 1 and 3 sentences long and describe a patient’s signs and symptoms and occasionally mention elements of the patient’s past medical history.

Participants were asked to classify each vignette into 1 of 3 triage categories, as defined by Semigran et al [11]: emergency care, involving “the advice to call an ambulance, go to an emergency department, or see a general practitioner immediately”; nonemergency care, which encompasses “advice to call a general practitioner or primary care provider, see a general practitioner or primary care provider, go to an urgent care facility, go to a specialist, go to a retail clinic, or have an e-visit”; and self-care, which is “advice to stay at home or go to a pharmacy.” The definition of each triage level was explained at the beginning of the survey. The understanding of these definitions by participants was ascertained by 3 control questions given before the case vignettes were presented. The questionnaire was piloted with 12 participants and refined

https://www.jmir.org/2021/3/e24475
according to their feedback to ensure readability and understandability.

Preparing the Case Vignettes

The 45 standardized case vignettes included 15 cases for each triage level. The vignettes, as chosen by Semigran et al [11], included both common and uncommon conditions with a wide range of chief complaints. The vignettes stemmed from various clinical sources, including material used to educate health care professionals.

For the purpose of our study, the vignettes were adapted to increase the comprehensibility of lay individuals. First, we transformed the bullet points into complete sentences. Second, we paraphrased technical terms. For example, we replaced "rhinorrhea" with "runny nose" and "tender" with "painful to the touch." In very few cases, explanations required elaboration. Our overall aim was to provide participants with the same information used by Semigran et al [11] to assess SCs. We deemed 1 case vignette vague regarding a crucial piece of information and had to supplement it with a detail left out in the Semigran et al [11] version of the vignette (see Multimedia Appendix 1 [11] for details). We retained the classification of the 45 case vignettes into 3 triage levels.

Understandability and paraphrasing were cross-validated by two native English speakers: one was a medical professional (RM) and the other was without a professional medical background (MALS). The adapted vignettes are shown in Multimedia Appendix 1.

Procedure

We recruited the participants through Amazon Web Service Amazon Mechanical Turk (MTurk), as it provides an established means to recruit US-based participants for sociopsychological surveys and is easy to access for researchers working outside of the United States [16]. Each participant received US $4.00 for completing the survey and a US $3.00 bonus if their overall accuracy in assigning the correct triage level was greater than or equal to 58%. The bonus was intended to provide an incentive for participants to pay close attention to the case vignettes and to assess a case’s urgency as accurately as possible. The chosen threshold of 58% corresponds to outperforming the SC average for participants to pay close attention to the case vignettes and to assess a case’s urgency as accurately as possible. The chosen threshold of 58% corresponds to outperforming the SC average reported by Semigran et al [11].

Two methods were employed to ensure that the participants paid close attention to the survey questions. First, we added 5 attention checks to the set of 45 case vignettes. These attention checks were formatted similarly to the case vignettes but included prompts to choose specific answer options. Participants were excluded from the analysis if they answered any of the 5 attention checks incorrectly. Second, upon completion of the survey, participants were asked to affirm that they were attentive and honest to improve the reliability of our data, as suggested in a reliability analysis on MTurk data [17]. We assured participants that they would be compensated for completing the survey even if they stated that they had responded inattentively or dishonestly. We analyzed data only from participants who affirmed their honesty and attentiveness.

The survey on MTurk was published on 3 different days (March 21, 2020, at 2 PM Pacific Daylight Time [PDT]; March 22, 2020, at 1:45 PM PDT; and March 29, 2020, at 1 PM PDT). By selecting the weekend day and early afternoon PDTs, we attempted to reach an MTurk population as diverse as possible, following a 2017 study on the intertemporal variation of the MTurk population [18]. On each day, participants were recruited within a few hours of publishing the survey.

Due to limited funding, the sample size was ultimately determined by the availability of funds and the number of participants who performed well enough to earn a bonus.

Data Analysis

Data were cleaned and explored using R 4.0.0 [19] and tidyverse packages [20]. Inferential analysis was conducted using the packages lme4 [21] and infer [22]. Figures were created using the package ggplot2 [23]. The data set containing participants’ triage assessments and their demographic variables was made publicly available [24].

Following Semigran et al [11], we refer to each instance of an SC or a participant assessing a case vignette as a “case evaluation.” For example, 2 participants each assessing all 45 case vignettes yielded 90 case evaluations.

Participant Characteristics

To assess the effects of demographic variables (age, sex, and educational level), a logistic regression was performed with the correct triage of a case vignette as a dependent variable. We calculated 95% CIs for the marginal probabilities of the fixed effects using the Wald method to assess whether demographic variables had a significant effect on participants’ accuracy. The α level was set at .05.

Comparing SCs and Participants

For the comparison of SCs and participants, we performed (1) a comparison between participants and all rated SCs aggregated and (2) between participants and individual SCs.

Aggregate Comparison of SCs and Participants

The performance of the SCs was obtained from the appendix of the audit study by Semigran et al [11]. Comparisons were made between SCs and participants in terms of (1) triage accuracy, (2) tendency to overtriage (risk aversion), and (3) how difficult each case vignette was for the respective group (SCs and participants). Of the 15 SCs, 4 (iTriage, Isabel, Symcat, and Symptomate) were designed to never suggest self-care, with 1 SC (iTriage) always advising users to seek emergency care. To ensure that our results were not skewed by these special SCs, we conducted the main aggregate analyses twice, including and excluding those 4 SCs, and reporting results for both.

Triage Accuracy

Following Semigran et al [11], we compared the performance of SCs and participants at an aggregate level and for each triage level separately and overall. This was performed by calculating the sample’s mean accuracy for SCs and participants, with accuracy defined as the proportion of vignettes solved correctly. For the participants, the standard error of the sampling mean with 95% CIs was estimated by bootstrapping the participant
data with 15,000 replications. The limits of the CI were calculated using the quantile method (2.5th and 97.5th quantile of the bootstrap sample means). The CIs for the SC sample were not calculated, as Semigran et al [11] sampled the SCs purposefully, that is, they selected which SCs to evaluate with care and not randomly.

**Risk Aversion**

The risk aversion of the SCs and the participants was determined using the ratio of overtriaged vignettes to undertriaged vignettes. We deemed a ratio greater than 1:1, which is more case vignettes overtriaged than undertriaged, as risk averse. To determine what type of triage mistakes were most likely to occur, we calculated the proportion of triage recommendations given in each triage category by SCs and by participants (eg, the proportion of evaluations in which participants recommended emergency care when self-care was appropriate or the proportion of evaluations in which SCs recommended nonemergency care when emergency care would have been the correct solution) and compared these proportions using the Pearson $\chi^2$ test.

**Difficulty of Case Vignettes**

To analyze whether SCs and participants were challenged by the same case vignettes, the degree of difficulty of a case was calculated using the proportion of SCs and participants correctly triaging it. For example, if a case vignette was solved correctly by every SC, the vignette’s degree of difficulty for SCs was 100%. SCs that did not evaluate the respective case vignette for technical reasons were not included in the denominator. A linear correlation analysis was then conducted to determine the relationship between case difficulty for SCs and case difficulty for participants.

**Comparing Individual SCs With Participants**

As users are likely to use only one or very few SCs, there is no basis for recommendations about using or not using SCs on an aggregated analysis alone. Therefore, additional analyses compared the performance of the participant group with each SC. Considering that most SCs did not evaluate every case vignette (due to technical reasons, see the study by Semigran et al [11]), the triage accuracy of the participants was calculated using only the cases evaluated by a specific SC, enabling a direct comparison. The CIs for participants’ mean accuracy were calculated as described above. We also determined the proportion of participants that managed to achieve higher accuracy across cases than the respective SC. Furthermore, risk aversion was also evaluated, given the specific set of case vignettes for any given SC by plotting the proportion of vignettes that were overtriaged against the proportion of those undertriaged for participants versus SC.

**Results**

**Participant Characteristics**

Our survey was accessed 142 times in 3 days during which it was available in total, 51 participants were excluded, either for failing attention checks (n=41) or for not fulfilling the eligibility criteria (n=10). All the remaining participants affirmed that they had paid close attention during the survey and answered honestly. This yielded a total of 91 participants, each having assessed all 45 case vignettes, which totaled 4095 case evaluations by participants, 1365 for each triage level (Table 1).

The median time for completion of the survey (excluding the time for obtaining informed consent) was 20 minutes and 12 seconds (1st quartile=15 minutes:43 seconds; 3rd quartile=27 minutes:23 seconds). There was no significant difference in the participants’ mean accuracy between the 3 sampling days. We detected no statistically significant influence of demographic variables on participants’ triage accuracy.
Table 1. Participant characteristics (N=91).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median (range)</td>
<td>37 (20-73)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>36 (40)</td>
</tr>
<tr>
<td>Male</td>
<td>55 (60)</td>
</tr>
<tr>
<td><strong>Education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Non–high school graduate</td>
<td>0 (0)</td>
</tr>
<tr>
<td>High school graduate</td>
<td>18 (20)</td>
</tr>
<tr>
<td>Some college</td>
<td>33 (36)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>36 (40)</td>
</tr>
<tr>
<td>Graduate degree</td>
<td>4 (4)</td>
</tr>
<tr>
<td><em><em>Recent</em> triage experience, n (%)</em>*</td>
<td></td>
</tr>
<tr>
<td>Recently consulted an SC</td>
<td>20 (22)</td>
</tr>
<tr>
<td>Recently faced triage decision</td>
<td>23 (25)</td>
</tr>
<tr>
<td>Neither faced triage decision nor consulted an SC recently</td>
<td>62 (69)</td>
</tr>
<tr>
<td><strong>Medical training, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>No training</td>
<td>80 (88)</td>
</tr>
<tr>
<td>Basic first aid training</td>
<td>11 (12)</td>
</tr>
</tbody>
</table>

*Recent was defined as “in the last 6 months.”

Comparing SCs’ and Participants' Triage Performance

**Participant Performance**

Overall, the participants triaged 3 out of 5 case vignettes correctly (2462/4065, 60.57%), and most participants qualified for the bonus payment (56/91, 62%). Their mean accuracy varied with triage level, roughly balanced for emergency and nonemergency situations (67.5% and 68.4%, respectively) but dropped below 50% for self-care vignettes. Of the 39.43% (1603/4065) of incorrect assessments, the majority (956/4065, 23.52%) were overtriaged, that is, participants assigned a more urgent triage level than necessary. Only about every sixth case vignette was undertriaged (647/4065, 15.92%), that is, participants assigned a less urgent triage level than necessary.

**Aggregated Comparison Analyses**

As most SCs were unable to evaluate at least one of the case vignettes, the 15 SCs assessing the 45 case vignettes yielded only 532 case evaluations (see the study by Semigran et al [11] for details): 183 for emergency vignettes, 175 for nonemergency vignettes, and 174 for self-care vignettes.

**Triage Accuracy**

At the aggregate level, SCs (58.0%; SD 12.8%) and participants (60.9%; SD 6.8%) showed very similar mean accuracies (Table 2). This remains to be the case when excluding the 4 SCs that did not suggest self-care (adjusted mean for the 11 SCs; 61.6%; SD 11.0%). Table 2 shows that differences become apparent when evaluating the triage levels separately: for emergency case vignettes, SCs outperformed the participants, whereas the participants outperformed the average SC in the nonemergency and self-care cases. For the least urgent triage level, this difference decreases when excluding those SCs that never recommend self-care.
Table 2. Mean triage accuracy of symptom checkers and participants.

<table>
<thead>
<tr>
<th>Triage level</th>
<th>Percent triage accuracy, mean (SD)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All 15 SCs&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Subset of 11 SCs&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Emergency cases</td>
<td>80.6 (17.9)</td>
<td>79.8 (17.2)</td>
</tr>
<tr>
<td>Nonemergency cases</td>
<td>58.5 (29.1)</td>
<td>61.6 (27.8)</td>
</tr>
<tr>
<td>Self-care cases</td>
<td>30.6 (25.7)</td>
<td>41.8 (20.3)</td>
</tr>
<tr>
<td>Overall</td>
<td>58.0 (12.8)</td>
<td>61.6 (11.0)</td>
</tr>
</tbody>
</table>

<sup>a</sup>SC: symptom checker.

<sup>b</sup>For the subset of 11 SCs, SCs never recommending self-care or always recommending emergency care by design were excluded.

<sup>c</sup>For the participant sample, 95% CIs were calculated using bootstrapping.

**Risk Aversion**

The SCs were risk averse and overtriaged in more than a third of the evaluations (182/532, 34.2%), whereas undertriaging occurred in only 9.2% (49/532). Although participants also tended to be risk averse, this tendency was less pronounced (Figure 1). The ratio of overtriage to undertriage errors was 1.5:1 for participants whereas it was 3.5:1 for SCs. The SCs misclassified self-care cases as emergencies 6 times more often than participants did (43/174, 24.7% vs 56/1365, 4.10%) and 4.5 times more often (23/127, 18.1% vs 56/1365, 4.1%) when considering the subset of 11 SCs. The pair-wise differences in recommendations per triage level were statistically significant between participants and SCs ($P=.002$ for triage-level emergency [$\chi^2=12.5$]; $P<.001$ for nonemergency [$\chi^2=46.3$] and self-care [$\chi^2=109.6$]). This holds true when comparing the participants’ performance with the subset of 11 SCs ($P=.02$ for an emergency [$\chi^2=8.1$] and $P<.001$ for a nonemergency [$\chi^2=19.0$] and for self-care [$\chi^2=47.1$]).

**Figure 1.** Triage evaluations by participants and SCs and triage level. “11 SCs” refers to the SC sample after exclusion of SCs that never recommend self-care (the least urgent triage level). SC: symptom checker.

**Comparing Case Vignette Difficulty for SCs and for Participants**

How challenging a case vignette was for SCs and participants varied widely: 3 vignettes were solved correctly by every SC and 1 vignette by none. Similarly, 4 vignettes were solved correctly by more than 90% of the participants and 2 by less than 10%. At every triage level, a broad variation in the degree of difficulty among case vignettes was observed. A very weak or no relationship could be detected for SCs and participants regarding case difficulty within each triage level (Figure 2).
Comparing Individual SCs With Participants

As previously mentioned, an aggregated analysis of SCs is less meaningful than a direct comparison between the participant population and each SC, as users are likely to consult only one or very few SCs. The overall trend shows that the accuracy of both participants and SCs decreases for self-care vignettes (Figure 3).

A total of 5 SCs (HMS [Harvard Medical School] Family Health Guide, Healthy Children, Steps2Care, Symptify, and Symptomate) managed to outperform the participant sample, achieving an overall accuracy greater than the mean of the participants and its CI’s upper limit (Table 3; see yellow dots in Figure 3). Five SCs had a triage capability lower than 80% (73/91) of the participants. This finding is partially explained by 3 of them apparently designed to never recommend self-care, hence failing in one-third of the cases owing to their design. One of these 3 SCs (Isabel) was outperformed only by a minority of participants (17/91, 18%), when self-care case vignettes were excluded from the analysis. The remaining 2 SCs (Symcat and iTriage) were still outperformed by most participants when self-care case vignettes were excluded. The participants’ mean accuracy was stable at approximately 60%, independent of the slightly different samples of vignettes assessed by the SCs, with 2 exceptions: the participants were challenged by the sample of vignettes evaluated by Healthy Children, reaching a mean accuracy that was approximately 10% lower than in the other samples; conversely, the participants fared much better in assessing the vignette sample considered by DoctorDiagnose.

All but 2 SCs (Family Doctor and Drugs.com) were risk averse, making more overtriage errors than undertriage errors. Although the best 5 SCs were inclined toward overtriage, only one of them overtriaged more vignettes than the average participant (Symptomate; Figure 4).

Figure 3. Accuracy of SCs and participants by triage level (Em), nonemergency, and S-c. The accuracy of individual participants is indicated with blue dots. The aggregate accuracies of participants are shown as box plots. Em: emergency; SC: symptom checker; S-c: self-care.
### Table 3. Comparison of accuracy between symptom checkers and participants.

<table>
<thead>
<tr>
<th>SC name</th>
<th>Accuracy&lt;sup&gt;c&lt;/sup&gt;, n (%)</th>
<th>Participants</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Percent accuracy&lt;sup&gt;d,e&lt;/sup&gt;, mean (SD)</td>
<td>95% CI</td>
</tr>
<tr>
<td><strong>HMS Family Health Guide, n=40</strong></td>
<td>32 (80)</td>
<td>59.5 (7.1)</td>
<td>58.0-60.9</td>
</tr>
<tr>
<td>Healthy Children, n=15</td>
<td>11 (73)</td>
<td>49.9 (10.1)</td>
<td>47.7-52.1</td>
</tr>
<tr>
<td>Steps2Care, n=42</td>
<td>30 (71)</td>
<td>59.7 (7.2)</td>
<td>58.2-61.1</td>
</tr>
<tr>
<td>Symptify, n=40</td>
<td>28 (70)</td>
<td>60.2 (7.2)</td>
<td>58.2-61.7</td>
</tr>
<tr>
<td>Symptomate&lt;sup&gt;f&lt;/sup&gt;, n=14</td>
<td>9 (64)</td>
<td>60.9 (11.6)</td>
<td>58.6-63.2</td>
</tr>
<tr>
<td>Drugs.com, n=42</td>
<td>25 (59)</td>
<td>60.6 (6.5)</td>
<td>59.3-61.9</td>
</tr>
<tr>
<td>FreeMD, n=44</td>
<td>26 (59)</td>
<td>60.2 (6.7)</td>
<td>58.9-61.6</td>
</tr>
<tr>
<td>Doctor Diagnose, n=16</td>
<td>10 (62)</td>
<td>69.5 (10.9)</td>
<td>67.3-71.7</td>
</tr>
<tr>
<td>Family Doctor, n=41</td>
<td>22 (53)</td>
<td>58.1 (7.0)</td>
<td>56.7-59.6</td>
</tr>
<tr>
<td>Early Doc, n=17</td>
<td>9 (52)</td>
<td>63.4 (11.4)</td>
<td>61.1-65.7</td>
</tr>
<tr>
<td>Isabel&lt;sup&gt;g&lt;/sup&gt;, n=45</td>
<td>23 (51)</td>
<td>60.9 (6.8)</td>
<td>59.4-62.2</td>
</tr>
<tr>
<td>NHS&lt;sup&gt;h&lt;/sup&gt;, n=44</td>
<td>23 (52)</td>
<td>62.0 (6.9)</td>
<td>60.9-63.4</td>
</tr>
<tr>
<td>Symcat&lt;sup&gt;f&lt;/sup&gt;, n=45</td>
<td>20 (44)</td>
<td>60.9 (6.8)</td>
<td>59.5-62.2</td>
</tr>
<tr>
<td>Healthwise, n=44</td>
<td>19 (43)</td>
<td>61.2 (7)</td>
<td>59.7-62.6</td>
</tr>
<tr>
<td>iTriage&lt;sup&gt;h,i&lt;/sup&gt;, n=43</td>
<td>14 (32)</td>
<td>60.5 (6.9)</td>
<td>59.1-61.9</td>
</tr>
</tbody>
</table>

<sup>a</sup>SC: symptom checkers  
<sup>b</sup>SCs are listed in order by the proportion of participants outperforming them.  
<sup>c</sup>Most SCs did not evaluate every case vignette. Their accuracy is given as the proportion of correctly solved vignettes of the total vignettes that they evaluated.  
<sup>d</sup>The participants’ accuracy is based on their assessment of the same case vignettes assessed by the respective SC.  
<sup>e</sup>For the participant sample, 95% CIs were calculated using bootstrapping.  
<sup>f</sup>HMS: Harvard Medical School.  
<sup>g</sup>Four SCs were apparently designed never to recommend self-care.  
<sup>h</sup>NHS: National Health Service.  
<sup>i</sup>One SC advised seeking emergency care for all case vignettes.
**Figure 4.** Comparison of the overtriage inclination of symptom checkers (SCs) and participants. The dashed line shows where proportions of over and undertriaged errors are equal. Proximity to the left lower corner indicates a high triage accuracy. The red dot marks the respective symptom checker. The faded blue dots refer to the performance of individual participants. The larger blue dot marks their average performance. The SCs are ordered from left to right and top to bottom by the proportion of participants outperforming them, with the lowest proportional difference at the top left and the highest proportional difference on the bottom right.

**Discussion**

**Principal Findings**

Our study suggests that an average SC has no greater overall triage accuracy than an average user. However, this does not imply that SCs are not useful. Specifically, our data confirm a prior study showing that the lay population has difficulties reliably identifying medical emergencies [25]. On average, participants failed to identify every third emergency, and 12% (11/91) of our participants identified emergencies less reliably than the worst-performing SC. Most SCs tended to overtriage. From a clinical and legal perspective, it can make sense to accept the resulting inflated cost of false alarms to avoid potentially missing an emergency (defensive decision making). In contrast, false alarms raised by SCs can functionally exacerbate overcrowding in health care services. In fact, the ability of some SCs to reliably detect emergencies can be partially attributed to their general tendency—by design—to recommend emergency care even for self-care cases (the least urgent triage level) where no medical care is warranted. This trade-off must be considered before recommending their use.
Studies on the effects of SC advice on users are scarce. Therefore, general recommendations on whether laypersons should use SCs cannot be formulated as yet. On the basis of a detailed analysis of the performance variation among SCs and human decision makers, we showed that the five best SCs that Semigran et al [11] included in their sample outperformed almost all our participants and thus could be seen as beneficial to users. In contrast, SCs mistake self-care cases for emergencies a substantial number of times. This hints at SCs being better suited to help users who are looking for an answer on where they should seek professional help (ie, by discriminating between emergency and nonemergency cases) rather than on whether they should seek medical care at all (ie, by discriminating between self-care and non–self-care cases).

Finally, SCs and participants struggled with different kinds of case vignettes, that is, SCs performed poorly in some clinical situations, whereas in others, their performance was superior to that of their users. For example, the 15 pediatric cases evaluated by the SC Healthy Children appear to have been more challenging for participants (mean accuracy of 49.9%) than the 30 nonpediatric cases (mean accuracy of 66.3%). To provide a more differentiated picture of SC triage performance, further analyses should also investigate performance differences with respect to different types of cases.

Limitations

Compared with the general population of the United States [26], our participants were better educated and included more men than women. The median and mean ages were similar to those of the general US population. One study suggests that the groups most likely to seek health information online are younger White females from high-income households, most with a bachelor’s degree or higher [1]. Most participants in a survey among users of a specific SC (Isabel) were female and White but older than the average population [27]. Despite the fact that our sample’s demographic distribution did not fully resemble the US population or, presumably, the population of SC users, we consider our findings to have at least some external validity for these populations, as demographic variables showed no significant influence on triage accuracy.

The data on SCs date back to a study published in 2015 [11], where the specific versions of the SCs assessed were not specified. Therefore, changes in performance due to possible upgrades were not considered. Such upgrades are likely, and new SCs have since entered the market. Other SCs included in the Semigran et al sample [11] are no longer available online, including the best-performing SC (HMS Family Health Guide). This speaks to the general problem that future research evaluating the performance of SCs will have to address the rapidly changing markets and technological developments.

As we built our study on the materials of the Semigran et al study [11], we also inherited their limitations: the chosen 45 case vignettes do not cover the entire spectrum of prehospital case presentations, especially with the omission of mental health–related scenarios. In addition, some case vignettes lacked a proper diagnosis and stated only the presenting complaints (eg, “Vomiting” for vignette 45, “Constipation” for vignette 40, “Back pain” for vignette 20). This prevented a plausibility check of the gold standard triage level that should be assigned to each vignette.

In general, assessing triage capability with case vignettes has limited validity. This limitation is arguably greater for human participants than for SCs. Although SCs assess a case with a set algorithm and are therefore dependent only on input, contextual (social, emotional, etc) factors play a greater role in human decision making. In a real-life setting, humans might also notice and process more or less information than presented in a case vignette. In addition, reading “back pain” in a dry case vignette is surely a different matter than experiencing it. Thus, our results might be more valid for situations where SC users utilize the tool to triage someone other than themselves. Research shows that this is common practice, as up to 50% of online health information seekers do so on behalf of someone else [1].

Conclusions

Prior publications have emphasized the need for a framework within which the safety and usefulness of SCs should be analyzed. Assessing the average performance of SCs, as has often been done, fosters few actionable recommendations. Given the high-performance variability among SCs, we consider benchmarking with case vignettes as a valuable first step in identifying the best SCs, which could then be tested extensively against relevant competitors.

Although comparing SCs’ triage capability against that of health care professionals is certainly useful [28], this approach implicitly asks whether the former could replace the latter, rather than assessing whether and under which circumstances a user should rely on an SC or refrain from using it. Similar to the common practice of testing a new medicine against a placebo, we suggest that SCs should be benchmarked against a realistic alternative, for example, an SC user relying on his own appraisal (stand-alone triage capability).

Following this approach, our study suggests that the lay population would benefit from some SCs to some extent. Although SCs detect emergencies more reliably than the average user, they are more risk averse than the general population and recommend emergency care more often than is actually necessary. This is a cause for concern, as it might unnecessarily increase the burden on already overwhelmed health care services. Thus, advice on when not to seek emergency care would be the most useful feature of SCs, but it is precisely in that situation that they performed the worst. Further research should investigate which user groups benefit the most from using SCs and whether it is possible to identify the characteristics of scenarios where laypersons are superior to SCs in assessing triage levels. The detailed analyses presented in this paper provide a first step toward a framework for comparatively assessing the respective weaknesses and strengths of both SCs and human decision makers to be able to determine when humans should rely on SCs rather than on their gut feeling and vice versa.
Acknowledgments

The authors express their gratitude to the participants, to Felix Grün for his support in designing the questionnaire and for his valuable feedback, to Eike Richter for his advice on statistical methods, and to Frances Lorié for proofreading the manuscript. The project was funded by the home institutions of the previous authors (MF and FB). No external funding was required for this study. The authors acknowledge support from the German Research Foundation (DFG) and the Open Access Publication Fund of Charité—Universitätsmedizin Berlin.

Authors' Contributions

MS conceived the study, created the questionnaire, designed and conducted the analyses, and wrote the first draft of the paper. MALS assisted with case vignette adaptations. RM assisted with case vignette adaptations and manuscript development. FB and MF provided critical input and advised on the study and questionnaire design, analysis methods, and drafts of the paper. FB and MF contributed equally and share the last authorship. All authors accept full responsibility for the final version of the paper. The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Conflicts of Interest

All authors have completed the International Committee of Medical Journal Editors uniform disclosure form and declare no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; and no other relationships or activities that could appear to have influenced the submitted work.

Multimedia Appendix 1
Adapted case vignettes and case difficulty level.

References


Abbreviations

HMS: Harvard Medical School
MTurk: Mechanical Turk
PDT: Pacific Daylight Time
SC: symptom checker

Edited by G Eysenbach; submitted 24.09.20; peer-reviewed by M Hill, E Berner, J Knitza; comments to author 04.10.20; revised version received 22.10.20; accepted 18.01.21; published 03.03.21.

Please cite as:
PMID:33688845

©Malte L Schmieding, Rudolf Mörgei, Maike A L Schmieding, Markus A Feufel, Felix Balzer. Originally published in the Journal of Medical Internet Research (http://www.jmir.org), 10.03.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use,
distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited. The complete bibliographic information, a link to the original publication on http://www.jmir.org/, as well as this copyright and license information must be included.