Journal of Medical Internet Research

Journal Impact Factor (JIF) (2023): 5.8
Volume 19 (2017), Issue 7 ISSN 1438-8871 Editor in Chief: Gunther Eysenbach, MD, MPH

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Viewpoint

Enabling Open Science for Health Research: Collaborative Informatics Environment for Learning on Health Outcomes (CIELO)

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Abstract

Background: There is an emergent and intensive dialogue in the United States with regard to the accessibility, reproducibility, and rigor of health research. This discussion is also closely aligned with the need to identify sustainable ways to expand the national research enterprise and to generate actionable results that can be applied to improve the nation's health. The principles and practices of *Open Science* offer a promising path to address both goals by facilitating (1) increased transparency of data and methods, which promotes research reproducibility and rigor; and (2) cumulative efficiencies wherein research tools and the output of research are combined to accelerate the delivery of new knowledge in proximal domains, thereby resulting in greater productivity and a reduction in redundant research investments.

Objectives: AcademyHealth's Electronic Data Methods (EDM) Forum implemented a proof-of-concept open science platform for health research called the Collaborative Informatics Environment for Learning on Health Outcomes (CIELO).

Methods: The EDM Forum conducted a user-centered design process to elucidate important and high-level requirements for creating and sustaining an open science paradigm.

Results: By implementing CIELO and engaging a variety of potential users in its public beta testing, the EDM Forum has been able to elucidate a broad range of stakeholder needs and requirements related to the use of an open science platform focused on health research in a variety of "real world" settings.

Conclusions: Our initial design and development experience over the course of the CIELO project has provided the basis for a vigorous dialogue between stakeholder community members regarding the capabilities that will add the greatest value to an open science platform for the health research community. A number of important questions around user incentives, sustainability, and scalability will require further community dialogue and agreement.

(J Med Internet Res 2017;19(7):e276) doi:10.2196/jmir.6937

KEYWORDS

healthcare research; information dissemination; open access to information; social networking; reproducibility of results

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Introduction

There is an emergent and intensive national dialogue regarding the accessibility, reproducibility, and rigor of health research. This discussion is also closely aligned with the need to identify sustainable ways to expand the national research enterprise and to generate actionable results that can be applied to improve the nation's health. The principles and practices of *Open Science* offer a promising path to address both goals by facilitating (1) increased transparency of data and methods, which promotes research reproducibility and rigor [1-4]; and (2) cumulative efficiencies wherein research tools and the output of research are combined to accelerate the delivery of new knowledge in proximal domains, thereby resulting in greater productivity and a reduction in redundant research investments [5-7]. For the purposes of the remainder of this viewpoint, we provide the following working definition for Open Science: "Open Science is the practice of science in such a way that others can collaborate and contribute and where research data, lab notes, and other research processes are freely available under terms that enable reuse, redistribution, and reproduction of the research and its underlying data and methods" [8].

Unfortunately, contradictory and sometimes conflicting positions on open science—and the way the open science paradigm might best be operationalized—demonstrate the need for greater community engagement to test the theory that open science in the health sciences can indeed improve the rigor and efficiency of research. This challenge is exemplified by the recent controversy regarding research "parasites," [9] and the vigorous debate that ensued as a result. In response to these important and timely issues, in this viewpoint, we describe a set of lessons learned and future directions associated with an open science initiative conducted by AcademyHealth's Electronic Data Methods (EDM) Forum, called the Collaborative Informatics Environment for Learning on Health Outcomes (CIELO) [10], targeting the broad health research community. We also highlight policy, social, cultural, and implementation-level issues, setting the stage for a vigorous community-wide dialogue concerning future activities as are needed to achieve a compelling vision of open science in health care research and all of its concomitant benefits.

Methods

As mentioned above, we implemented a proof-of-concept open science platform for health research called CIELO [11]. Our primary goal in developing CIELO was to explore real-world information needs and end-user expectations for health research, a domain in which data provenance, privacy, security, and stewardship are of utmost importance. In pursuit of these goals, CIELO was designed and implemented based upon a set of conceptual models and functional requirements informed by systematic and rigorous user needs assessments involving representatives from the academic, private, and public sectors.

During the course of the aforementioned user-centered design process, we elucidated a number of important and high-level requirements for a research data and analytics commons. The essential requirements are as follows:

First, *a successful data and analytics commons must be able to interoperate with and leverage a variety of technologies and approaches.* There are an increasing number of technologies that can be used to enable open science, such as content management systems and standard data-centric APIs (application programming interfaces). To be successful, a commons must be able to interoperate with such technologies in a scalable and user-friendly manner.

Second, *the "app store" paradigm reflects a user experience (UX) paradigm that is comfortable and desirable for both technical and nontechnical users and can create an effective marketplace for sharing ideas across disciplines.* There exists a similarly promising body of "app store" constructs for the user-friendly submission, quality assurance, distribution, and community-wide documentation of technical artifacts, all of which can be leveraged to build an effective exchange.

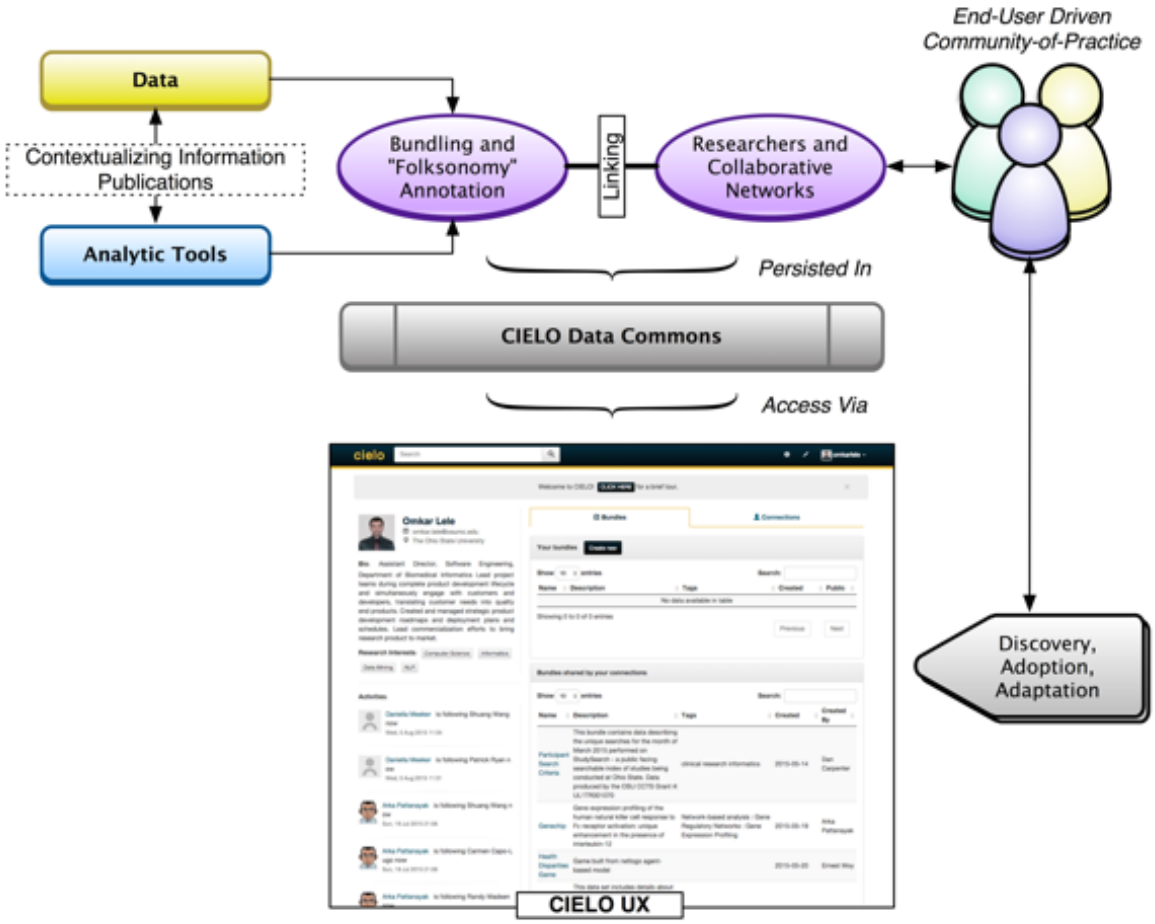
Third, *social search and discovery is a critical feature to promote interaction with data and analytical tools in a data and analytics commons.* The need for social search and discovery is reflective of the primary foci of many potential commons users who seek to engage in collaborative data and analytics projects with a group of trusted and known colleagues.

In response to these preliminary user needs, CIELO was developed to provide the members of the health care research communities with *a fully functional platform and dynamic community-of-practice designed to collectively reduce time and cost of research while enhancing the reproducibility, transparency, and rigor of health research.* To achieve these aims, we implemented CIELO using a combination of the following three key features: (1) a content and version management system (such as GitHub); (2) a "folksonomy"-driven annotation and search mechanism; and (3) a simplified user experience leveraging prevailing Web application technologies. All software design and implementation activities associated with CIELO used an agile and user-centered design and evaluation process, with a specific emphasis on end-user engagement in all project phases.

The resulting platform enabled the users to create analytic "bundles" (comprising both data and analytical code) to show and share their work (see Figure 1). As an early proof-of-concept to provide user feedback and demonstrate the potential impact of CIELO, we undertook a public beta release program. At the time of this submission, nearly 90 registered users from more than 20 different institutions had used CIELO.

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Figure 1. Overview of the Collaborative Informatics Environment for Learning on Health Outcomes (CIELO) architecture and workflow, emphasizing the bundling of data and analytic tools and the provisions of social search capabilities.



Results

By implementing CIELO and engaging a variety of potential users in its public beta testing, we were able to elucidate a number of additional information needs and requirements based on using an open science platform focused on health in a "real world" setting, which are as follows:

- It is important to *allow users to bundle data and code in variable ways* (eg, mapping multiple versions of code to multiple versions of data, as opposed to a one-to-one mapping of such artifacts).
- There is a need to *support multi-level sharing permissions that can evolve gracefully over the lifecycle of a project or bundle* (from private collaborative or enclaves to fully open releases of data and code).
- *Flexible and dynamic metadata management functionality* can assist in responding to the ongoing evolution of standards and requirements.
- *Cross-linkage to external data and code resources where contribution to a centralized repository is not possible,* due diverse data and code stewardship, ownership, and technical requirements, is highly desirable.
- *Support for provisioning of durable resource identifiers, such as digital object identifiers (DOIs), can increase uptake and impact.* DOIs enable attribution of work and create a value proposition for both the contribution and subsequent reuse, adaptation, and recontribution of data and analytics bundles, particularly for scholars.

Discussion

Our initial design and development experience over the course of the CIELO project has provided the basis for a vigorous dialogue between stakeholder community members regarding the capabilities that will add the greatest value to an open science platform for the health research community. Particularly because CIELO is designed to address the needs of multidisciplinary collaborators, we believe that CIELO project provides a successful technical prototype to facilitate collaboration in health research. We have also raised a number of important questions that will require further community dialogue and agreement, as follows: How do we incentivize and sustain *participation* in these types of platforms and sharing frameworks (for example, current funding and career advancement models and metrics of scholarly success may serve as a barrier to participation)?

How do we create a sustainable *fiscal* strategy that aligns with the evolving needs of a high performing healthcare research community and the ways in which it may utilize such a commons platform?

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How can we make such a platform elastic and scalable from a technical standpoint so that is can evolve gracefully over time and not become obsolete? For example, in parallel to the development of CIELO, a robust community has also arisen around the Open Science Framework (OSF) [12], which we envision as providing a complementary platform for shared data analytics workflow management and sharing of such workflows and their products. It will be important for environments such as CIELO to interoperate with those like OSF in order to create a broad-based open system "ecosystem."

Despite these open questions, we see CIELO as a proof-of-concept for what is required to establish a functional data and analytics commons reflecting the technical and sociocultural needs of our intended end-user community. Encouraged by the robust capabilities of the platform and early user experiences, we will continue to explore the potential of CIELO by (1) identifying opportunities to deliver reference datasets within the environment that will make it even easier for individuals to share their analytics tools when source data sharing is infeasible; (2) creating incentive models to encourage the adoption and use of CIELO by a variety of stakeholders; (3) investigating novel methods to address diverse and challenging privacy and data-sharing constraints incumbent to health data in a systematic manner; and (4) continuing rigorous user-centered design processes to highlight additional functional requirements representative of end-user needs and expectations. Ultimately, we believe that projects such as CIELO represent an important effort to enable the health research community to achieve greater parity with other scientific communities, such as the natural and physical sciences, that have adopted open science paradigms and seen concomitant and exponential increases in research productivity as impact [5,6,13,14], setting the stage for achieving a compelling vision of open science and all of its concomitant benefits in the health research domain.

Acknowledgments

CIELO is a collaborative project of AcademyHealth's EDM Forum, which is funded through a cooperative agreement from the Agency for Healthcare Research and Quality (Grant #U18 HS022789).

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
CIELO: Collaborative Informatics Environment for Learning on Health Outcomes
DOI: digital object identifiers
EDM: Electronic Data Methods
OSF: Open Science Framework
UX: user experience

Edited by G Eysenbach; submitted 02.11.16; peer-reviewed by S Pais, J Till, J Apolinário-Hagen; comments to author 01.12.16; revised version received 24.05.17; accepted 10.06.17; published 31.07.17.

Please cite as:
Payne P, Lele O, Johnson B, Holve E
Enabling Open Science for Health Research: Collaborative Informatics Environment for Learning on Health Outcomes (CIELO)
J Med Internet Res 2017;19(7):e276
URL: http://www.jmir.org/2017/7/e276/
doi:10.2196/jmir.6937
PMID:28760728

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Original Paper

Desirable Components for a Customized, Home-Based, Digital Care-Management App for Children and Young People With Long-Term, Chronic Conditions: A Qualitative Exploration

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Abstract

Background: Mobile apps for mobile phones and tablet devices are widely used by children and young people aged 0-18 years with long-term health conditions, such as chronic kidney disease (CKD), and their healthy peers for social networking or gaming. They are also poised to become a major source of health guidance. However, app development processes that are coproduced, rigorously developed, and evaluated to provide tailored, condition-specific, practical advice on day-to-day care management are seldom systematic or sufficiently described to enable replication. Furthermore, attempts to extrapolate to the real world are hampered by a poor understanding of the effects of key elements of app components. Therefore, effective and cost-effective novel, digital apps that will effectively and safely support care management are critical and timely. To inform development of such an app for children with CKD, a user requirements-gathering exercise was first needed.

Objective: To explore the views of children with CKD, their parents, and health care professionals to inform future development of a child-focused, care-management app.

Methods: Using age- and developmentally appropriate methods, we interviewed 36 participants: 5-10-year-olds (n=6), 11-14-year-olds (n=6), 15-18-year-olds (n=5), mothers (n=10), fathers (n=2), and health care professionals (n=7). Data were analyzed using Framework Analysis and behavior change theories.

Results: Of the 27 interviews, 19 (70%) interviews were individual and 8 (30%) were joint—5 out of 8 (63%) joint interviews were with a child or young person and their parent, 1 out of 8 (13%) were with a child and both parents, and 2 out of 8 (25%) were with 2 professionals. Three key themes emerged to inform development of a software requirement specification for a future home-based, digital care-management app intervention: (1) Gaps in current online information and support, (2) Difficulties experienced by children with a long-term condition, and (3) Suggestions for a digital care-management app. Reported gaps included the fact that current online information is not usually appropriate for children as it is “dry” and “boring,” could be “scary,” and was either hard to understand or not relevant to individuals’ circumstances. For children, searching online was much less accessible than using a professional-endorsed mobile app. Children also reported difficulty explaining their condition to others, maintaining treatment adherence, coping with feeling isolated, and with trying to live a “normal” life. There was recognition that a developmentally appropriate, CKD-specific app could support the process of explaining the condition to healthy peers, reducing isolation, adhering to care-management plans, and living a “normal” life. Participants recommended a range of media

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and content to include in a tailored, interactive, age- and developmentally appropriate app. For example, the user would be able to enter their age and diagnosis so that only age-appropriate and condition-specific content is displayed.

Conclusions: Future development of a digital app that meets the identified information and support needs and preferences of children with CKD will maximize its utility, thereby augmenting CKD caregiving and optimizing outcomes.

(J Med Internet Res 2017;19(7):e235) doi:10.2196/jmir.7760

KEYWORDS

child; adolescent; long-term condition; chronic condition; self-management; self-care; mobile apps; apps; qualitative

Introduction

The number of children and young people (children) with long-term/chronic health conditions is increasing and their information and support needs vary according to age and developmental stage. Providing appropriate information to children can promote better emotional health, less distress during treatments, greater satisfaction with health care, and optimal self-management and autonomy, which become crucial as they transfer to adult services [1].

Most children experience challenges throughout childhood and the transition into adulthood, but those with long-term conditions can experience additional challenges due to condition-specific needs. The Internet and mobile apps are increasingly used to communicate health-related information, but few websites or apps target children with long-term conditions; those that exist do so with variable quality and reliability [2]. A growing volume of literature on the self-management support needs of 5-18-year-olds with long-term conditions [1,3,4] indicates poor outcomes compared to other patient groups [5]. Those with chronic kidney disease (CKD) are particularly vulnerable due to complex medical and dietary regimens [6-8] and on transfer to adult services, treatment adherence often diminishes [9,10]. As CKD is progressive, poor adherence can lead to renal failure, which is fatal without renal replacement therapies [11,12]. Apps for mobile phones and tablet devices are now poised to become a major source of psychoeducational health guidance. However, to our knowledge, there are few coproduced, rigorously developed, evaluated apps providing tailored, CKD-specific, practical advice on day-to-day care management [13-20] and development processes for those that do exist are not systematic. Therefore, effective novel, digital solutions to guide child, young person, and parent consumers toward effective apps are critical and timely [14,21-29].

Acquiring the clinical skills and knowledge to manage treatment regimens effectively is a key factor in competent self-management. Therefore, robust, user-led, well-developed information and support interventions are needed that address children's identified needs and preferences and that are supplemented by parents' and health care professionals' (professionals) views on what is realistic and achievable. The first author (RN), therefore, consulted with The Young People's Advisory Group that she coleads at a UK children's hospital. All group members reported using the Internet to find health information, were aware that websites varied in regards to accuracy and quality, and confirmed a need for research to develop and test reliable child-friendly apps for long-term conditions. Members thought that an app providing information about managing CKD, wider health education, vocational and social issues, and opportunities for safe interaction with others living with CKD could be very valuable.

A recent systematic review of the effectiveness of mobile apps for 10-24-year-olds with physical long-term conditions—published by authors of this manuscript—found a dearth of rigorously developed and evaluated user-led apps for this population [14]. Therefore, this study aimed to explore the views of children with CKD, their parents, and key professionals to inform the future development of a digital care-management app.

Methods

The research aim of this study is to begin development and evaluation of an interactive child-led app to support home-based CKD management.

Objectives

The first objective of this study is to determine the desirable components for a CKD- and child-focused app. The second objective of this study is to complete the theoretical modeling stage of our phased approach toward development and evaluation of a CKD-specific, home-based, digital care-management app.

Methodology

Our study was founded on a key objective of the *life-stage approach* to UK policies for children with long-term conditions [30], which states that every child should have access to developmentally appropriate services. This includes resources that can be accessed easily, confidentially, at no cost to individuals, and in varied settings. We used the Medical Research Council (MRC) complex intervention development and evaluation framework to guide our study [31,32].

Study Design and Sampling

A qualitative design was adopted that often uses small sample sizes to explore participants' beliefs and practices within their natural context, rather than aiming to produce generalizable findings from large samples [33]. In two UK pediatric kidney units, participants were purposively sampled and included children with CKD and their parents. To achieve maximum variation regarding the children's age, developmental stage, ethnicity, and sex, we aimed to recruit 6-8 participants from each of the following groups: 5-10-year-olds, 11-14-year-olds, 15-18-year-olds, and parents or carers of children with CKD.

Building on our prior work on *distributed expertise* [34], we aimed to invite 6-8 professionals (eg, clinical psychologists,

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dieticians, doctors, nurses, social workers, and play specialists) with experience in supporting families with CKD. Potential participants were identified by our two local principal investigators (SF and EB), who work clinically with children with CKD and their families. Once verbal consent was gained for the researcher (RN) to contact potential participants, age and developmentally appropriate written information was provided.

Data Collection

Using a combination of semistructured individual or focus group interviews, depending on the individuals' preferences [33,35], we collected data in child-friendly settings, such as children's hospital-based venues or patients' homes. Where children were interviewed jointly with their parents, we emphasized at the start of each interview that we would initially focus on the child's views; therefore, all questions were directed at the child first, using developmentally appropriate language. We found that in some cases, the presence of the parent facilitated the child to share their views; for example, they would "translate" the researcher's question to make it more relevant to their child, or prompt further response by using pertinent examples. Interviews were supported by topic guides that were developed by the research team in collaboration with members of our virtual research advisory group; these were based on our previous research and on behavior change theories.

We used age- and developmentally appropriate, technology-supported methods to explore children's views on the strengths and limitations of existing Web and mobile resources relating to CKD or general health issues. For example, we demonstrated existing Web resources, such as websites and mobile apps, focused on children with CKD and other long-term conditions to facilitate discussion about desirable components, potential barriers and facilitators to using Web and/or mobile apps, preferred designs, functionality, and levels of interaction. Creative methods were used, in particular with 5-10-year-olds who may have more difficulty expressing themselves verbally [36,37]. For example, we used drawing to find out what impact CKD has on a "typical" day and to encourage child participants to express their ideas for what they thought should be included in an app. This activity was offered to all children who were either chronologically or developmentally in the 5-10-year-old group and 2 participants chose to draw; 1 drew himself in the hospital and 1 produced images of games to include in the app. Advantages of these types of research techniques include the following: engaging children and encouraging their participation; relevance to children's own styles of expression and interest in images; and creative tasks that can help sustain attention and interest, going beyond standard ways of answering questions and leaving time for participants to reflect and think [38]. The 2 participants who created images were asked to explain these to the researcher; these conversations were recorded, transcribed, and analyzed in conjunction with the images produced.

Interviews with parents and professionals were also technology supported and focused on their views on existing apps, gaps in existing resources for children, and suggestions for desirable components for a child-focused, CKD-specific, information and support app. We explored participants' views on content, patient information services, peer-to-peer interactions, security, and data sharing.

Interventions based on behavior change theories are reported to be more effective than those lacking a theoretical basis. One of the most influential behavior change theories in health apps and Internet resources is Bandura's social cognitive theory, an interpersonal theory that covers both determinants of behavior and methods for behavior change [17,39,40]. A major determinant of behavior that social cognitive theory describes is self-efficacy (eg, feeling self-confidence in managing the condition). This approach proposes that an individual's belief in their own self-efficacy comes from the following: mastery experiences (eg, improved communication skills about their condition with family, friends, and professionals, or learning by practicing clinical skills); vicarious experiences (eg, observing how professionals effectively deliver clinical skills or how peers with a similar condition enact healthy behaviors); verbal persuasion (eg, reading about or listening to others explain how they successfully manage certain self-management experiences); and physiological or affective experiences (eg, decreased worry about themselves when they have mastered ways to deal with negative emotions relating to their condition). Efficacy in self-management enhances adoption and maintenance of positive health habits such as adherence to treatment regimens. In the context of developing an information and support app, the theory provided a schema for how self-efficacy beliefs about self-management could potentially be promoted by the app. Therefore, because of the need for individual support and because rigorously developed apps are more likely than not to improve users' self-efficacy, in our analysis we drew upon social cognitive theory and self-efficacy [41].

Data Analysis

Data were analyzed using Framework [33,42], a recognized, systematic method for handling large amounts of qualitative data. Framework builds findings by moving back and forth between collecting data, identifying themes, coding and labeling data, identifying categories, detecting patterns, and seeking possible interpretations. Independent reviews of data samples were discussed by the authors (RN, AH, CG, and VS) until a consensus was achieved. We interviewed participants until reaching theoretical saturation [33].

Ethical Considerations

For children, age- and developmentally appropriate written and verbal information was provided. Participants under 16 years of age provided assent and their parents provided consent for their child's participation. Approval was obtained from the Health Research Authority, a National Health Service (NHS) Research Ethics Committee (reference No. 16/NW/0227), and the NHS Trust Research and Development Departments.

Patient and Public Involvement

Patient and public involvement (PPI) was instrumental in our study. INVOLVE defines PPI as "research being carried out 'with' or 'by' members of the public rather than 'to,' 'about,' or 'for' them," as seen on page 6 of its Briefing Notes for

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Researchers [43]. We used this definition to establish a virtual research advisory group comprising young people with CKD and parents of children with CKD. Group members advised on the following: study management (parents were active members of the study steering group), interview topic guides, Web resources used during interviews, data analysis and dissemination.

Results

Overview

A total of 36 participants were interviewed. Table 1 provides information about the participants.

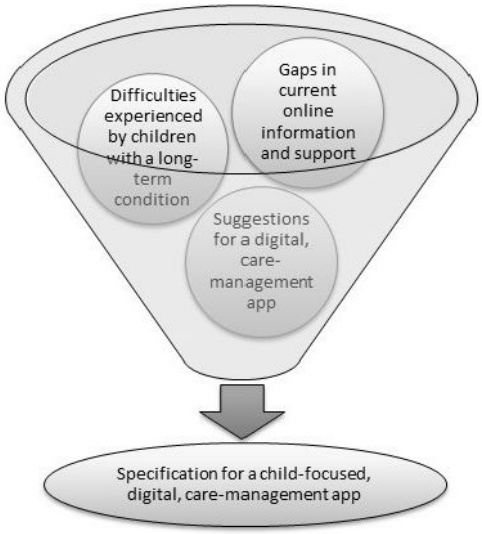
Of the 27 interviews conducted, 19 (70%) were individual and 8 (30%) were joint—5 out of 8 (63%) joint interviews were with a child or young person and their parent, 1 out of 8 (13%) were with a child and both parents, and 2 out of 8 (25%) were with 2 professionals. For convenience, 25 out of 27 (93%) interviews were face-to-face and 2 out of 27 (7%) were telephone interviews. Interviews lasted between 8 and 55 minutes, were digitally recorded, and later transcribed verbatim. The first author (RN) conducted 22 of the 27 (81%) interviews—3 jointly with another author (CG)—and the last author (VS) conducted 5 out of 27 (19%) interviews. Analysis identified three key themes to inform development of a software requirement specification [44]: (1) Gaps in current online information and support, (2) Difficulties experienced by children with a long-term condition, and (3) Suggestions for a digital care-management app (see Figure 1).

Table 1. Participant characteristics.

Participant characteristics	Children aged 5-10 years (n=6), n (%)	Young people aged 11-14 years (n=6), n (%)	Young people aged 15-18 years (n=5), n (%)	Parents (n=12), n (%)	Professionals (n=7), n (%)
Gender					
Female	3 (50)	3 (50)	2 (40)	10 (83)	N/A[a]
Male	3 (50)	3 (50)	3 (60)	2 (17)	N/A
Ethnicity					
White British	4 (67)	5 (83)	4 (80)	N/A	N/A
Other	2 (33)	1 (17)	1 (20)	N/A	N/A
Profession					
Doctor	N/A	N/A	N/A	N/A	1 (14)
Nurse	N/A	N/A	N/A	N/A	2 (29)
Play specialist	N/A	N/A	N/A	N/A	1 (14)
Social worker	N/A	N/A	N/A	N/A	2 (29)
Therapist	N/A	N/A	N/A	N/A	1 (14)

[a]N/A: not applicable.

Figure 1. Overview of study findings.



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Gaps in Current Information and Support

Child and parent participants advised that they obtained the majority of their information and support from professionals in the renal multidisciplinary team responsible for their care. Those who looked online for information visited a range of websites including the following: NHS Choices, infoKID, and the National Kidney Foundation. Reported gaps in current online information and support were related to issues such as content, trustworthiness, child friendliness, and accessibility.

Young people, professionals, and parents with older children thought the information on websites was quite basic, lacked detail, and was unhelpful in developing self-confidence in managing the condition. One parent stated the following:

> *...a couple of times he [son] has told me he's looked things up on the Internet. But I try to dissuade him from doing that because I don't think you ever get any real reassurance, because it's so wide, isn't it, the Internet, it's not tailored to specifics.* [Parent A of 13-year-old child]

All participant groups concluded that to gain information that was specific to the child's situation, the most helpful source of information was the professionals involved in their care. They recognized that professionals could provide tailored information that was relevant, timely, and individual specific, but online information could be "scary," as it was either hard to understand or not relevant to the individual's circumstances.

Concern was expressed about whether websites contained accurate information and, therefore, whether they could be relied upon to promote mastery, although those from recognized organizations (eg, NHS Choices and the National Kidney Foundation) were viewed as more trustworthy, as this quotation illustrates:

> *Most of the sites regarding stuff like diet are like forums, so anyone can post, so there's not really that much reliability...the Kidney Foundation or something, that's pretty reliable obviously 'cause it's a government website, so I use that mostly.* [Young person, aged 17 years]

Current online information was described as not appropriate for children, as it is "dry," "boring," or as one professional said:

> *...the written information's a bit dull, I think a lot of it's been written by doctors and it's not hugely fit for purpose, it's not interactive, you know. You look at kids now and the way they learn is through iPads and apps, and it's all of this isn't it? And I think we're [professionals] quite behind on that, but it's just trying to find the time to develop that.* [Professional]

Parent and young people participants expressed concerns about the accessibility of online information, reporting difficulties with searching for, and finding, information. Though some reported that professionals had recommended specific websites, for others the preference was to ask their professional, rather than "trawl" through information online. For some young people, searching online was considered much less accessible than using a mobile app:

> *I don't really go online to look about kidney things, so I think if there was an app because people are very "oh my phone, oh look, have you seen this app?" these days, so it would be quite accessible.* [Young person A, aged 11 years]

Difficulties Experienced by Children With a Long-Term Condition

All participant groups described difficulties experienced by children living with CKD. This included the following: the need for information to support self-care and, therefore, promote feelings of self-efficacy; explaining their condition to others; treatment adherence; feeling isolated; and living a "normal" life.

All participants viewed the provision of information and support to children and their families as essential. Nevertheless, it could be difficult to understand some information provided by professionals, especially at stressful times such as diagnosis, or when treatments changed. Some parents found it challenging to ensure their child had information they could understand, especially if their child was diagnosed when young or became unwell suddenly.

The difficulties associated with explaining their condition to others, including friends and extended family members, were discussed by many child, young person, and parent participants. This appeared particularly resonant for families where the condition is invisible, in that there are no outward effects on the child, such as CKD. Child and young person participants talked of describing their condition, to whom they disclosed this information, and others' responses:

> *I only have one friend, but she always asks how I am and everything, and I tell her, because she understands what I've been through. But the only thing is, I only tell her, but I think she keeps telling everyone, when I say at the end of our conversation, "please don't tell anyone else, because they tell everyone else as well.*" [Young person B, aged 11 years]

There was recognition that a developmentally appropriate, CKD-specific app could support the process of explaining the condition to others.

All participant groups talked about the complex and often unpleasant treatments needed by children with CKD, including the need to master medication, dietary and fluid restrictions or targets, catheterization, and dialysis. There was discussion around the difficulties of following treatment regimens, which seemed to result from forgetting, deciding not to adhere, or misunderstanding due to changes in treatment, as illustrated by this interview excerpt from a young person who had recently received a kidney transplant:

> *Because a lot of children think, like, before [being diagnosed with CKD] I was allowed to eat that; now you tell me I'm not allowed to eat it. And then after they've had an operation [kidney transplant] and you tell them, you can eat it now, they don't understand*

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> *why they weren't allowed to eat it, and now they can eat it.* [Young person C, aged 11 years]

Feeling isolated due to having CKD was discussed by some children and parents. Some children talked of the difficulty of not knowing anyone else with CKD and feeling like they were "the only one." Many said they would value being able to connect with others with a similar condition.

> *I don't really like looking at the websites...because it reminds me of how much I'm different from all the rest of my friends.* [Child, aged 8 years]

Though some children felt different from their peers, the importance of living a "normal" life, despite having CKD, was explored during interviews. The impact of having CKD was discussed, including missing school to attend hospital appointments and manage treatment regimens. Discussing the techniques used to cope, such as keeping active and avoiding thinking about how the condition may affect them in the future, meant many children felt they were able to lead a "normal" life. Parent participants also viewed this as important, as this quotation illustrates:

> *...he'll have his transplant and then he'll move on and have a relatively normal life. And that's what I want for him as a parent. So I want him to feel like he understands his condition and everything, but I don't want it to define him. I want it to just be something that's part of him.* [Parent A of 13-year-old child]

Suggestions for a Digital Care-Management App

Participants from all groups recommended an interactive, age- and developmentally appropriate care-management app, whereby the user could enter their age and their diagnosis, so only age- and condition-specific content is displayed.

There was some discussion about whether a mobile app or a website would be preferable. Participants who preferred a website thought the content would be more suitable for a webpage layout and were concerned about the potential size of the app on their device. However, many participants thought an app would be preferable as they were more accessible and interactive:

> *I think an app would probably be better, rather than going on a website to do it, because apps are more convenient. You don't have to type anything up and you can just click on it.* [Young person, aged 16 years]

Other key features suggested were endorsement of the app by renal professionals, as it was important for children and their families to know the information in the app was accurate and trustworthy. It was also thought important that the app be promoted as a supplement, not a replacement for individual advice and support from professionals. Participants from all groups suggested the app should emphasize the importance of consulting with professionals for information, advice, and support and the need to contact them with unanswered questions or concerns.

All participant groups suggested the app should contain information about the human body, with a particular focus on the kidneys and how they interact with other body systems. Information about kidney conditions, symptoms, and stages of kidney disease was thought useful, though some parent and professional participants expressed concerns that children viewing information about how their condition could progress could potentially view it as "scary." It was also suggested that information about common tests and procedures should be included in the app to help children feel better prepared for such procedures. Additionally, participants from all groups requested information about different treatments for kidney disease, including medication, diet, dialysis, and transplant, as illustrated in the following quote:

> *The knowledge about the transplant process, and pictures, and she can look at it for herself, instead of me telling her, or somebody else telling her.* [Parent B of 13-year-old child]

It was thought this could help a child understand about their current treatment and could potentially help with learning about what the future may involve. Finally, information about the potential impact of having kidney disease on (1) physical well-being and (2) emotional well-being/mental health was viewed as important, while ensuring there is an emphasis on what children with CKD can still do and how to lead a normal life.

Participants from all groups suggested it would be beneficial if the app could be used to record information, including details of their treatment regimen (eg, medication, fluid target, and diet), appointments, and linkup with existing electronic patient records. This could promote treatment adherence by providing reminders and alarms, for example, for their medication and encourage children to record when treatment had been completed. This is illustrated in the following quote:

> *Some sort of planner on it, when their appointments are, little alerts for medication, that might help, especially as they're beginning to transition, giving them a bit more independence.* [Professional]

Some professional participants suggested the app could also be used to record emotions and physical symptoms. It was suggested that professionals managing the children's CKD could also review the recorded information; however, some professionals expressed concerns around this in case children thought professionals were monitoring this information and would respond if anything required immediate attention.

Information related to the vicarious experiences of other children regarding the consequences of adhering or not adhering to treatment (eg, medication, fluids, and diet) and other lifestyle choices (eg, smoking and drinking alcohol) was suggested by participants from young person, parent, and professional groups. It was thought this could help children make "smarter" decisions as they would have a clearer understanding of the consequences of choosing not to follow advice from professionals. The idea of decision-making tools was discussed, as illustrated by this quotation from a young person who discussed the benefits of being able to use her phone to scan barcodes on food products to identify the ingredients:

> *I'm on a low-phosphate diet, and I have to be careful of things that have phosphate in them, sometimes you*

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> *have to look at the packaging. But some companies don't have to put in if it has phosphate, so it's hard to know what you're eating...If I was in a shop and I could, like, scan something, and if it told me what it had in it...and it could rule out if it has phosphate, and it could tell you what's in it, and if it's a bad thing, that you're not allowed, it could be in red, so you know that it's bad.* [Young person, aged 13 years]

Many participants, in particular children and parents of children under 13 years, thought games should be included in the app; for example, games with information about how the kidney or treatments work and incorporating elements of game design, such as scoring points and progressing through levels. It was suggested that gamification would encourage children to engage with the app and learn about their condition.

However, some participants expressed concerns around gamification; older teenagers thought games could work to engage younger children, but thought it unlikely that older teenagers would play a CKD-focused game. There was recognition of the addictive nature of many games and while some parent and professional participants thought this beneficial as a way to engage children, others expressed concerns as illustrated by this quotation:

> *I don't think we want to be over-hip, (a) because I don't think it would work and (b) because I think I don't want to go so far down the gaming culture that...in a way that I think would be unhelpful for some young people.* [Professional]

There were suggestions that a safe, moderated forum where children with CKD could communicate with their peers would be beneficial, as it could provide access to vicarious experiences from other children similar to themselves who are succeeding in self-management; this could potentially increase their beliefs that they, too, can master self-management. The value of being able to interact, ask questions, and share experiences was recognized by many child and young person participants who sometimes felt isolated as a result of having CKD:

> *So this person can see that person and make them feel better about it, because people knowing that other people have it [CKD] makes them feel better.* [Child, aged 10 years]

Although children and professionals currently interact through a range of methods, including appointments, telephone, and email, some young person participants thought it would also help to be able to interact via the app. Suggestions included having live question-and-answer sessions and having professionals be able to access the children's forum so they could contribute to discussions.

Hearing other children's experiences of living with CKD was suggested by many participants from all groups as important to include in the app, for example, via blogs, vlogs, and photos to share the challenges of having CKD and adhering to treatment:

> *It's not all about, "yes, it's brilliant, I'm really relaxed here," they've got to say something about the other sides to it, and then they can relate to it.* [Parent B of 13-year-old child]

Linking patient stories into other parts of the app that focused on supporting children to make "smarter" decisions was recommended as a way that could potentially encourage children to develop self-management skills. Some also thought that hearing about celebrities and/or young adults' achievements despite having CKD could be useful.

Parent and professional participants thought the app could contain signposting and links to other relevant and trustworthy websites, such as infoKID, charities, and websites with information about available support, community and social activities, and research.

Finally, participants from all groups made suggestions about the design and usability of a digital care-management app, which are listed in Multimedia Appendix 1.

Discussion

Principal Findings

Few studies have sought the views of children with long-term conditions on the desired components of a child-friendly, information and support software app as part of a phased approach to development and evaluation of a complex intervention [31,32]. To our knowledge, this is the first study that has explored this issue with children living with CKD. However, although this study focused on children with CKD, the methodology used and many of our findings are potentially transferrable to other long-term conditions.

Our main finding is that due to important gaps in current information and support and the difficulties experienced by children with CKD, there is strong support among children, parents, and professionals for a CKD-specific, child-focused software app. This would complement information and support provided by professionals to enhance self-management and optimize high-quality care. Participants' suggestions reflect their/their child's age or developmental stage, so it is critical that the app be appropriate for a wide range of children and that there is flexibility in how it could be used.

Our findings correspond with reports in the literature about the importance of interventions that aim to improve general self-efficacy among children with long-term conditions, to enhance confidence and the ability to deal effectively with difficult and/or unexpected self-management events [45,46]. Self-efficacy is an individual's judgment of his or her capability to accomplish a certain level of performance in a given set of skills. In preparation for future research to empirically optimize the app before taking the optimal version forward to a national confirmatory trial, we will also consider other determinants of behavior that are described by social cognitive theory, such as outcome expectations or a person's judgment of the likely consequences of a behavior (eg, "When I follow the correct procedure for cleaning my central venous line catheter insertion site, I will prevent the introduction of infection."). Bandura was explicit about the interrelation between outcome expectations and self-efficacy, claiming that judgments of ability to perform a behavior greatly influence expected outcomes. When a person is in a situation in which outcome expectations are positive and strong, but self-efficacy for that behavior is low, a situation of

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avoidance may occur and the individual is unlikely to attempt the behavior. Therefore, interventions that aim to improve general self-efficacy are expected to be beneficial.

Our findings also highlight a significant need for mobile phone games (ie, gamification) that aim to optimize self-efficacy and positively alter health behaviors in chronic disease self-management. This corresponds with a recent systematic review that reports the following: (1) few health apps currently employ gamification, (2) there is a wide variation in the use of behavior change theories and techniques, (3) this may limit potential to improve health outcomes, and (4) further research is required in this field [46].

Software App Specification Development

As illustrated in Figure 1, our data were analyzed and used to develop a software requirement specification for a child-focused, home-based, digital care-management app. The emergent themes were mapped onto functional requirements within a functional specification document; this describes the externally visible behavior of a proposed software app and forms part of a systems requirement document—the basis for much software development. The interviews with participants were in effect treated as a detailed and rigorous user requirement-gathering exercise, and our analysis as a robust method to determine key desired components within a potential app. The interview data that was gathered and coded into themes provided the design and functionality detail for each of the components identified. As Goldsmith [47] notes, a software app is unlikely to be better than its requirements; often, the typical methods to gather information about what potential app users need and prefer tend to only deliver partial requirements, resulting in users' needs frequently getting "lost in translation" when the app is designed.

In the emerging field of evidence-based app development for children with long-term conditions [48-50], a partial, misinterpreted or distorted understanding of children's, parents', and professionals' requirements can lead to the development of health care apps that are suboptimal and not fit for purpose. While there is significant debate around the rigor and transferability of qualitative health research findings, in particular Framework Analysis as used in this study [33,51], little attention is paid to the following: (1) the growing need to use qualitative research methods to gather information about users' requirements and (2) the development of integrated health apps for personal mobile devices for children in a participatory way [14]. Adopting a rigorous qualitative approach within a participatory and ethical research environment can only strengthen the effectiveness, functionality, quality, and efficient development of such apps.

Our study drew the discipline of qualitative research into the early stages of software development and produced a functional specification; next, it needs to draw methods from software development into the qualitative research space. From the functional specification, tools can be produced and used as objects to prompt further consideration and refinement of user needs; these tools can include use cases, which illustrate the interaction an app user will have with the software system to achieve a given task, and wireframes, a graphical representation of content and functionality of the app [52]. It is after this point that the additional elements of the full requirements specification can be considered, which include system requirements, technical requirements, constraints, assumptions, and acceptance criteria. Once an app is developed, it will undergo a rigorous and iterative process of testing and refinement as outlined by the MRC guidance on development and evaluation of complex interventions [31].

Practice Implications

Professionals are responsible for empowering children with long-term conditions, such as CKD, and their parents to develop self-management skills. Good-quality information and support is essential to help children and parents understand and cope with the condition. However, professionals need to be mindful of individual families' information needs and tailor further information provision and signposting to resources that are age and stage appropriate [6,35,53,54]. As illustrated in our study, families often need help to identify reliable sources of information online and to recognize the limitations of this information.

It would be beneficial if multidisciplinary teams are aware of the lived experience of children with long-term conditions and which additional sources of support are important; for example, social isolation has been highlighted as a problem by both children with CKD and their parents [55] who often live a long way from face-to-face professional support, thus necessitating supplementary digital support.

There is a clear need to address children's information and support needs in ways that take account of individual and family circumstances and, therefore, enhances children's adjustment to, and mastery of, the demands of living with a long-term condition. It is acknowledged that the methods used by professionals within the NHS to deliver high-quality information to children has not kept pace with advances in available technology [14]. Given the ubiquity of mobile phone use by children, developing online and mobile apps that support self-management and are used to complement professionals' individualized advice is an important step in providing a range of interventions to support children with long-term conditions [56]. For example, in pediatric diabetes care, a number of online resources have been developed [57]; however, it is unclear how these apps were developed and whether their impact on self-management has been evaluated. There is also emerging evidence that the use of software apps could potentially engage patient groups, which professionals have struggled to reach with more traditional interventions, though further research is needed in this area [58].

Strengths and Limitations

A key strength of our study was the participatory approach using age-appropriate and technology-supported interviews that included drawing and the use of existing software apps; this enabled us to interview children between the ages of 5 and 17 years. Ensuring interviews were a visual and interactive experience encouraged verbal interaction, particularly with 5-10-year-olds who may have more difficulties expressing themselves verbally and are more concrete in their thinking [59].

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Additionally, PPI throughout the study brought a different perspective to our work and helped ensure its relevance to children with CKD and their families.

A final strength of our study was the multidisciplinary research team, which consisted of researchers, an educational technologist, and clinicians, including a clinical psychologist and nurses, with experience of working with children living with CKD and diabetes. Having this range of expertise and different viewpoints benefitted the study and enabled us to explore the transferability of our approach and findings to children living with other long-term conditions.

Our sample included children between the ages of 5 and 17 years and it was evident that children's needs and preferences differ based on many factors, including their age, developmental stage, and individual preferences. However, due to our small sample size, we were only able to reach speculative conclusions regarding their needs and preferences. Further research to explore this issue would be beneficial as part of a phased approach to developing a child-focused software app to support self-management.

Conclusions

Developing an evidence-based mobile app that meets the information and support needs of children with long-term conditions such as CKD will maximize its utility, thereby augmenting their ability to learn to confidently manage their condition and optimize their outcomes. Through working collaboratively with patients, parents, and professionals, and by employing a conceptual framework that explicitly acknowledges the importance of promoting children's self-efficacy, we can offer new insights into the digital support and information needs of patients at different developmental stages. These insights highlight the gaps in current information and support, including that provided via mobile apps, the difficulties experienced by children with a long-term condition, and suggestions for a digital care-management app. This study has provided a responsive framework with which to further develop and evaluate digital app resources for children with CKD.

Acknowledgments

This manuscript reports on independent research funded by a research award from the British Renal Society and the British Kidney Patient Association. This work was also supported by funding from the National Institute for Health Research Clinical Research Network: North Thames. We gratefully acknowledge the following people for their valuable contributions to the study: the children, young people, parents, and professionals who participated in research interviews; the local principal investigators for assistance with local NHS Research and Development processes and for facilitating access to their teams, patients, and parents; the Study Steering Group; and the young people and parents who formed our virtual Research Advisory Group.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Suggestions for the design and usability of a digital care-management app.

[PDF File (Adobe PDF File), 21KB - jmir_v19i7e235_app1.pdf]

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Abbreviations

CKD: chronic kidney disease
MRC: Medical Research Council
N/A: not applicable
NHS: National Health Service
PPI: patient and public involvement

Edited by G Eysenbach; submitted 29.03.17; peer-reviewed by L Whitehead, A McPherson; comments to author 20.04.17; revised version received 08.05.17; accepted 12.05.17; published 04.07.17.

Please cite as:
Nightingale R, Hall A, Gelder C, Friedl S, Brennan E, Swallow V
Desirable Components for a Customized, Home-Based, Digital Care-Management App for Children and Young People With Long-Term, Chronic Conditions: A Qualitative Exploration
J Med Internet Res 2017;19(7):e235
URL: http://www.jmir.org/2017/7/e235/
doi:10.2196/jmir.7760
PMID:28676470

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Original Paper

Preventing Prescription Drug Misuse in Work Settings: Efficacy of a Brief Intervention in Health Consciousness

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Abstract

Background: It is becoming more commonplace for employees to use prescription medication outside of intended use. Opioid and other prescription misuse has implications for the health and productivity of workers. Easy-to-access webinars that help employees learn about alternatives to prescription use may decrease risk.

Objective: The aim of this study was to examine the efficacy of an interactive but brief health consciousness and prescription drug intervention for a diverse sample of employees and show effectiveness via both Internet-delivered webinar and classroom delivery.

Methods: Employees from a variety of workplaces filled out pre- and post-questionnaires upon completion of a one-hour long intervention.

Results: A total of 114 participants completed the pre- and post-questionnaires. Results showed that, compared with before the training, participants reported significantly more knowledge about prescription drug misuse and alternatives to prescription drug use after the training (t_{113}=7.91, P<.001). Moreover, the medium of presentation (ie, face-to-face vs webinar) did not significantly impact effectiveness of the training ($F_{1,98}$=1.15, P=.29).

Conclusions: In both webinar and classroom formats, participants gained knowledge about alternatives to prescription drug use. This intervention appears to be beneficial to employees and assists in the awareness of prescription drug use in general and in the workplace.

(J Med Internet Res 2017;19(7):e242) doi:10.2196/jmir.7828

KEYWORDS

prescription drugs; health; consciousness; education; workplace; substance-related disorders

Introduction

The current “opioid epidemic” has significant implications for employers as prescription misuse impacts productivity [1-3], absenteeism, and safety issues [4,5]. Beyond opioid abuse, stimulant misuse is also a growing concern [6], as workers show a trend of abusing stimulants for their performance effects [7].

Most approaches to prescription drug (Rx) misuse focus on harm reduction and risk mitigation rather than building protective factors, even though the latter can be effective [8]. Most attempts to address Rx issues can be categorized as upstream (policy), midstream (organizational), or direct (individual) [9]. Upstream interventions include physician training, abuse-deterrent formularies, prescriber education, Naloxone education, dose limitations, and use of state Prescription Drug Monitoring Programs [10]. At the organizational level, the National Safety Council suggests drug-free workplace programs, management education on policies pertaining to prescription use, as well as employee education [11]. For direct methods, the Food and Drug Administration (FDA) advises individuals to talk with their doctor, read labels, know medicines, avoid drug interactions, and monitor doses and effects [12]. There is also growing consumer awareness of effective alternatives to prescription drugs to help those at risk [13].

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To help increase primary prevention, we developed a training to educate employees on protective factors, specifically healthy alternatives to prescription drug misuse. People use prescription drugs outside of medical advice to deal with symptoms such as pain, sleeplessness, and lack of energy. Proactively informing those who struggle with these symptoms of healthy alternatives can help them make better choices. An "Empowered Health Consciousness" intervention was designed to help employees identify and, if appropriate, consider using these alternatives. A presentation and accompanying slide deck was developed to educate employees on these issues.

Empowered Health Consciousness may be presented either in person or via webinar as a "lunch and learn" health promotion program. Both the brief classroom and webinar training uses fun, interactive exercises, as well as case studies to educate employees on well-being, brain health, and various approaches to dealing with symptoms (eg, massage and acupuncture for pain). Such features have been shown to increase presentations' effectiveness, including webinars [14]. Webinar presentations have been found effective in previous workplace studies [15,16]. Whereas they have the added benefit of allowing participant involvement [17], we found no studies that compared webinar and classroom interventions for work settings. A pilot study found that health educators perceived the webinar version to be helpful and needed [18].

Accordingly, the current research assessed the impact of the intervention on a sample of employees and considers whether webinar is equivalent to in-person presentation. Employees who volunteered to participate in this research completed pretest items tapping their knowledge of, and attitudes toward, prescription drug risks and alternatives, took part in the intervention (either in person or via webinar), and then completed a posttest version of these same items. Overall, our goal was to provide an initial test of the effectiveness of a brief and positively-oriented program for workers, especially given the rising concern among employers.

Methods

Sample

Potential participants were recruited by email announcements and workplace fliers. Of those who were informed about the webinar, 114 participants volunteered to complete the program and questionnaires (56 out of 98 [57%] were female, aged 18-65 years; 56 out of 86 [65%] were white). Of those, 30 participated in the program as an in-person intervention, and 84 participated on the Web via a webinar software (participation via face-to-face vs webinar was dependent on participants' organizational need and availability; see Limitations). Eighty-seven were employees at small- to medium-sized engineering firms (30-150 employees), 14 were employees at a large health care firm (200-500 employees), and 13 attended through a national Substance Abuse and Mental Health Services Administration-(SAMHSA) sponsored event.

Measure

We created a 10-item measure specifically for this study. Participants were asked 10 questions about prescription drug risks and healthy alternatives on a 5-point Likert-type scale that ranged from 1 (not true about me) to 5 (very true about me). A list of the items in the measure can be found in Table 1.

Table 1. Evaluation of Empowered Health Consciousness: pre-post ratings (N=114).

Survey items	Pretraining Mean (SD[a])	Posttraining Mean (SD)	*t* value[b]	*P* value
I know the differences between proper use, misuse, and abuse of prescription drugs.	4.46 (0.79)	4.71 (0.74)	−3.32	.001
I am confident that I have the skills I need to avoid misuse of prescription drugs.	4.53 (0.66)	4.68 (0.67)	−2.73	.007
I am motivated to understand factors that could lead me to misuse prescription drugs.	4.32 (0.85)	4.56 (0.75)	−3.57	.001
I can identify healthy alternatives for dealing with pain or stress other than use of prescription drugs.	4.15 (0.78)	4.70 (0.59)	−7.95	.001
Staying conscious of my own health can protect me from misusing prescription drugs.	4.41 (0.66)	4.67 (0.61)	−4.37	.001
I clearly understand the reasons for not sharing prescription drugs at work.	4.71 (0.56)	4.84 (0.47)	−2.99	.003
I know things that parents can do to prevent their teenagers from abuse of prescription drugs.	3.45 (1.15)	4.39 (0.80)	−9.62	.001
I have healthy life-style and coping factors that keep me from misusing such drugs.	4.37 (0.74)	4.61 (0.65)	−3.57	.001
I can weigh the benefits and risks of using prescription drugs.	4.43 (0.75)	4.76 (0.52)	−5.39	.001
Overall, I am confident that I can avoid misusing or sharing prescription drugs.	4.62 (0.6)	4.83 (0.48)	−3.93	.001

[a]SD: standard deviation.

[b]Degrees of freedom=113.

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Figure 1. Screenshots of the Empowered Health Consciousness Program.



Procedure

After giving consent, participants responded to a 10-item measure created for this protocol. They were given the intervention either in person or via webinar. The training, entitled **"**Empowered Health Consciousness and Prescription Drugs: Special Focus on Workplace and Parents," comprises a PowerPoint presentation, a Jeopardy game on Rx knowledge (in which participants were divided into teams to answer relevant questions about the topic), handouts, safety guidelines, a review of brain health, and case studies (See Figure 1 for screenshots of the program). Participants are guided to assess three aspects of health consciousness: their motives for Rx use, the risks and benefits of use, and healthy alternatives. Immediately following the intervention, participants filled out the same 10-item measure either in person or on the Web.

Results

As shown in Table 1, paired *t* tests on all 10 items reached statistical significance; participants improved on all of the items over the course of the training. Also, averaging across these items, participants reported significantly more knowledge about prescription drug misuse and alternatives to prescription drug use after the training (overall mean=4.68, standard deviation [SD]=0.49) compared with before the training (overall mean=4.34, SD=0.52, t_{113}=7.91, P<.001). There were no preprogram differences between the face-to-face and webinar participants (t_{113}=1.29, P=.21) . Furthermore, in a mixed analysis of variance (ANOVA), this pre-post difference was not moderated by delivery method (face-to-face vs webinar; $F_{1,98}$=1.15, P=.29). Additional mixed ANOVAs on each of the 10 items confirmed that none of the interactions with delivery method reached significance (Ps>.05).

Discussion

In late 2016, two national surveys pointed to the need for more Rx prevention in workplaces. First, although 70% of employers are negatively impacted by Rx abuse, less than 25% educate workers on prevention [19]. Second, although 30% of benefits managers report that employee Rx addiction (eg, oxycodone and morphine) is prevalent in the populations they serve [20], far fewer provide access to alternative treatments promoted in the training described here.

Current findings provide initial evidence for a solution. Specifically, results suggest a brief and easy-to-deploy training can benefit employees in diverse settings. They gained knowledge about prescription drug use, misuse, and alternatives to use. Encouragingly, one of the strongest improvements occurred with the item, "I can identify healthy alternatives for dealing with pain or stress other than use of prescription drugs." This finding is supported by a comment from one participant who shared that she was grateful for the training because "I can say personally that it hit home. I don't want to be dependent (on Xanax) forever. I definitely need to use our EAP and need to find a good holistic medicine doctor." Furthermore, there was no difference between webinar and in-person presentations, which is advantageous as webinars are more affordable and allow for easier dissemination.

There is bourgeoning evidence, including the present research, to encourage employers to incorporate some type of Rx misuse prevention strategy that brings more positive psychology messages to employees. In comparison, a sole focus on risk reduction could limit effectiveness. As more companies use well-being programs, there is an opportunity to integrate prescription drug education into those programs. Placing these messages in a broader context of positive health efforts helps destigmatize substance abuse prevention [21]. Electronic interventions, such as Empowered Health Consciousness, further support integrating health promotion and substance abuse prevention within work settings.

There are a few limitations to be noted for this project. This was a brief study and the program used is still in the developmental stages. Additionally, a convenience sample was used to facilitate program dissemination. Organizations that were interested in the program being given for free to their employees sent out an email and posted signs around their office notifying potential participants of the voluntary training. Additionally, changes in behavior were not assessed, only changes in knowledge and attitudes, which could lead to behavior change. Future research should assess program impact in a randomized sample of workers, include a comparison no-training control group, and include long-term outcomes that sample prescription use behaviors. Ideally, this type of trial would explore impact for those at-risk for Rx misuse and also ask parents if they had implemented suggested tips to help prevent misuse with their children.

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Acknowledgments

We thank the Substance Abuse and Mental Health Services Administration (SAMHSA) for funding the initial design of the intervention. Thanks to Deborah Galvin (SAMHSA), Ted Miller (Pacific Institute for Research and Evaluation), and Diane Deitz (ISA Associates) for their input in early stages of program design.

Conflicts of Interest

The authors are employed in a for-profit research business that provides training in the program reviewed here. No author profited from the study.

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Abbreviations

ANOVA: analysis of variance
FDA: Food and Drug Administration
SAMHSA: Substance Abuse and Mental Health Services Administration
SD: standard deviation

Edited by G Eysenbach; submitted 05.04.17; peer-reviewed by D Deitz, K Griffin; comments to author 11.05.17; revised version received 17.05.17; accepted 23.05.17; published 06.07.17.

Please cite as:
Lucas G, Neeper M, Linde B, Bennett J
Preventing Prescription Drug Misuse in Work Settings: Efficacy of a Brief Intervention in Health Consciousness
J Med Internet Res 2017;19(7):e242
URL: http://www.jmir.org/2017/7/e242/
doi:10.2196/jmir.7828
PMID:28684383

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Original Paper

A Self-Regulation-Based eHealth Intervention to Promote a Healthy Lifestyle: Investigating User and Website Characteristics Related to Attrition

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Abstract

Background: eHealth interventions can reach large populations and are effective in increasing physical activity (PA) and fruit and vegetable intake. Nevertheless, the effects of eHealth interventions are overshadowed by high attrition rates. Examining more closely when users decide to leave the intervention can help eHealth developers to make informed decisions about which intervention components should be reshaped or simply removed. Investigating which users are more likely to quit an intervention can inform developers about whether and how their intervention should be adapted to specific subgroups of users.

Objective: This study investigated the pattern of attrition in a Web-based intervention to increase PA, fruit, and vegetable intake. The first aim was to describe attrition rates according to different self-regulation components. A second aim was to investigate whether certain user characteristics are predictors for start session completion, returning to a follow-up session and intervention completion.

Methods: The sample consisted of 549 adults who participated in an online intervention, based on self-regulation theory, to promote PA and fruit and vegetable intake, called "MyPlan 1.0." Using descriptive analysis, attrition was explored per self-regulation component (eg, action planning and coping planning). To identify which user characteristics predict completion, logistic regression analyses were conducted.

Results: At the end of the intervention program, there was an attrition rate of 78.2% (330/422). Attrition rates were very similar for the different self-regulation components. However, attrition levels were higher for the fulfillment of questionnaires (eg, to generate tailored feedback) than for the more interactive components. The highest amount of attrition could be observed when people were asked to make their own action plan. There were no significant predictors for first session completion. Yet, two subgroups had a lower chance to complete the intervention, namely male users (OR: 2.24, 95% CI=1.23-4.08) and younger adults (OR: 1.02, 95% CI=1.00-1.04). Furthermore, younger adults were less likely to return to the website for the first follow-up after one week (OR: 1.03, 95% CI=1.01-1.04).

Conclusions: This study informs us that eHealth interventions should avoid the use of extensive questionnaires and that users should be provided with a rationale for several components (eg, making an action plan and completing questions). Furthermore, future interventions should focus first on motivating users for the behavior change before guiding them through action planning. Though, this study provides no evidence for removal of one of the self-regulation techniques based on attrition rates. Finally, strong efforts are needed to motivate male users and younger adults to complete eHealth interventions.

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(J Med Internet Res 2017;19(7):e241) doi:10.2196/jmir.7277

KEYWORDS

physical activity; healthy diet; eHealth; attrition; self-regulation

Introduction

eHealth is defined as "the use of information and communications technology, especially the Internet, to improve or enable health and health care" [1]. Compared with traditional face-to-face health interventions, eHealth interventions have the potential to reach large populations in a time-efficient way. Furthermore, these interventions can be tailored to users' needs and have shown to be effective in changing health behavior, such as increasing physical activity (PA) [2-4] and fruit and vegetable intake [5]. Despite the promising results, the effects of eHealth interventions are often plagued by high attrition rates. With attrition rates reaching 60-80%, loss of participants during the intervention seems to be the rule rather than the exception in eHealth research [6]. Possible effects of the intervention may then be compromised due to low exposure to the intervention content [7]. That way, high attrition rates are a threat for the internal and external validity of the intervention results [8].

According to Eysenbach [9], 2 types of attrition in eHealth can be identified. The first type, called nonusage attrition, refers to attrition from the intervention and occurs when participants stop using the eHealth intervention. This problem can arise at any given moment, for example, when participants do not complete a website session or when they do not return to the website anymore. The second type of attrition refers to participants withdrawing from the study itself. The phenomenon of participants not returning for follow-up assessment sessions is described by the term dropout attrition. Both types of attrition can challenge eHealth research. Nonusage attrition can undermine the potential effect of an intervention (due to low exposure to the intervention content), whereas dropout attrition might influence the power and the results of the study that evaluates the intervention [10].

Investigating patterns of nonusage attrition can provide valuable information for the development of eHealth interventions [9]. By examining when users discontinue the intervention, possible obstacles can be identified. Researchers often describe attrition rates at the end of the intervention and investigate predictors of intervention completion [8,11-13]. However, attrition can occur at all stages of the intervention. To our knowledge, no study has examined nonusage attrition early on in the intervention, that is, during an intervention program. Examining more closely when users decide to leave the intervention can help eHealth developers to make informed decisions about which parts or components of the intervention tool should be redesigned or simply removed. Attrition should thus be investigated as a function of different meaningful intervention components.

Many eHealth interventions require participants to fill out questionnaires for either providing tailored feedback or research purposes. However, it is it not known whether this affects the attrition rates of the eHealth program. Furthermore, self-regulation techniques (eg, action planning, coping planning, and monitoring) play an important role in many behavior change theories [14-16] and are therefore often implemented in eHealth interventions (eg, see [17-19]). These techniques are theory-based and elicit behavior change [20]. However, there is a lack of research that investigates whether participants easily adopt using these techniques, or rather whether the implementation of these techniques in eHealth interventions is related to attrition. Thus, identifying critical components in an intervention, that is, moments during which nonusage attrition peaked, can provide useful information.

Of further importance is to identify who is less likely to complete the eHealth intervention. For example, research shows that the utilization of eHealth tools depends upon the age of its users, with younger adults being more likely to show higher levels of nonusage attrition than older adults [6,21,22]. Also, men and users with a lower level of education have higher chances to show low levels of eHealth utilization [21,23,24]. However, to our knowledge, attrition according to age, sex, or education level has not been thoroughly investigated in self-regulation-based eHealth interventions. Finally, body mass index (BMI) could be predictive for the completion of eHealth interventions, although previous research on the predictive value of BMI in completing weight-loss interventions shows inconsistent results [25-29]. Identifying groups of users who are more likely to quit a Web-based program can inform developers about whether and how an intervention should be adapted to specific subgroups of users. Further research can then help us define the unaddressed needs of these subgroups. By doing so, the reach and effectiveness of future eHealth interventions can be ameliorated.

This paper investigates nonusage attrition from the eHealth intervention "MyPlan 1.0". MyPlan 1.0 is a website that aims to increase PA and the intake of fruit and vegetables in the adult population [30]. This intervention is based on self-regulation theory [14], which is the process of goal selection, goal pursuit, and goal maintenance. MyPlan 1.0 thus includes different self-regulation techniques that can be investigated for their likelihood of increasing or decreasing attrition. The first technique included in MyPlan 1.0 is providing tailored feedback. Therefore, participants complete questionnaires regarding their current behavior and receive advice that compares their behavior with the guidelines and provides examples on how they could improve their behavior. A second technique is coping planning, in which users identify possible obstacles and solutions. The program also contains action planning. Here users define what they want to achieve and when and where exactly they are planning to do so. Also included is self-monitoring of behavior, which is facilitated by prompting users to reflect upon how they will keep track of their behavior (eg, in their diary or via cellphone). Finally, the use of social support is encouraged by providing users the opportunity to email their personal plan to a friend or family member. More information on how the techniques were implemented in the website is described in the

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Multimedia Appendix 1. These techniques were carefully selected based on their potential effectiveness, described in the current literature. Previous research demonstrated the effectiveness of MyPlan 1.0 as a whole to increase PA and the consumption of fruit and vegetables in adults [31-33]. However, like many eHealth interventions, MyPlan 1.0 is challenged by high rates of attrition: at the end of the intervention a loss of 64.0% (235/367) of the participants was observed [32]. In this program, participants that caused nonusage attrition were automatically causing dropout attrition since participants completed all measures in the Web-based program. In this article, we focus on nonusage attrition and aim to identify the components that make people stop using an intervention in which they initially showed interest.

The aim of this paper is two-fold. First, we aim to identify critical moments of attrition in the eHealth intervention MyPlan 1.0 using an explorative and quantitative approach. Therefore, we will describe the rates of website utilization according to the different self-regulation-based intervention components (namely providing feedback, action planning, coping planning, self-monitoring, and social support) and the general components (namely filling in demographic information and filling in a questionnaire). This may help us understand which components in an eHealth intervention discourage users to continue with the program. For this aim, we will also report the usage half-life of MyPlan 1.0, which is the moment where 50% of the users have stopped using the tool [9]. Our second aim is to investigate if certain user characteristics (ie, sex, education, age, and BMI) are predictors of start session completion, returning to a follow-up session, and intervention completion. This may provide information about whether the intervention distinguishes between certain subpopulations of users.

Methods

Participants and Design

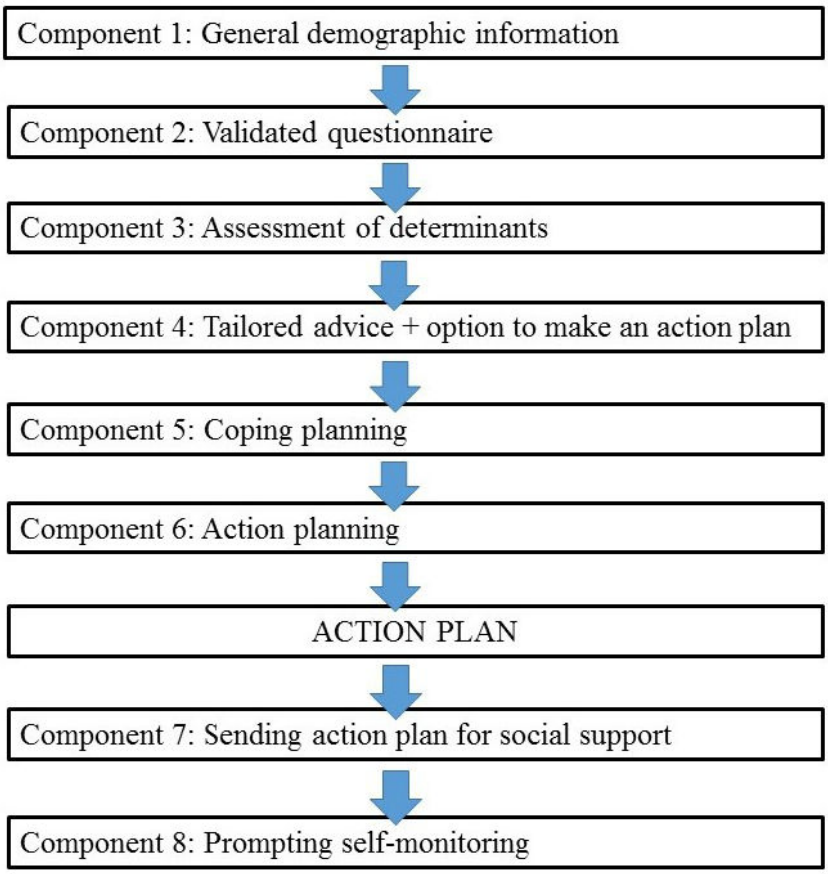
The sample consisted of adults who participated in a Web-based intervention to promote a healthy lifestyle, called MyPlan 1.0, from November 2014 to September 2016. Participants were recruited via the general practice setting. Both researchers in the waiting room and general practitioners provided the participants with a flyer that directed them to the intervention website. There were also tablets available in the waiting room, where participants could start to fill in the intervention program. When they were not able to finish the program in the waiting room, they received a link to complete the intervention program at home. The inclusion criterion was a minimum age of 18 years. All data entered by participants were, just as the information about website use, collected and stored in LimeSurvey (LimeSurvey Project Hamburg, Germany). Participants did not receive any kind of incentive. The study was approved by the Ghent University Hospital Ethics Committee.

Intervention

The Web-based intervention website MyPlan 1.0 was developed using the intervention mapping protocol [30] and has proven to be effective and feasible [32]. The intervention targets behavior change in three domains: PA, fruit intake, and vegetable intake. In a first step, participants choose which behavior they prefer to change. Thereafter, the structure of the intervention is identical for the three behaviors. The intervention consists of 3 sessions: one start session, and two follow-up sessions. In the start session, participants are making personal health action plans for the first time. After 1 week, they get an invitation by email to complete the second session of the intervention (follow-up 1, FU1). In this follow-up session they get feedback on their behavior change and can choose to keep or adapt their personal action plan according to their success or failure. One month after the first session, the third and last session (follow-up 2, FU2) is activated, in which they evaluate their behavior change a second time. The intervention is based upon self-regulation theory [14,34] and guides participants in their behavior change through different mandatory components based on self-regulation techniques (namely providing feedback, action planning, coping planning, self-monitoring, and social support). Figure 1 illustrates the flow of the start session, in which all self-regulation techniques are incorporated. Within this first session, participants start by filling in general demographic information. Thereafter, they complete a validated questionnaire regarding the chosen behavior (International Physical Activity Questionnaire [IPAQ] [35]; The Flemish Fruit Test and Vegetable Test, [36]) and get tailored feedback on their current level of PA or fruit or vegetable intake. For study purposes, participants also fill out an assessment of determinants of behavior change such as self-efficacy and motivation. After the tailored advice, participants can choose to make an action plan or to leave the website. In order to make an action plan, participants complete a coping planning and an action planning component, respectively. In the coping planning component, they identify possible difficulties and make a plan to overcome these barriers. In the action planning component, they are guided to define where, when, and in which way they would like to be physically active or eat more fruit or vegetables. Participants also get the option to state implementation intentions [37,38], that is, to formulate an if-then plan (eg, if I come home from work, I go walking in the neighborhood for half an hour). This information is collected and shown in a comprehensive action plan. Participants can choose to send their action plan to family or friends in order to get social support. At the end, the website asks participants how they are going to keep track of their activity or fruit or vegetable intake in order to prompt self-monitoring of behavior change.

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Figure 1. Overview of the start session components.



Measures and Statistical Analysis

Description of the Nonusage Attrition Pattern

To analyze the nonusage attrition during the intervention (aim 1), the start session was divided into 8 components according to the different self-regulation techniques and the general information part, as described previously and depicted in Figure 1. If the last question of the component was answered or the last choice option was filled in, the component was considered as completed. If not, nonusage attrition occurred during that specific component. Attrition as a function of the different components was described in terms of absolute and relative numbers. Critical components during the follow-up sessions were not analyzed because the self-regulation techniques included in these sessions were very similar to the ones in the start session.

Predictors of Intervention Completion

Besides nonusage attrition in the start session, predictors (ie, users' demographic information) of intervention completion were also investigated (aim 2). Demographic characteristics were obtained from the answers given in the start session of the website intervention. Demographic measures included sex, educational level, age, height, and weight. Regarding educational level, a college degree was considered as high educational level, whereas no education, primary school, and secondary school were considered as low educational level. BMI was calculated by dividing weight (in kilogram) by height (in meter) squared. Participants were classified as not overweight if they had a BMI under 25 kg/m² and as overweight if their BMI was 25 kg/m² or higher.

Completion was defined as follows: if the last question of the start session was filled in, the session was considered as completed. Returning to the website was defined as accessing FU1, or more specifically, "filling in the first question of FU1." If the last question of the last session (FU2) was filled in, the whole intervention was considered as completed. To investigate aim 2, three logistic regression analyses were conducted in SPSS version 23 (IBM Corporation): (1) to identify predictors of start session completion, (2) to investigate predictors of a first return to the website after start session completion (ie, accessing FU1), and (3) to examine predictors of FU2 completion (ie, intervention completion). After checking for multicollinearity, all demographic variables (ie, sex, educational level, age, and BMI) were entered together into the regression as possible predictors. The level of significance was set at $P<.05$.

Results

Participant Characteristics

In total, 549 adults visited the intervention website and were therefore defined as "potential users". However, 127 of them

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only visited the home page and did not register (ie, fill in their name and email address). They were excluded from the analyses since no information about them was available. The remaining 422 were considered as "actual users"; 39.1% (165/422) of them chose to focus on PA, 41.0% (173/422) on fruit intake, and 19.9% (84/422) on vegetable intake. All participants that registered were included in the study, although it has to be noted that some people registered but did not complete (all) demographic measures.

An overview of the participant characteristics can be found in Table 1. In the total sample, 55.7% (235/422) were female and 28.2% (119/422) were male. Furthermore, 41.7% (176/422) of the people had a low educational level, whereas 42.2% (178/422) had a high educational level. The mean age of the sample was 43.92 years (SD 14.23), ranging from 18-81 years. Finally, 48.3% (204/422) of the sample was overweight, whereas 48.6% (205/422) had a normal weight. The mean BMI was 25.96 (SD 5.39) kg/m².

Table 1. Overview of participant's demographic characteristics (N=422).

Characteristics		n (%)	Mean (SD)
Sex			
	Male	119 (28.2)	
	Female	235 (55.7)	
	Missing	68 (16.1)	
Education			
	Low	176 (41.7)	
	High	178 (42.2)	
	Missing	68 (16.1)	
BMI (kg/m²)			25.96 (5.39)
	Overweight	204 (48.3)	
	Not overweight	205 (48.6)	
	Missing	13 (3.1)	
Age (years)			43.92 (14.23)
	Missing	68	

Description of the Nonusage Attrition Pattern

In total, 55.7% (235/422) of the participants completed the start session. Only 43.1% (182/422) of the total sample returned to the first follow-up session. Therefore, the usage half-life is situated between the start session and FU1. Of the total sample, 21.8% (92/422) completed FU2. Hence, at the end of the intervention program, there was a nonusage attrition rate of 78.2% (330/422).

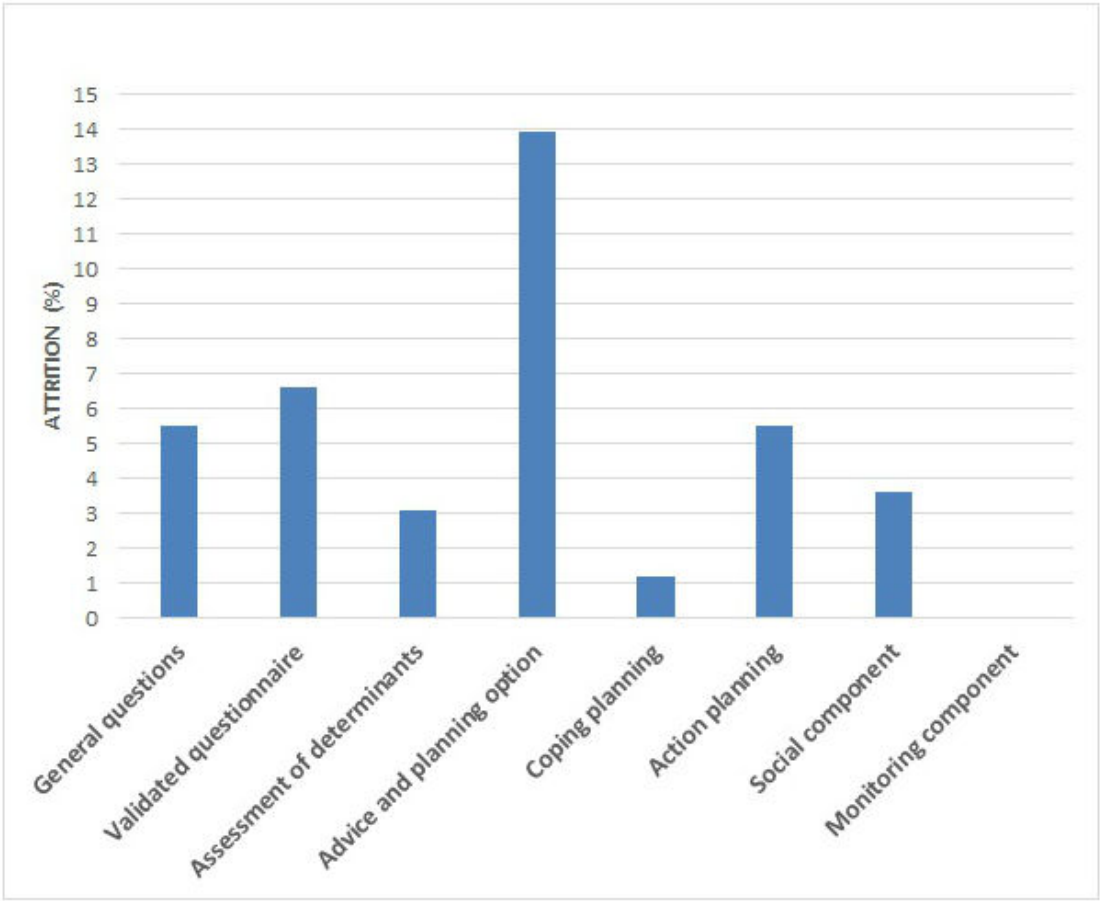
To identify components (eg, action planning and coping planning) in which nonusage attrition is the highest, the start session was divided into eight components, as described in the methods section. The critical moments were defined separately for the three target behaviors (PA, fruit intake, and vegetable intake) in order to get a more detailed insight in possible obstacles during intervention fulfilment. The extent to which attrition occurred per component can be found in Table 2. Results are also visualized in Figures 2-4 for the PA, fruit, and vegetable module, respectively. All components show attrition rates of less than 5%. The only component for which attrition rates are higher than 5% in all three modules is the advice and planning option.

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Table 2. Attrition rates per website component.

Session	Website component	Physical activity (n=165)		Fruit intake (n=173)		Vegetable intake (n=84)	
		n	% (cumulative %)	n	% (cumulative %)	n	% (cumulative %)
Start session		65	39.4 (39.4)	85	49.1 (49.1)	37	44.0 (44.0)
	General questions	9	5.5 (5.5)	5	2.9 (2.9)	0	0 (0)
	Validated questionnaire	11	6.6 (12.1)	7	4.0 (6.9)	5	6.0 (6.0)
	Assessment of determinants	5	3.1 (15.2)	8	4.7 (11.6)	5	5.9 (11.9)
	Advice and planning option	23	13.9 (29.1)	55	31.8 (43.4)	22	26.2 (38.1)
	Coping planning	2	1.2 (30.3)	3	1.7 (45.5)	2	2.4 (40.5)
	Action planning	9	5.5 (35.8)	3	1.7 (46.8)	1	1.2 (41.7)
	Social component	6	3.6 (39.4)	4	2.3 (49.1)	2	2.3 (44)
	Monitoring component	0	0 (39.4)	0	0 (49.1)	0	0 (44)
Follow-up 1		57	34.5 (73.9)	40	23.2 (72.3)	27	32.2 (76.2)
Follow-up 2		7	4.3 (78.2)	4	2.3 (74.6)	8	9.5 (85.7)

Figure 2. Attrition percentage per website component in the start session of the physical activity module.



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Figure 3. Attrition percentage per website component in the start session of the fruit module.

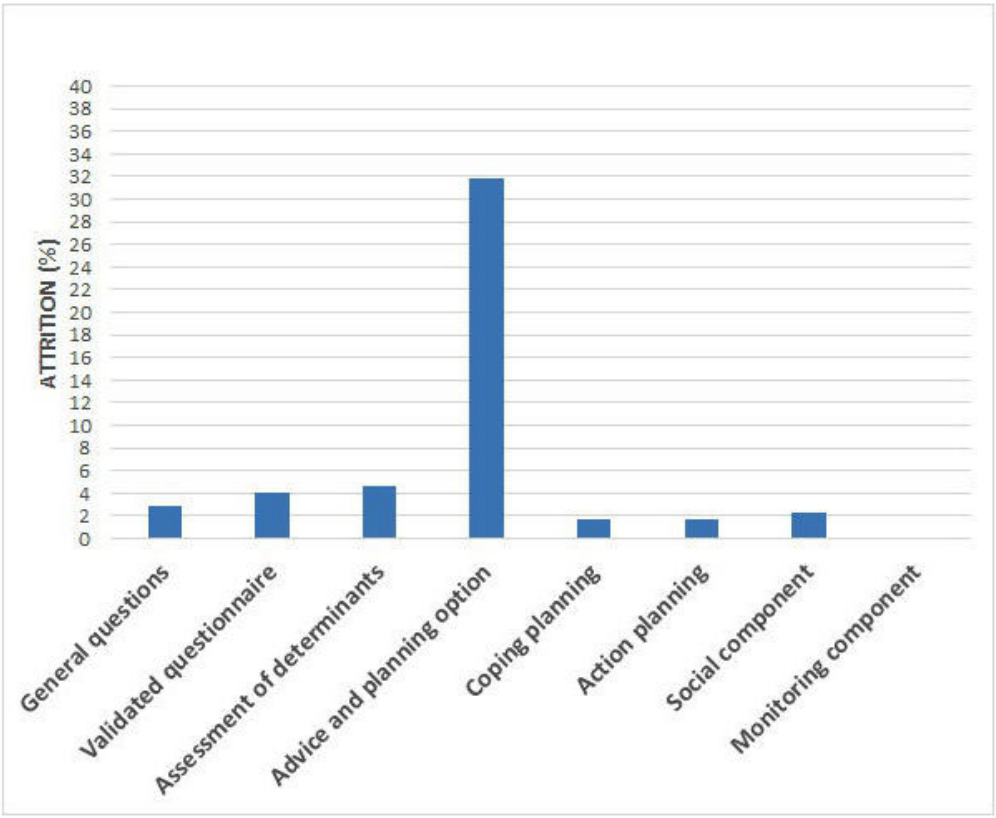
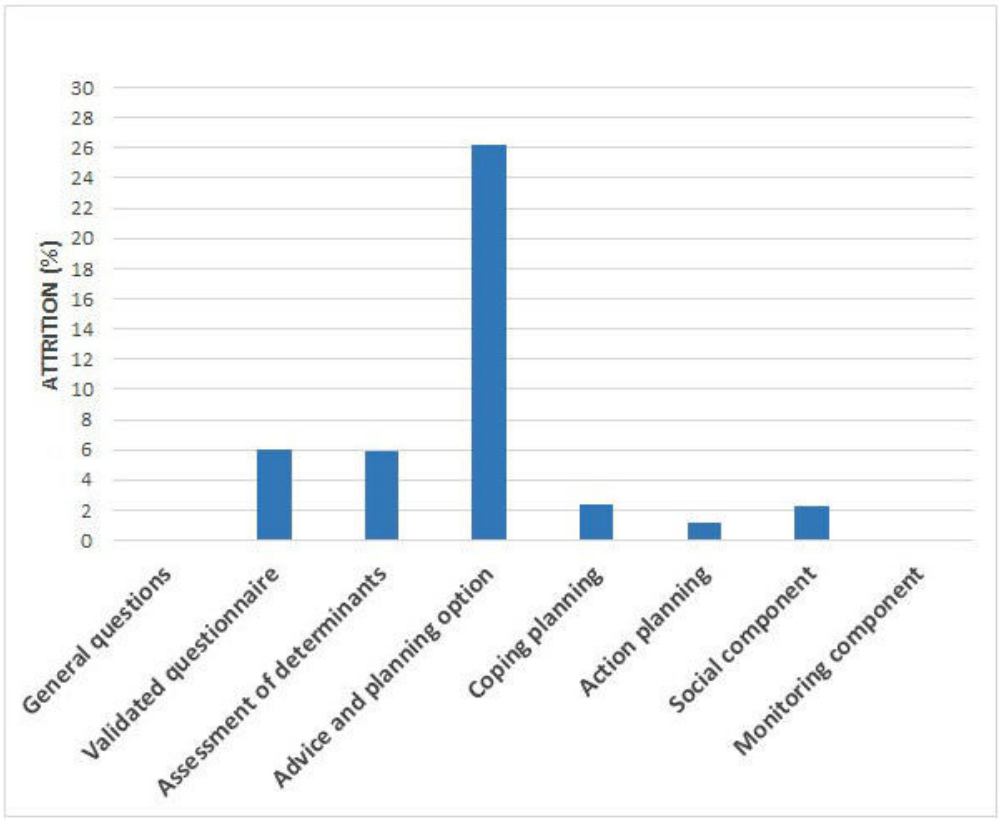


Figure 4. Attrition percentage per website component in the start session of the vegetable module.



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Table 3. Predictors for start session completion, returning after start session completion, and intervention completion.

Session		Exp (B)[a]	SE[b]	95% CI
Start session completion				
	Sex	1.35	0.23	0.85-2.12
	Education	1.10	0.22	0.72-1.68
	Age	1.01	0.01	0.99-1.02
	Overweight or not	1.15	0.23	0.74-1.79
Returning to FU1[c]				
	Sex	1.22	0.24	0.77-1.94
	Education	1.07	0.22	0.69-1.64
	Age	1.03	0.01	1.01-1.04
	Overweight or not	1.41	0.23	0.90-2.20
Intervention completion				
	Sex	2.24	0.31	1.23-4.08
	Education	1.15	0.26	0.69-1.92
	Age	1.02	0.01	1.00-1.04
	Overweight or not	1.28	0.27	0.75-2.16

[a]Exp(B): exponential function of the coefficient B. This indicates the odds ratio for the predictor.

[b]SE: standard error.

[c]FU1: follow-up 1.

Predictors of Intervention Completion

There were no significant predictors for start session completion (see Table 3). However, there was one significant predictor for returning after start session completion (see Table 3). Age group significantly predicted whether participants would return to the website after 1 week (Odds ratio [OR]=1.03, 95% CI 1.01-1.04), with older participants being more likely to return than younger participants. There were two significant predictors for FU2 completion as well (see Table 3). Both age (OR=1.02, 95% CI 1.00-1.04) and sex (OR=2.24, 95% CI 1.23-4.08) could predict intervention completion, with older participants and women being more likely to complete the intervention.

Discussion

Principal Findings

This paper investigated both website and user characteristics related to nonusage attrition levels from a self-regulation-based eHealth tool (MyPlan 1.0). First, possible obstacles were identified by exploring attrition rates for the self-regulation techniques and general components of the start session. Second, we investigated which user characteristics predicted whether users finished the start session, returned to the website (ie, logged in for the second session), and completed the whole intervention (ie, the third session). Results show an overall attrition rate of 78.2%. Although attrition rates were similar for the various components, attrition levels were higher for filling out questionnaires (eg, to generate tailored feedback) than for the more interactive components (such as action planning, coping planning, etc). The highest amount of attrition could be observed when people were shown the advice and asked to make their own action plan. There were no significant predictors for first session completion. Yet, younger adults were less likely to return to the website for the follow-up after 1 week. Furthermore, male users and younger adults had a lower chance to complete the intervention.

A notable finding is that a large amount of users did not register when visiting the website. Previous research has already indicated that a registration procedure can be a barrier for starting an intervention [39]. This could be due to the loss of anonymity: people might be concerned about their privacy or afraid of spam mail. Providing information about the necessity to register and how personal data will be used, could overcome this problem [39]. This result further shows that not only piloting the active components (ie, behavior change techniques such as action planning), but also the more technical components (eg, registration procedure) of eHealth programs in the population of interest is very important to investigate the acceptability and feasibility of the whole intervention.

The attrition rates were similar for the various health behaviors, which may indicate that our findings are not limited to one particular behavior. Furthermore, we found that attrition levels were higher during the first components than during the later ones. This might be due to the fact that the first three components included questionnaires, whereas the latter components contained self-regulation techniques that allowed more interaction between the website and the user (eg, the user indicates possible barriers and the website offers possible solutions). Moreover, a lot of questions were added for research purposes without immediate value for the users of the intervention. Completing long questionnaires without knowing the specific purpose might have discouraged users and

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consequently made them stop using the intervention. Previous research already indicated that including lengthy questionnaires in an eHealth tool should be discouraged [39]. Although questionnaires are needed to enable tailored feedback, which has shown to be more effective than generic [40], the length of these questionnaires should be kept to a minimum. Furthermore, it might also be important to inform users about the necessity of providing information in order to make the tailoring possible. Tailoring could be made explicit by explaining how users' answers shape the advice they get. Another possible explanation for higher attrition rates during the first components could be that users tend to discontinue an intervention mostly at the beginning of an intervention. When already further advanced in the intervention, users might be more motivated and have invested more, so they are less likely to quit. For example, we could observe that users who completed the first follow-up session were highly likely to complete the second follow-up session (attrition rates for FU2<10%).

The most critical moment (ie, the component for which attrition levels were the highest) occurred when users were shown the tailored advice and were asked whether they would like to create an action plan. Since previous research indicated that most users experienced the advice as personally relevant, interesting, and clear [32], we assume that users were rather discouraged by the question to make a plan than by seeing the advice. A possible explanation for attrition at this moment could be that users have gained what they needed from the intervention (eg, see [41]). From this perspective, attrition is not necessarily detrimental. When people are reaching the health norms, no intervention to change their behavior is needed. The fact that people are shown feedback on their behavior and potentially realize that they are reaching the norms might result in attrition at that moment. An additional analysis showed indeed that many of the users that were already physically active or eating enough fruit and vegetables at baseline, quitted the intervention at this point. For PA, 20 of the 113 users who met the guidelines, quitted at this moment, whereas in the fruit and vegetable module this was 28 of the 29 and 7 of the 7 users, respectively. Providing users with feedback regarding whether or not they reach the health norms can thus be beneficial as the original sample is narrowed down to a sample mainly consisting of users that the intervention aims to target.

However, other participants who did not meet the guidelines stopped using the intervention: for PA, 3 out of 32 users; for fruit, 27 out of 136 users; and for vegetables, 16 users out of 77. There are several possible reasons for attrition at this moment (ie, the choice option to make a personal action plan) in the target population. First, since the website was openly accessible, many users might not have been motivated enough to actually improve the chosen health behavior. Previous research has already indicated that people who are not motivated to change their health behavior will be reluctant to make specific plans to do so [42]. Open-access eHealth tools might attract a subgroup of users who are still ambivalent toward change (contemplators) (Stages of Change; [43]). These users are likely to explore the website without actually making specific plans for behavior change. According to the Stages of Change theory, these users should not be pushed toward immediate behavior change but provided with information and persuasive arguments to increase their motivation to change [43]. This could be implemented in eHealth interventions by giving users tailored information in relation to the stage they are in (eg, providing knowledge vs helping to plan change) and by providing the opportunity to easily return to the website, when they feel ready. Second, users might perceive the creation of an action plan as a more demanding task than answering multiple choice questions. Third, users might not have been aware of the advantages of making a specific plan to increase their PA, fruit or vegetable intake, and might have had the idea that the information and tailored advice were sufficient to put their newly elicited intentions into action. To overcome the latter two problems, it will be important that eHealth tools clearly explain why creating a specific action plan is beneficial during behavior change. Furthermore, not only highlighting the importance of creating an action plan but also communicating this component to the users in an engaging way is required. Components that cause high attrition rates should not immediately be thrown overboard, but they demand a process of reshaping. Researchers should search for a way to present theoretical components in an attractive way, for example, by minimizing the cognitive effort involved in component-specific tasks. Further qualitative research with possible users can help us understand why this component elicited high levels of attrition and can provide valuable information for reshaping the intervention.

We also explored which user characteristics predict returning to the website and completing the first and last module. We found that 2 subgroups had a lower chance to complete the intervention, namely male users and younger adults. Younger adults were also less likely to return to the website after 1 week. Male users were less likely to start with the intervention as well (28.2% male users in comparison with 55.7% female users in the sample). The phenomenon of younger users and male users being more likely to discontinue an intervention has been described as a recurring problem in eHealth [6,11,21,22]. Furthermore, previous research with MyPlan 1.0 showed that older users found the personal advice more interesting, informative, and motivating than the younger users did [32]. New opportunities to motivate younger adults and male users to use eHealth for an extended period of time need to be explored. Specifically involving these subgroups during the development of an eHealth intervention could help to make the intervention more acceptable. For example, Vandelanotte et al [44] conducted focus groups with middle-aged men regarding website and mobile-phone delivered PA and nutrition interventions and found that men are willing to use Web-based interventions provided that these interventions are quick and easy to use. Remarkably, education or BMI did not predict attrition in this eHealth intervention. This indicates that the intervention does not distinguish between low and high educated users and can be applied in an overweight population. Previous qualitative research already showed that the intervention was well accepted for high and low educated users [32].

Strengths and Limitations

This study has several strengths. To our knowledge, this is the first study to investigate nonusage attrition during users' first

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use of an eHealth intervention. Many articles have investigated attrition in eHealth but most of them focused on attrition related to the follow-up sessions [6,24]. Furthermore, this study was also the first to investigate attrition according to different website self-regulation components. Second, this study was conducted with a relatively large group of users with a balanced distribution in age, educational level, and BMI. Third, MyPlan 1.0 always offers users the possibility to log out and save their answers. So when users discontinue using the intervention because they are disturbed, they always had the possibility to continue on a later moment in time. Therefore, nonusage attrition here is most likely caused by the program itself rather than by external events.

This study has also some limitations. First, there was a disproportion in men versus women (28.2% vs 55.7%, respectively, cf. Table 1). Second, nonusage attrition was calculated based on the last mandatory question of each component. Therefore, no conclusions regarding specific questions within a certain component can be made. Third, the intervention only targeted PA, fruit intake, and vegetable intake for behavior change. More research is needed to investigate attrition in interventions targeting other behaviors (eg, smoking and weight loss). Fourth, we do not know why people stopped using the intervention during the specific intervention components. Therefore, further qualitative research might reveal why people struggle with certain components and provide insight in how the implementation of self-regulation techniques can be improved.

Conclusions

In conclusion, this study indicates that eHealth developers should be aware that attrition already occurs during the first contact with the program and that lessons can be learned by analyzing attrition patterns. Besides investigating website characteristics, also exploring the predictive value of user characteristics is important to gain insight in the users' needs. Combining these findings with qualitative research can help developers make informed decisions when adapting and optimizing intervention programs.

Acknowledgments

The authors, Louise Poppe and Maïté Verloigne, are funded by the Research Foundation – Flanders (FWO). We would also like to acknowledge Dr Jolien Plaete for the development of MyPlan 1.0 and her contribution to the data gathering.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Implementation of the self-regulation techniques in MyPlan 1.0.

[PDF File (Adobe PDF File), 730KB - jmir_v19i7e241_app1.pdf]

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Abbreviations

PA: physical activity
BMI: body mass index
FU1: follow-up 1
FU2: follow-up 2
IPAQ: International Physical Activity Questionnaire

Edited by T Kool; submitted 06.01.17; peer-reviewed by A Rebar, L Morrison; comments to author 10.02.17; revised version received 06.04.17; accepted 26.04.17; published 11.07.17.

Please cite as:
Van der Mispel C, Poppe L, Crombez G, Verloigne M, De Bourdeaudhuij I
A Self-Regulation-Based eHealth Intervention to Promote a Healthy Lifestyle: Investigating User and Website Characteristics Related to Attrition
J Med Internet Res 2017;19(7):e241
URL: http://www.jmir.org/2017/7/e241/
doi:10.2196/jmir.7277
PMID:28698168

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Original Paper

Use of a Connected Glucose Meter and Certified Diabetes Educator Coaching to Decrease the Likelihood of Abnormal Blood Glucose Excursions: The Livongo for Diabetes Program

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Abstract

Background: The Livongo for Diabetes Program offers members (1) a cellular technology-enabled, two-way messaging device that measures blood glucose (BG), centrally stores the glucose data, and delivers messages back to the individual in real time; (2) unlimited BG test strips; and (3) access to a diabetes coaching team for questions, goal setting, and automated support for abnormal glucose excursions. The program is sponsored by at-risk self-insured employers, health plans and provider organizations where it is free to members with diabetes or it is available directly to the person with diabetes where they cover the cost.

Objective: The objective of our study was to evaluate BG data from 4544 individuals with diabetes who were enrolled in the Livongo program from October 2014 through December 2015.

Methods: Members used the Livongo glucose meter to measure their BG levels an average of 1.8 times per day. We estimated the probability of having a day with a BG reading outside of the normal range (70-180 mg/dL, or 3.9-10.0 mmol/L) in months 2 to 12 compared with month 1 of the program, using individual fixed effects to control for individual characteristics.

Results: Livongo members experienced an average 18.4% decrease in the likelihood of having a day with hypoglycemia (BG <70 mg/dL) and an average 16.4% decrease in hyperglycemia (BG >180 mg/dL) in months 2-12 compared with month 1 as the baseline. The biggest impact was seen on hyperglycemia for nonusers of insulin. We do not know all of the contributing factors such as medication or other treatment changes during the study period.

Conclusions: These findings suggest that access to a connected glucose meter and certified diabetes educator coaching is associated with a decrease in the likelihood of abnormal glucose excursions, which can lead to diabetes-related health care savings.

(J Med Internet Res 2017;19(7):e234) doi:10.2196/jmir.6659

KEYWORDS

SMBG; blood glucose self-monitoring; diabetes remote monitoring; diabetes management; diabetes mellitus; self-care

Introduction

Diabetes mellitus affects over 387 million people worldwide. Its prevalence has increased dramatically over the past two decades (from 9.8% to 12.4% in the United States), with the costs of diabetes now estimated at over US $150 billion annually in the United States [1-3]. Blood glucose (BG) excursions out of the normal range (70-180 mg/dL, or 3.9-10.0 mmol/L [4]) are important drivers of these extraordinary costs, often leading to unnecessary emergency department visits, hospitalization, urgent care visits, and office visits as well as missed work days.

Self-monitoring of BG (SMBG) is an integral part of successful diabetes management. Self-monitoring of BG has been demonstrated to be a beneficial approach for the achievement

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of long-term glycemic control in patients with both type 1 [5] and type 2 diabetes [6]. It also supports preventive strategies for acute and chronic complications of diabetes by increasing a patient's awareness of hyperglycemia and hypoglycemia [7].

Traditional BG meters provide glucose measurements and store these data within the meter. These data must be actively retrieved and analyzed by the user, health care provider, software, or mobile app to guide treatment decisions [3,8-10]. The Livongo for Diabetes Program, currently available in the United States which is offered directly to patients or as a benefit through their self-insured employer, provider, or health insurance, leverages cloud technology to offer patients (1) a cellular technology-enabled, two-way messaging device that measures BG, centrally stores the glucose data and other contextual data, and delivers relevant algorithmic messages back to the individual; (2) unlimited glucose test strips, and (3) access to a team of certified diabetes educators (CDEs) for questions, goal setting, and immediate support in the setting of extreme glucose excursions.

An "alert" interaction between patients and a Livongo CDE coach occurs when a BG value transmitted through the meter is over 400 mg/dL (22.2 mmol/L) or below 50 mg/dL (2.8 mmol/L), or whatever thresholds a member elects. Approximately 27% of the members have received alert outreach from the CDE team. Patients may also interact with a Livongo CDE coach through a telephonic, one-to-one scheduled coaching session. Over 10% of members have completed at least one of these scheduled coaching sessions.

Other educational interactions include algorithmic, personalized messages that are sent through the meter in response to each BG reading. For example, if a BG value is below 50 mg/dL, the message on the BG meter will read "Your reading is very low, drink 4 oz of juice or take 4 glucose tabs and check BG again in 15 minutes." If the BG value is above 400 mg/dL, the message will read "Drink a glass of water, take medication as prescribed and check BG again in 30 minutes."

We hypothesized that the tools provided to Livongo members would decrease the likelihood of BG excursions outside of the normal glucose range (70-180 mg/dL or 3.9-10.0 mmol/L).

Methods

Study Design and Data

We collected registration data from individuals with diabetes who enrolled in the program between October 1, 2014 and December 30, 2015. This member-input data included sex, date of birth, diabetes type, insulin use, date of diagnoses, and other health-related information.

We collected BG data on each member using a cellular, cloud-connected BG meter that was shipped to each individual with test strips after registration. The BG readings and member-input details (such as how the member is feeling; relation of BG reading to meal or exercise, insulin taken, carbohydrates eaten) were automatically transmitted to the cloud in real time. All members used the same version of the glucose meter, and no significant device changes were made during the study period. Members with fewer than two total glucose readings were excluded from the analysis because no BG comparison could be made over time. No specific guidelines about BG testing frequency were given to members; rather, they were instructed to follow their health care provider's advice.

Key Variables

The main outcomes of interest were binary variables derived from the BG values collected from the meter. We defined a day with hyperglycemia as having at least one BG measure above 180 mg/dL in that day. We defined a day with hypoglycemia as having at least one BG measure below 70 mg/dL in that day.

We linked key variables from the registration data with the BG data using the individual identifier. These variables were age, sex (female, male), diabetes type (type 1, type 2, and unknown), and insulin use.

Statistical Methods

We fit a series of logistic regression models to understand the predicted probability of hyperglycemia (days with BG >180 mg/dL) or hypoglycemia (days with BG <70 mg/dL) in months 2 to 12 compared with month 1.

In the absence of BG data prior to enrollment in Livongo, we used month 1 as a proxy for baseline. We hypothesized that members would have a lower probability of hyperglycemic and hypoglycemic events as their time in the program increased.

We included a fixed effect for each individual in order to control for all unobserved heterogeneity across members that may be correlated with the independent variables (ie, presence of a day with hypoglycemia or hyperglycemia in a given month), including lifestyle or the propensity to use technology that might influence BG control [11]. That is, $Y_{it} = \beta_{oi} + \beta_2 month2 + \beta_3 month3 + \ldots + \beta_{12} month12 + \varepsilon_{it}$, where Y_{it} is member-days with BG >180 or <70 mg/dL for individual i in month t; β_{oi} is the individual intercept that is swept out in the fixed-effects model; and $\beta_s \ldots \beta_{12}$ represents the effects in months 2 to 12 compared with month 1.

Next, we stratified participants by insulin use, diabetes type, sex, insulin use, and age group (18-44, 54-64, ≥65). We conducted all modeling and statistical analyses using Stata 13 (StataCorp LP).

Results

Of 4974 total Livongo members, 4544 had at least two BG measures during the period and were included in the analysis. Over the entire study period, members were enrolled for a mean of 95 days, and the mean total number of BG measurements was 114. Table 1 reports descriptive statistics for the sample population and Figure 1 shows the distribution of time in the program across members.

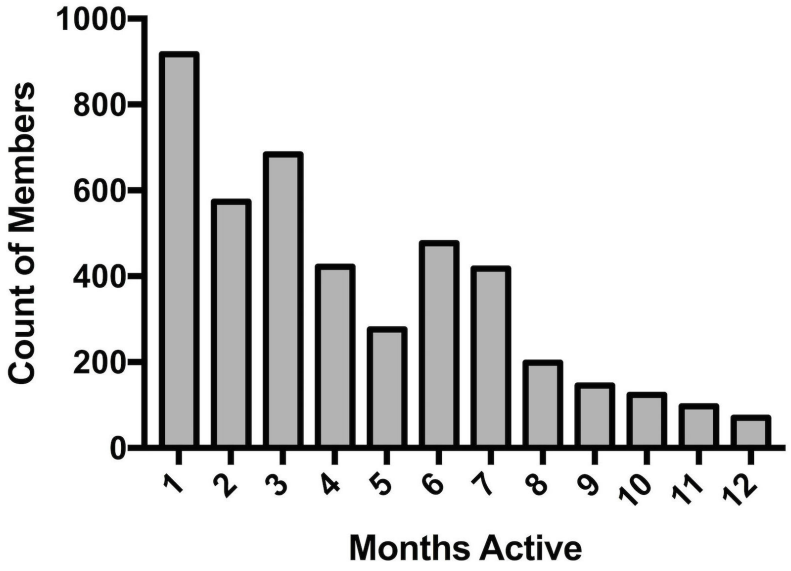
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Table 1. Descriptive characteristics of the study population of Livongo members with more than 1 blood glucose (BG) check (n=4544)[a].

Characteristics		n (%) or mean (SD)
Female, n, (%)		2499 (55.00)
Age (years), n (%)		
	18-44	1254 (27.60)
	45-64	2853 (62.79)
	≥65	436 (9.60)
Diabetes type, n (%)		
	1	709 (15.60)
	2	3303 (72.69)
	Unknown	532 (11.71)
Insulin use, n (%)		
	Yes	1704 (37.50)
	No	2213 (48.70)
No. days of Livongo participation, mean		95
Frequency of BG checks per day, mean		1.8
Mean no. of days with BG >180 mg/dL, n (%)		31.7 (33.4)
	Within-person SD	35.2%
	Between-person SD	34.2%
Mean no. of days with BG <70 mg/dL, n (%)		5.8 (6.1)
	Within-person SD	20.4%
	Between-person SD	11.9%
BG (mg/dL), mean (SD)		152 (54)
	Within-person SD	39
	Between-person SD	54

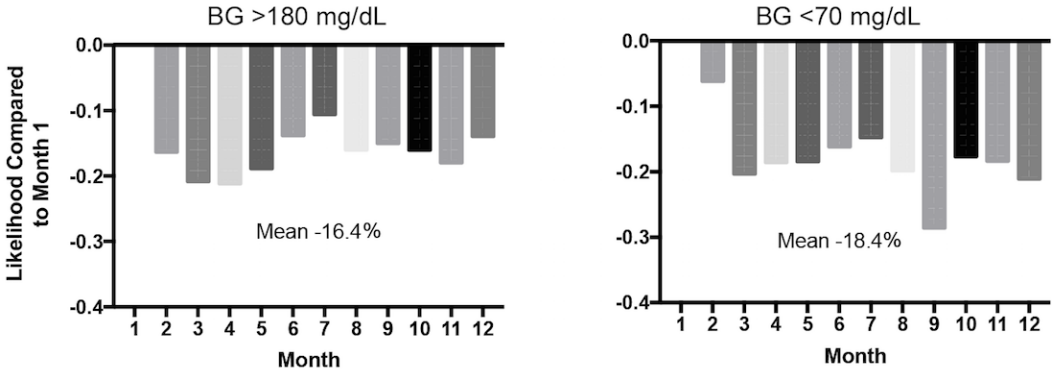
[a]Proportions do not always sum to 100 due to missing values.

Figure 1. Distribution of members across months of Livongo program participation.



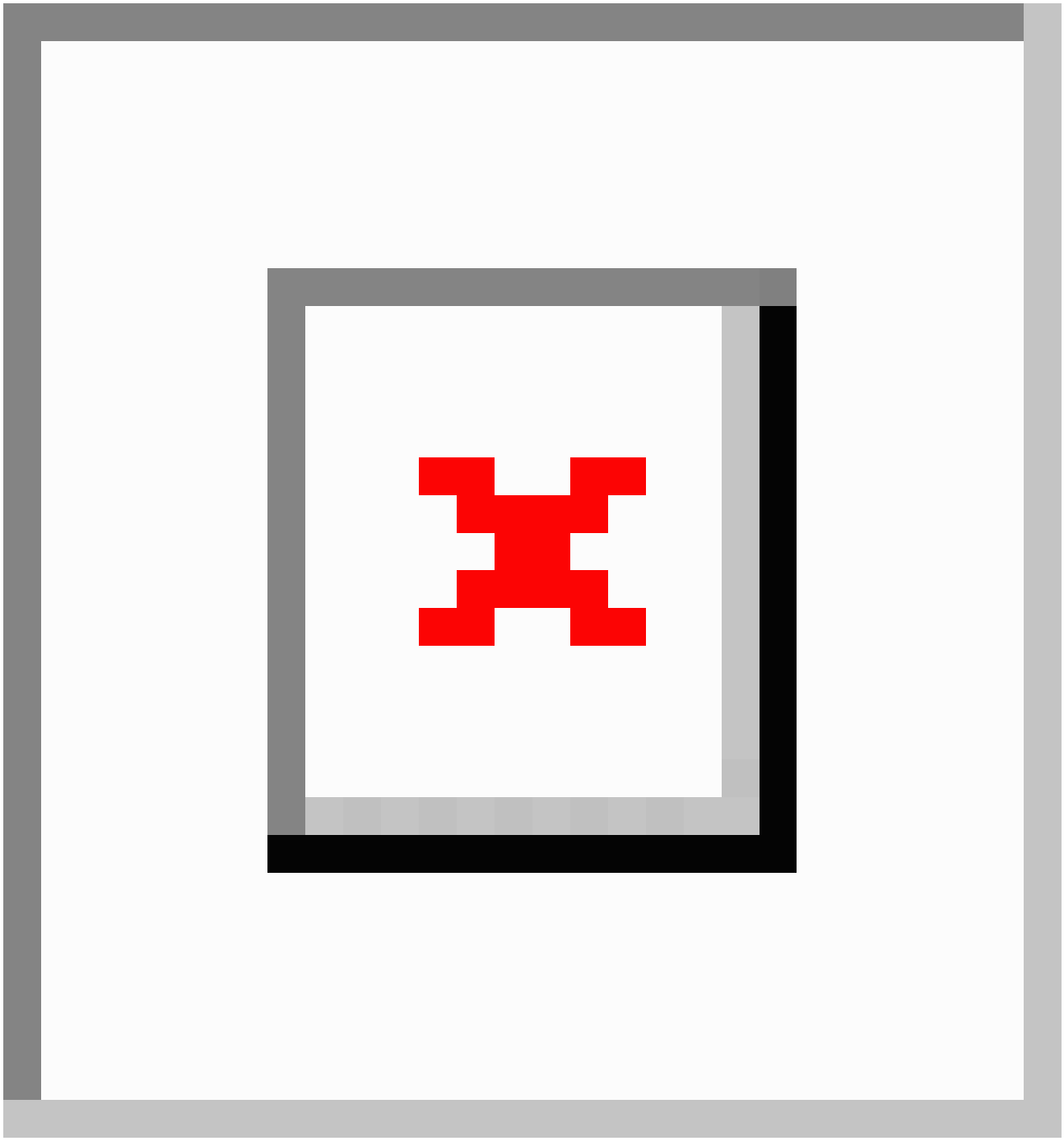
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Figure 2. Likelihood of having blood glucose (BG) >180 mg/dL (left) and <70 mg/dL (right) in months 2-12, compared with month 1, for all members.



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Figure 3. Likelihood of blood glucose (BG) >180 mg/dL (left, top and bottom) and <70 mg/dL (right, top and bottom) in months 2-12, compared with month 1, for users (top; n=1704) and nonusers (bottom; n=2213) of insulin.



Over the entire time period, the mean proportion of days with a BG value above 180 mg/dL was 33.4% with a within-person standard deviation of 35.2% and between-person standard deviation of 34.2%. The mean proportion of days with a BG value below 70 was 6.1% with a within-person standard deviation of 20.4% and a between-person standard deviation of 11.9%. More than half of individuals were female (55%), 15.6% had type 1 diabetes, 37.5% used insulin, and over half of the population (52.1%) had been active on Livongo for 4 or more months at the time of the analysis.

The mean BG for the entire population was 152 (SD 54) mg/dL (8.4, SD 3.0 mmol/L) over the 12 months and it was significantly higher for members with type 1 (163 mg/dL, or 9.0 mmol/L) compared to those with type 2 diabetes (150 mg/dL, or 8.3 mmol/L $P<.001$).

Figure 2 displays the predicted probabilities of hyperglycemia and hypoglycemia for the entire population. On average, the likelihood of having a day with a high BG reading (>180 mg/dL) in months 2-12 was 16.4% lower than in month 1. Specifically, in month 3, the likelihood of having a day with a hyperglycemic event was 21% lower than in month 1 (95% CI –0.195 to –0.131). For hypoglycemia, for each month, the likelihood of having a low BG reading (<70 mg/dL) was 18.4% lower than in month 1. In month 9, for example, the likelihood of having a hypoglycemic event was 29% lower (95% CI –0.105 to –0.018).

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Figure 3 presents the results for hyperglycemia and hypoglycemia stratified by insulin use. For those who reported using insulin at Livongo program registration (n=1704), the likelihood of a day with hyperglycemia was decreased on average by 8.4% and the likelihood of hypoglycemia decreased by 12.5% in months 2-12 compared with month 1 (Figure 3, top). Individuals who reported not using insulin at registration experienced the biggest reduction in days with hyperglycemia by 25.2%, but also experienced an overall increase in hypoglycemic events of 6.7% starting in month 6 of the program (Figure 3, bottom). Changes in medication use were not systematically captured from individuals during the study period.

Discussion

Our findings show that use of a technology-enabled connected glucose meter combined with open access to CDE support is effective in improving BG excursions for a diverse real-world population of adults with diabetes. Health care delivery based on episodic, in-person interactions between health care teams and patients does not fully address the real-time needs of patients with diabetes [12], which is a data-intensive condition requiring continuous management and the support of a multidisciplinary team. Tools provided by Livongo enable patients with diabetes to track their progress, and to collaborate with their providers and others such as family and friends who are positioned to provide critical support for patients who want to take an active role in managing their health. Additionally, this self-management program, like other technology-enabled solutions, can be a cost-effective strategy by empowering patients with engaging tools.

The limitations of this analysis include, first, that we did not have BG data for members prior to their enrollment in the Livongo program. We therefore used the first month of program participation as a proxy for baseline. This may underestimate the program's impact, and our results should be interpreted as conservative.

Second, we were unable to capture medication or other treatment changes that can affect BG excursions, which could be relevant to the increased likelihood of hypoglycemia seen in members who reported not using insulin at the beginning of the program. In this group, 77.00% (3499/4544) of members reported taking oral medications and 16.99% (772/4544) reported taking no diabetes-related medications at baseline. Improved medication adherence and optimization of these members' medication regimen to include starting insulin or an oral medication, such as a sulfonylurea, that can cause hypoglycemia could explain this finding.

Third, examination of overall diabetes control by laboratory-based hemoglobin A_{1c} assessment would have been useful to better understand whether the reduced frequency of hyperglycemic events in people with type 2 diabetes drove overall hemoglobin A_{1c} improvement, since the magnitude of either hypoglycemia or hyperglycemia was not factored into our model.

In summary, we examined a real-world population of people with diabetes using the connected Livongo meter and the Livongo for Diabetes Program to support diabetes self-care. Using the first month of the program as a baseline, the likelihood of both having a day with BG below 70 mg/dL and having a day with BG above 180 mg/dL decreased across the population. This is an important finding, as extreme hypoglycemic and hyperglycemic excursions are significant drivers of quality of life and health care costs for people with diabetes.

Conflicts of Interest

All authors were employees of or consultants for Livongo Health at the time of analysis.

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Abbreviations

BG: blood glucose
CDE: certified diabetes educator

Edited by A Moorhead; submitted 17.09.16; peer-reviewed by L Whitehead, M Peeples; comments to author 15.10.16; revised version received 18.05.17; accepted 10.06.17; published 11.07.17.

Please cite as:
Downing J, Bollyky J, Schneider J
Use of a Connected Glucose Meter and Certified Diabetes Educator Coaching to Decrease the Likelihood of Abnormal Blood Glucose Excursions: The Livongo for Diabetes Program
J Med Internet Res 2017;19(7):e234
URL: http://www.jmir.org/2017/7/e234/
doi:10.2196/jmir.6659
PMID:28698167

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Original Paper

Effectiveness of Digital Medicines to Improve Clinical Outcomes in Patients with Uncontrolled Hypertension and Type 2 Diabetes: Prospective, Open-Label, Cluster-Randomized Pilot Clinical Trial

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Abstract

Background: Hypertension and type 2 diabetes mellitus are major modifiable risk factors for cardiac, cerebrovascular, and kidney diseases. Reasons for poor disease control include nonadherence, lack of patient engagement, and therapeutic inertia.

Objective: The aim of this study was to assess the impact on clinic-measured blood pressure (BP) and glycated hemoglobin (HbA1c) using a digital medicine offering (DMO) that measures medication ingestion adherence, physical activity, and rest using digital medicines (medication taken with ingestible sensor), wearable sensor patches, and a mobile device app.

Methods: Participants with elevated systolic BP (SBP ≥140 mm Hg) and HbA1c (≥7%) failing antihypertensive (≥2 medications) and oral diabetes therapy were enrolled in this three-arm, 12-week, cluster-randomized study. Participants used DMO (includes digital medicines, the wearable sensor patch, and the mobile device app) for 4 or 12 weeks or received usual care based on site randomization. Providers in the DMO arms could review the DMO data via a Web portal. In all three arms, providers were instructed to make medical decisions (medication titration, adherence counseling, education, and lifestyle coaching) on all available clinical information at each visit. Primary outcome was change in SBP at week 4. Other outcomes included change in SBP and HbA1c at week 12, and low-density lipoprotein cholesterol (LDL-C) and diastolic blood pressure (DBP) at weeks 4 and 12, as well as proportion of patients at BP goal (<140/90 mm Hg) at weeks 4 and 12, medical decisions, and medication adherence patterns.

Results: Final analysis included 109 participants (12 sites; age: mean 58.7, SD years; female: 49.5%, 54/109; Hispanic: 45.9%, 50/109; income ≤ US $20,000: 56.9%, 62/109; and ≤ high school education: 52.3%, 57/109). The DMO groups had 80 participants (7 sites) and usual care had 29 participants (5 sites). At week 4, DMO resulted in a statistically greater SBP reduction than usual care (mean –21.8, SE 1.5 mm Hg vs mean –12.7, SE 2.8 mmHg; mean difference –9.1, 95% CI –14.0 to –3.3 mm Hg) and maintained a greater reduction at week 12. The DMO groups had greater reductions in HbA1c, DBP, and LDL-C, and a greater proportion of participants at BP goal at weeks 4 and 12 compared with usual care. The DMO groups also received more therapeutic interventions than usual care. Medication adherence was ≥80% while using the DMO. The most common adverse event was a self-limited rash at the wearable sensor site (12%, 10/82).

Conclusions: For patients failing hypertension and diabetes oral therapy, this DMO, which provides dose-by-dose feedback on medication ingestion adherence, can help lower BP, HbA1c, and LDL-C, and promote patient engagement and provider decision making.

Trial Registration: Clinicaltrials.gov NCT02827630; https://clinicaltrials.gov/show/NCT02827630 (Archived by WebCite at http://www.webcitation.org/6rL8dW2VF)

(J Med Internet Res 2017;19(7):e246) doi:10.2196/jmir.7833

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KEYWORDS

digital medicine; hypertension; type 2 diabetes; patient engagement, medication adherence; therapeutic inertia

Introduction

Hypertension (HTN) and diabetes mellitus are major risk factors for cardiac diseases, stroke, and kidney diseases [1-5]. Despite the widespread availability of effective treatments, approximately half of treated patients do not have adequate blood pressure (BP) or glycemic control [4,6,7]. Poor medication adherence, lack of patient engagement, and therapeutic inertia are major contributors to patients not reaching their therapeutic targets [8-12]. Medication nonadherence alone costs US $290 billion annually in the United States and is difficult to assess and improve [13,14].

The psychology literature suggests that human beings in general are poor intuitive statisticians in that they cannot estimate their risk for consequences related to nonadherence and poor disease control [15]. Proteus Digital Health (Redwood City, CA, USA) hypothesized that this problem might be addressed by a common solution: detailed feedback to patients and physicians of actual dosing behavior. This would present patients with a clear adherence target while allowing physicians to discern lack-of-response calling for dosage or medication changes from patient nonadherence.

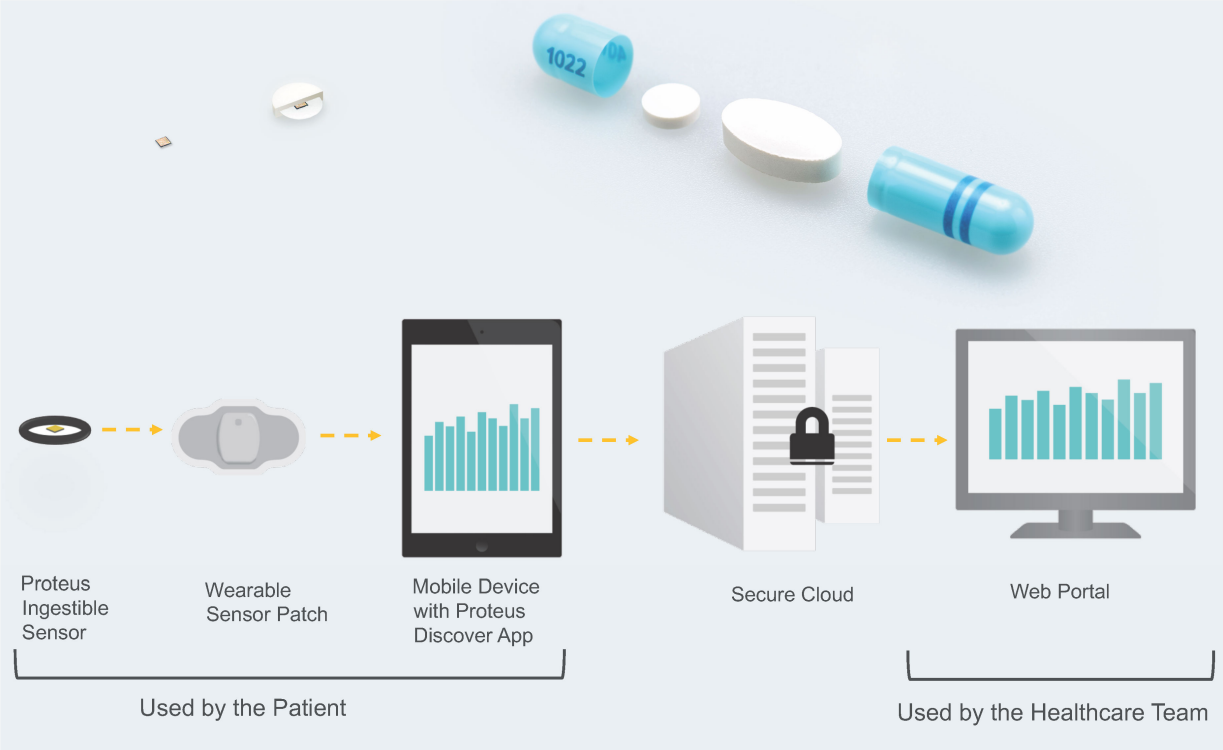
Proteus Discover, a digital medicine offering (DMO) from Proteus Digital Health, was designed specifically to provide feedback for medication taking and other health behaviors to both patients and providers. It consists of an ingestible sensor (contained inside a placebo pill), an adhesive wearable sensor patch, a patient mobile app, and a provider Web portal. After being swallowed, the ingestible sensor is activated and sends a signal with a specific code that is detected by the patch. When the ingestible sensor pill is taken with medication (now a digital medicine), the DMO can measure medication ingestion adherence. To ensure that the ingestible sensor and medication are taken simultaneously, the two can be co-encapsulated by a pharmacist (as was done during this study). The patch also measures activity, body angle, heart rate, and step count. Data from the patch are transmitted to a mobile device (eg, mobile phone) and then to the cloud. Patients can visualize the DMO data on their mobile device via an app and providers can view summaries of the DMO data for their patients on the Web portal. The mobile device app also prompts the patient to take their medication doses as scheduled. The goal of the DMO is to improve clinical outcomes through better patient self-care, enhanced patient-provider dialog, and data-driven optimization of therapy. (See Figure 1 for an overview of the DMO.)

Prior clinical studies demonstrated the accuracy, safety, and feasibility of using the DMO in patients across a range of medical conditions, including HTN and type 2 diabetes mellitus (T2DM), and suggested this DMO can identify reasons for uncontrolled HTN and help patients achieve BP control [16-21]. However, these uncontrolled studies did not focus on disease control. A prior hypertension registry study conducted in several primary care centers in the United Kingdom demonstrated the ability of a prior version of the DMO with no patient feedback (ie, digital medicines plus patch) to uncover a root cause for uncontrolled HTN in all participants after 2 weeks of use. Additionally, 37% of participants achieved BP control after 2 weeks with no adjustments to their antihypertensive medications [20].

In this study, patients with uncontrolled T2DM and HTN with current therapy were offered the DMO or usual care (to compare with the current standard that patients receive today). The design of the HTN registry was used to determine the duration of DMO use in this study; the first 2 weeks of DMO use allowed providers to understand the root cause for elevated BP (nonadherence, inadequate medication, or both) and the subsequent 2 weeks allowed the provider to see the effect of the medical decision on BP after the first 2 weeks [20]. The primary objective was to study the effect of the DMO on BP. Additional objectives were to assess the effect on glycemic and lipid control, engagement, and provider decision making.

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Figure 1. Top left: ingestible sensor and ingestible sensor pill. Top right: coencapsulation of a medication with an ingestible sensor pill. Bottom: components of the DMO and data flow.



Methods

Study Design and Participants

This 12-week, open-label, prospective, cluster-randomized, controlled, three-arm pilot study was executed at 13 outpatient primary care sites across California and Colorado. There were three additional sites that did not enroll any patients. Sites were selected based on the size of their HTN and T2DM population. Use of a cluster-randomized design mitigated the risk of investigator bias by ensuring providers cared for participants assigned to only one arm. Sites were randomized to the treatment arms: DMO use for 4 weeks (4-week DMO), DMO use for 12 weeks (12-week DMO), or usual care. Enrolled participants were assigned to the treatment arm of their clinical site.

Adults with uncontrolled HTN (systolic BP [SBP] ≥140 mm Hg) and T2DM (glycated hemoglobin A_{1c} [HbA_{1c}] ≥7%) who failed treatment with two or more antihypertensive medications available as part of the DMO medicine panel (Table 1) or dose-equivalent medicines from the same classes, and metformin and/or a sulfonylurea were eligible for enrollment. Participants either needed to be able to use a mobile phone or tablet or the investigator determined the participant could learn to use a smart mobile device. Investigators also assessed whether their participants could be treated for HTN during the study period using the DMO medication panel exclusively; if medically necessary, participants could be prescribed off-panel antihypertensive medicines. Exclusion criteria included body mass index (BMI) >40 kg/m^2, skin sensitivity to adhesive medical tape or metals, active or chronic dermatitis, secondary causes for uncontrolled HTN or T2DM, evidence of hypertensive emergency, and use of insulin or other injectables to treat T2DM within the past year.

Copernicus Group Independent Review Board, a central institutional review board, approved and monitored the study. Participants provided written informed consent prior to screening and were compensated (US $150 to US $525 based on study arm and site-specific guidelines for participant compensation) for participation.

During the study, changes were made to make the inclusion and exclusion criteria less restrictive to promote recruitment. Notably, we included a Spanish version of the consent form and removed an exclusion of non-English speakers.

Interventions

Investigators were instructed to make medication changes and to provide patient education and counseling as clinically appropriate (versus using specific dose-escalation protocols) to ensure the decisions were similar to those in a real clinical practice setting. Blood pressure recorded at each visit was the mean of two or more BP measurements obtained using the recommended measurement guidelines from the American Heart Association [22]. Participants had their BP measured after 5 or more minutes of rest, comfortably seated in a quiet room with their feet touching the floor. Each BP measurement was taken at least 1 minute apart. If the first two BP readings were more than 5 mm Hg different, then the BP was measured at least two more times; the mean of all BP values from one visit were used as the final reading. Laboratory test results were drawn at screening, and at weeks 4 and 12, for HbA_{1c} (screening and week 12), fasting plasma glucose (FPG), total cholesterol, and directly measured low-density lipoprotein cholesterol (LDL-C).

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Participants also completed the 10-question Patient Activation Measure (PAM), a validated measure of patient activation that includes person's beliefs, motivation, and actions for self-care at these visits [9,23,24]. During each visit, participants and investigators jointly reviewed the data and collaboratively set goals for medication adherence, physical activity, and rest.

Participants in the DMO arms were prescribed DMO for either 4 or 12 weeks and medicines co-encapsulated with ingestible sensors (see digital medicine panel in Table 1). Participants were allowed to switch to medications on the digital medicine panel in a dose-equivalent manner from the same drug classes. The DMO investigators were instructed to review DMO reports on the Web portal during study visits.

Table 1. Digital medicine offering panel.[a]

Therapeutic area and class	Medication	Doses
Hypertension		
Angiotensin-converting enzyme inhibitor	Lisinopril	10 mg, 20 mg, 40 mg
Angiotensin receptor blocker	Losartan	100 mg
Thiazide diuretic	HCTZ	12.5 mg, 25 mg
Dihydropyridine calcium channel blocker	Amlodipine	5 mg
Hypercholesterolemia		
Statin	Atorvastatin	20 mg
Diabetes		
Biguanide	Metformin	500 mg
Sulfonylurea	Glipizide	5 mg

[a]Participants could take more than one medication dose at any one time (eg, ingesting two atorvastatin 20 mg capsules to get a total dose of 40 mg).

All investigators could titrate medications, provide patient education, and/or counseling at any time during the study as per usual care based on all available clinical data, with the exception that investigators in the DMO arms were instructed to await the DMO report from the first 2 weeks of DMO use before making changes to the antihypertensive medications (or other medical decision) to try to ensure this decision was made using the DMO data.

Providers trained participants on use of the DMO and, along with customer support provided by the sponsor, assisted participants in troubleshooting issues with the DMO.

Study Outcomes

The primary endpoint was change in SBP from baseline to week 4. Secondary endpoints included changes from baseline in SBP and HbA_{1c} at week 12, changes in diastolic BP (DBP) and FPG at weeks 4 and 12, proportion of participants at BP goal (SBP <140 mm Hg and DBP <90 mm Hg) at weeks 4 and 12, medication adherence rate, and mean daily step count and duration of physical activity and rest (DMO only), and medical decisions. Exploratory outcomes included change in LDL-C from baseline at weeks 4 and 12 in patients using digital atorvastatin (DMO arms) or any statin (usual care) and change in PAM score.

Statistical Analysis

Target enrollment in this pilot study was 120 participants to ensure at least 90 evaluable participants at the end of the study. This study was primarily performed to understand the effect size of the DMO intervention. Although there was prior data from the hypertension registry study, the product and study design were different: participants in the hypertension registry study used a DMO without feedback for 2 weeks. It was hypothesized that with feedback to the participant and provider and a longer intervention, the effect size would be larger. Due to the pilot nature of the study, there were no a priori hypotheses for this study; *P* values are not reported on study outcome data. *P* values were only calculated for baseline differences between groups.

Values and change for continuous variables were summarized descriptively (mean and SE) and 95% confidence intervals (95% CI) were calculated for all changes. Differences between groups were calculated using a mixed-effects regression model that incorporated covariates found to be significant in the model: baseline value, gender, age (<65 years vs ≥65 years), and race (African American vs other). Proportions as well as differences between groups were summarized descriptively.

The SE was adjusted for cluster (study site) effects as well as the intracluster correlation coefficient (ICC) calculated using a one-way analysis of variance to adjust for any imbalances between and within clusters. Confidence intervals were calculated for differences between groups.

Participants with at least one follow-up BP were included in this modified intention-to-treat (ITT) analysis, which represented the minimal data needed for a pre/post comparison for each participant. Missing data were handled using last observation carried forward. Safety assessments were performed on all enrolled participants. Analyses were performed for 4-week DMO, 12-week DMO, and combined DMO (both DMO arms combined). Because both DMO groups had the same intervention for the first 4 weeks, the two groups were combined for all week 4 endpoints and measures (eg, mean medication adherence).

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Figure 2. CONSORT flow diagram of participants.

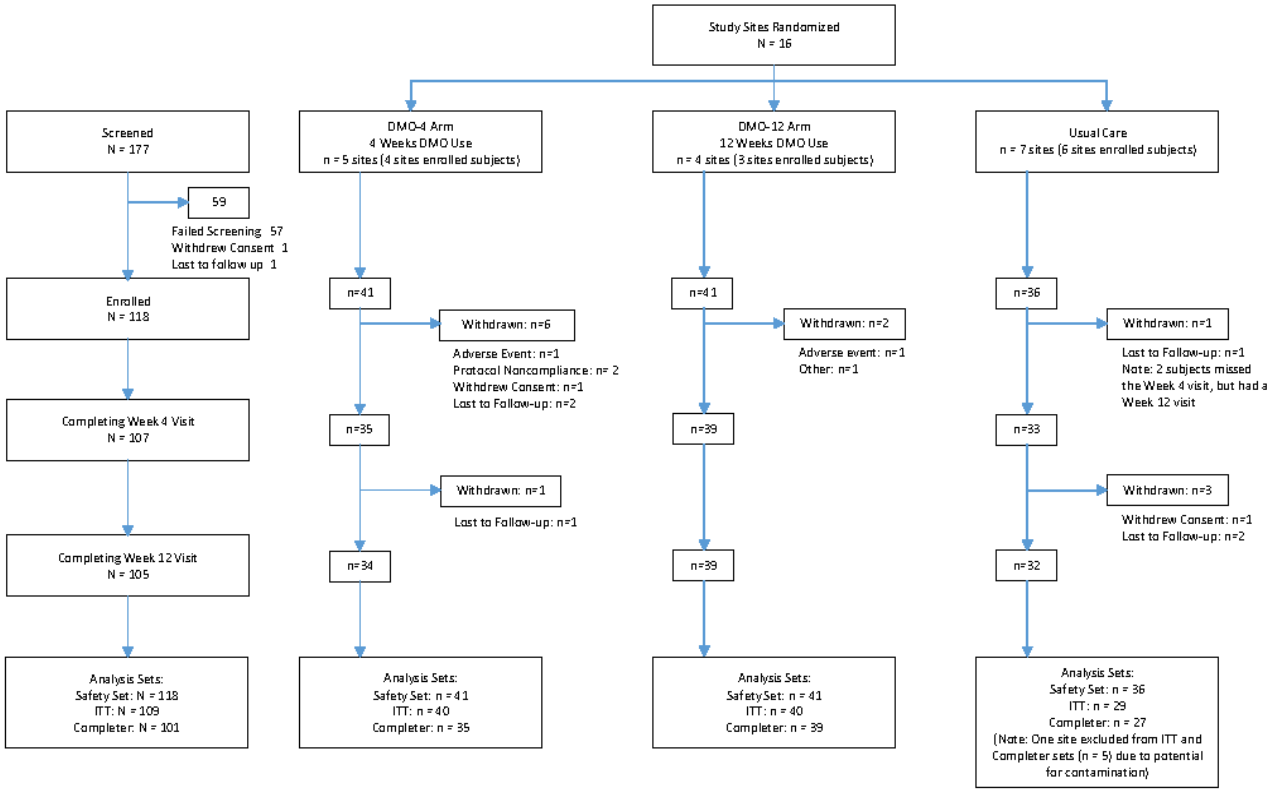


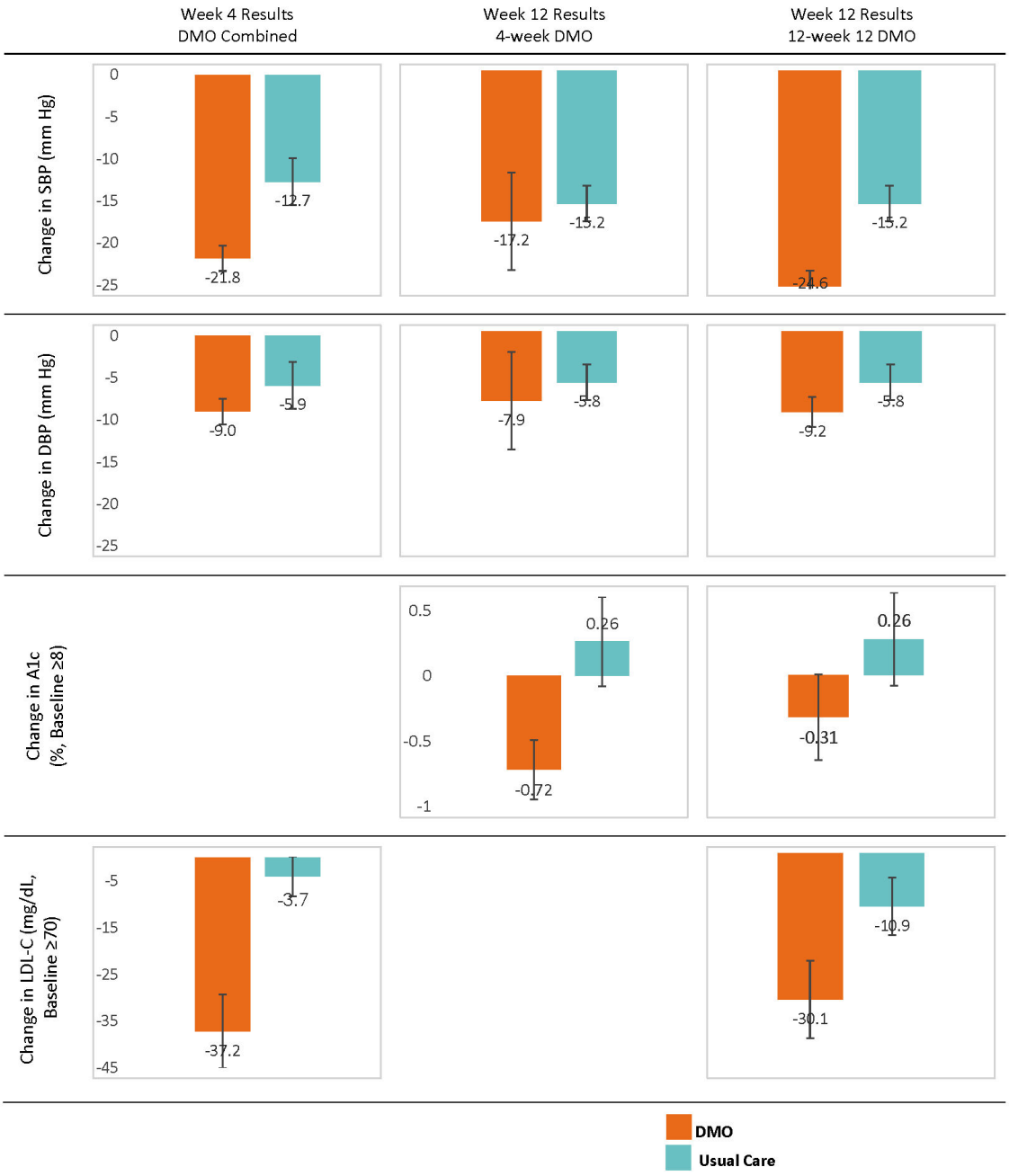
Table 2. Demographics and baseline characteristics of participants (N=109).

Parameter	4-week DMO (n=40)	12-week DMO (n=40)	Combined DMO (n=80)	Usual care (n=29)
Age (years), mean (SE)	58.8 (1.4)	56.7 (1.8)	57.8 (1.1)	61.6 (1.7)
Female, n (%)	21 (53)	24 (60)	45 (56)	10 (35)
African American, n (%)	11 (28)	3 (8)	14 (18)	3 (10)
Caucasian, n (%)	29 (73)	24 (60)	53 (66)	19 (66)
Asian, n (%)	0 (0)	13 (33)	13 (16)	2 (7)
Hispanic ethnicity (includes all races), n (%)	22 (55)	15 (38)	37 (46)	14 (45)
Income ≤ US$20,000, n (%)	23 (58)	21 (53)	44 (55)	18 (62)
Education <high school, n (%)	18 (45)	6 (15)	24 (30)	10 (34)
Employed, n (%)	18 (45)	24 (60)	42 (53)	9 (31)
Weight (kg), mean (SE)	91.5 (5.9)	85.7 (3.4)	88.6 (3.3)	89.7 (4.7)
BMI (kg/m^2), mean (SE)	32.8 (1.4)	30.7 (0.9)	31.8 (0.9)	31.3 (1.0)
Systolic BP (mm Hg), mean (SE)	152.2 (1.6)	146.5 (0.8)[a]	149.3 (1.5)[a]	155.4 (3.0)
Diastolic BP (mm Hg), mean (SE)	90.5 (2.8)	82.0 (5.1)	86.2 (3.2)	83.9 (2.9)
HbA_{1c} (%), mean (SE)	8.8 (0.3)	8.5 (0.2)	8.7 (0.2)	8.3 (0.4)
FPG (mg/dL), mean (SE)	174.2 (13.6)	191.4 (16.2)	182.8 (9.9)	165.0 (8.5)
LDL-C (mg/dL), mean (SE)	110.7 (5.3)	107.1 (6.6)	108.9 (3.9)	99.1 (6.2)
HDL-C (mg/dL), mean (SE)	47.8 (2.6)	45.2 (1.5)	46.5 (1.4)	40.6 (2.5)
Triglycerides (mg/dL), mean (SE)	211.2 (28.1)	195.7 (17.3)	203.4 (16.2)	226.1 (36.2)
Total cholesterol (mg/dL), mean (SE)	190.2 (6.5)	175.3 (6.0)	182.8 (4.5)	174.4 (13.2)

[a]Difference compared to usual care was statistically significant ($P<.05$).

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Figure 3. Highlighted clinical results for changes in systolic and diastolic blood pressure (SBP and DPB), glycated hemoglobin (HbA1c), and low-density lipoprotein cholesterol (LDL-C) for the combined digital medicine offering (DMO) groups at week 4, week-4 DMO, and 12-week DMO. Error bars represent SE.



Medication adherence data and medical decisions (provider treatment decisions in response to DMO data) were summarized descriptively. Medication adherence was calculated only for the DMO users because measurement of medication adherence was an intrinsic aspect of the intervention.

Analyses of efficacy variables were performed on R version 3.2.2 with lme4 version 1.1.11 for building generalized linear mixed models. An interim analysis was performed in October 2015 to get preliminary data on the primary outcome.

Results

Between June and October 2015, 118 participants were enrolled across the 13 sites; 107 participants completed the week 4 visit and 105 completed the week 12 visit by December 30, 2015. Three usual care participants missed the week 4 visit, but were included in the analysis because they returned for the week 12 visit. One usual care site with five participants was not included in the final analysis over concern about violation of the cluster randomization. This usual care site was activated in September and was joined by the lead study coordinator from a 4-week DMO site previously activated in May; this study coordinator

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had intervened with both DMO and usual care participants. The final modified-ITT group included 109 participants (40 in 4-week DMO, 40 in 12-week DMO, and 29 in usual care) (Figure 2).

The study included a large portion of low-income participants (56.9%, 62/109 earned ≤ US $20,000 per year) and minorities (52.3%, 57/109 Hispanics) (Table 2). In addition, 22.0% (24/109; 25%, [20/80] in DMO and 14%, [4/29] in usual care) had psychiatric comorbidities.

Primary Outcome

At week 4, combined DMO had a mean change in SBP from baseline of –21.8 (SE 1.5) mm Hg compared to –12.7 (SE 2.8) mm Hg for usual care (combined DMO–usual care: mean –9.1, SE 2.9, 95% CI –14.8 to –3.3 mm Hg; ICC=0; adjusted difference: mean –10.0, SE 3.1, 95% CI –16.1 to –3.9 mm Hg; effect size=0.69) (Figure 3). A sensitivity analysis showed that excluding the one usual care site did not impact the primary outcome; the change in SBP for usual care with the excluded site was mean –14.0 (SE 2.7; difference from combined DMO: –7.8, SE 2.8, 95% CI –13.3 to –2.3 mm Hg).

Secondary Outcomes

Hypertension

At week 4, a greater proportion of DMO participants achieved their BP goal (81%, 65/80) compared with usual care (33.3%, 9/27; mean difference 47.9%, SE 15.0%, 95% CI 18.5%-77.3%) (Table 3). DMO participants also had a greater reduction in DBP compared with usual care, but the results were not significant. The 12-week DMO group continued to show larger reductions in SBP from baseline (mean –24.6, SE 1.7 mm Hg), which was statistically larger compared to usual care (mean –15.2, SE 2.0 mm Hg; mean difference –9.4, SE 2.7, 95% CI –14.6 to –4.2 mm Hg). At week 12, 98% (39/40) of 12-week DMO participants achieved their BP goal compared with 51.7% of usual care participants (mean difference 45.8%, 95% CI 7.1% to 84.5%). The 4-week DMO group also had greater reductions in SBP and DBP at week 12 than usual care, but the results were not statistically significantly different (Table 4).

Diabetes

At week 12, DMO had a nonsignificant difference in HbA_{1c} reduction compared to usual care (4-week DMO: mean –0.32%, SE 0.22%; 12-week DMO: mean –0.08%, SE 0.22%; usual care: mean 0.28%, SE 0.35%). For participants with a baseline HbA_{1c} of 8% of more (n=65; 4-week DMO: n=26, 12-week DMO: n=24, usual care group: n=15), both DMO groups showed larger HbA_{1c} decreases (4-week DMO: mean –0.72%, SE 0.23%; 12-week DMO: mean –0.31%, SE 0.31%) compared to an increase in the HbA_{1c} seen in the usual care group (mean 0.26%, SE 0.34%; difference from 4-week DMO 0.98%, 95% CI –1.72 to –0.24; difference from 12-week DMO –0.57%, 95% CI –1.53 to 0.39) (See Figure 3 and Table 3). Adjusted differences for the change in HbA_{1c} between each DMO group and usual care were almost 1%. There were no significant differences in change in FPG between the DMO and usual care groups.

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Table 3. Summary of systolic and diastolic blood pressure (SBP and DBP), fasting plasma glucose (FPG), and glycated hemoglobin A_{1c} (HbA_{1c}) results for usual care and combined digital medicine offering (DMO).

Outcome	Usual care	DMO (combined)		
	Value	Value	Difference,[a] (95% CI)	Adjusted difference,[a] (95% CI)
SBP (mm Hg)				
Baseline, mean (SE)	155.4 (3.0)	149.3 (1.5)		
Week 4, mean change (SE)	–12.7 (2.8)	–21.8 (1.5)	–9.1 (2.9); (–14.0, –3.3)	–10.0 (3.1); (–16.1, –3.9)
Week 12, mean change (SE)	–15.2 (2.0)	–20.9 (3.4)	–4.6 (4.9); (–14.3, 5.1)	–4.8 (5.6); (–15.8, 6.3)
DBP (mm Hg)				
Baseline, mean (SE)	83.9 (2.9)	86.2 (3.2)		
Week 4, mean change (SE)	–5.9 (3.0)	–9.0 (1.6)	–3.4 (3.1); (–9.4, 2.7)	–2.4 (1.9); (–6.2, 1.3)
Week 12, mean change (SE)	–5.8 (2.2)	–8.6 (2.2)	–2.4 (3.4); (–9.1, 4.4)	–1.2 (3.4); (–7.2, 4.8)
Proportion at BP goal (%)				
Week 4, mean (SE)	33.3 (9.7)	81.2 (5.1)	47.9 (15.0); (18.5, 77.3)	N/A[b]
Week 12, mean (SE)	51.7 (15.6)	80.0 (9.3)	28.3 (24.6); (–19.9, 76.5)	N/A[b]
FPG (mg/dL)				
Baseline, mean (SE)	165.0 (13.6)	182.8 (9.9)		
Week 4, mean change (SE)	13.4 (15.8)	–9.4 (14.3)	–22.7 (22.0); (–66.7, 21.4)	–14.4 (21.7); (–57.0, 28.3)
Week 12, mean change (SE)	14.9 (12.0)	–4.9 (14.9)	–16.2 (22.1); (–59.5, 27.1)	–12.6 (20.1); (–52.0, 26.9)
HbA_{1c} (%)				
Baseline, mean (SE)	8.28 (0.38)	8.66 (0.18)		
Week 12, mean change (SE)	0.26 (0.35)	–0.19 (0.14)	–0.48 (0.29); (–1.04, 0.09)	–0.54 (0.41); (–1.3, 0.3)
HbA_{1c} baseline ≥8% (%)[c]				
Baseline, mean (SE)	9.25 (0.31)	9.54 (0.19)		
Week 12, mean change (SE)	0.26 (0.34)	–0.50 (0.20)	–0.77 (0.40); (–1.6, 0.02)	–0.94 (0.45); (–1.8, –0.1)

[a]Difference from usual care.

[b]N/A: Adjusted analysis was not performed.

[c]Usual care: n=15; DMO: n=50.

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Table 4. Summary of systolic and diastolic blood pressure (SBP and DBP), fasting plasma glucose (FPG), and glycated hemoglobin A1c (HbA1c) results for 4-week and 12-week digital medicine offering (DMO) groups.

Outcome	4-week DMO			12-week DMO		
	Value	Difference,[a] (95% CI)	Adjusted difference,[a] (95% CI)	Value	Difference,[a] (95% CI)	Adjusted difference,[a] (95% CI)
SBP (mm Hg)						
Baseline mean (SE)	152.2 (1.6)			146.4 (0.8)		
Week 4 mean change (SE)	–21.5 (2.5)	–8.8 (3.5); (–15.7, –1.9)	–8.5 (3.8); (–15.8, –1.1)	–22.1 (1.8)	–9.4 (2.9); (–15.1, –3.6)	–11.3 (3.3); (–17.6, –4.9)
Week 12 mean change (SE)	–17.2 (5.6)	–1.1 (5.9); (–12.6, 10.4)	–0.3 (6.2); (–12.5, 11.9)	–24.6 (1.7)	–9.4 (2.7); (–14.6, –4.2)	–11.0 (3.1); (–17.1, –4.9)
DBP (mm Hg)						
Baseline mean (SE)	90.5 (2.8)			82.0 (5.1)		
Week 4 mean change (SE)	–10.1 (1.6)	–4.3 (3.1); (–10.5, 1.8)	–1.6 (2.4); (–6.2, 3.0)	–7.8 (3.9)	–2.1 (5.2); (–12.2, 8.0)	–4.4 (2.5); (–9.4, 0.5)
Week 12 mean change (SE)	–7.9 (3.3)	–1.8 (4.0); (–9.7, 6.1)	2.0 (4.0); (–4.6, 8.6)	–9.2 (3.6)	–3.1 (4.1); (–11.2, 4.9)	–5.9 (4.1); (–13.3, 1.5)
Proportion at BP goal (%)						
Week 4 mean (SE)	72.5 (7.3)	39.2 (12.5); (14.7, 63.7)	N/A[b]	90.0 (6.7)	56.7 (16.4); (24.6, 88.7)	N/A[b]
Week 12 mean (SE)	62.5 (9.3)	10.8 (23.4); (–35.1, 56.6)	N/A[b]	97.5 (2.5)	45.8 (19.8); (7.1, 84.5)	N/A[b]
FPG (mg/dL)						
Baseline mean (SE)	174.2 (13.6)			191.4 (16.2)		
Week 4 mean change (SE)	4.7 (9.6)	–10.3 (19.9); (–49.2, 28.6)	–9.8 (23.5); (–56.0, 36.3)	–22.8 (31.1)	–38.7 (32.0); (–101.4, 24.1)	–15.9 (30.7); (–76.1, 44.3)
Week 12 mean change (SE)	20.9 (9.2)	6.8 (15.4); (–23.4, 37.0)	–0.5 (17.3); (–34.4, 33.4)	–28.9 (18.9)	–44.6 (21.8); (–87.4, –1.8)	–26.3 (22.9); (–71.2, 18.7)
HbA $_{1c}$ (%)						
Baseline mean (SE)	8.79 (0.29)			8.53 (0.20)		
Week 12 mean change (SE)	–0.32 (0.22)	–0.65 (0.44); (–1.52, 0.23)	–0.63 (0.54); (–1.69, 0.43)	–0.08 (0.22)	–0.35 (0.40); (–1.13, 0.42)	–0.50 (0.67); (–1.81, 0.81)
HbA $_{1c}$ baseline ≥8% (%)[c]						
Baseline mean (SE)	9.78 (0.30)			9.29 (0.23)		
Week 12 mean change (SE)	–0.72 (0.23)	–0.98 (0.38); (–1.72, –0.24)	–0.98 (0.45); (–1.86, –0.10)	–0.31 (0.31)	–0.57 (0.49); (–1.53, 0.39)	–0.98 (0.58); (–2.12, 0.16)

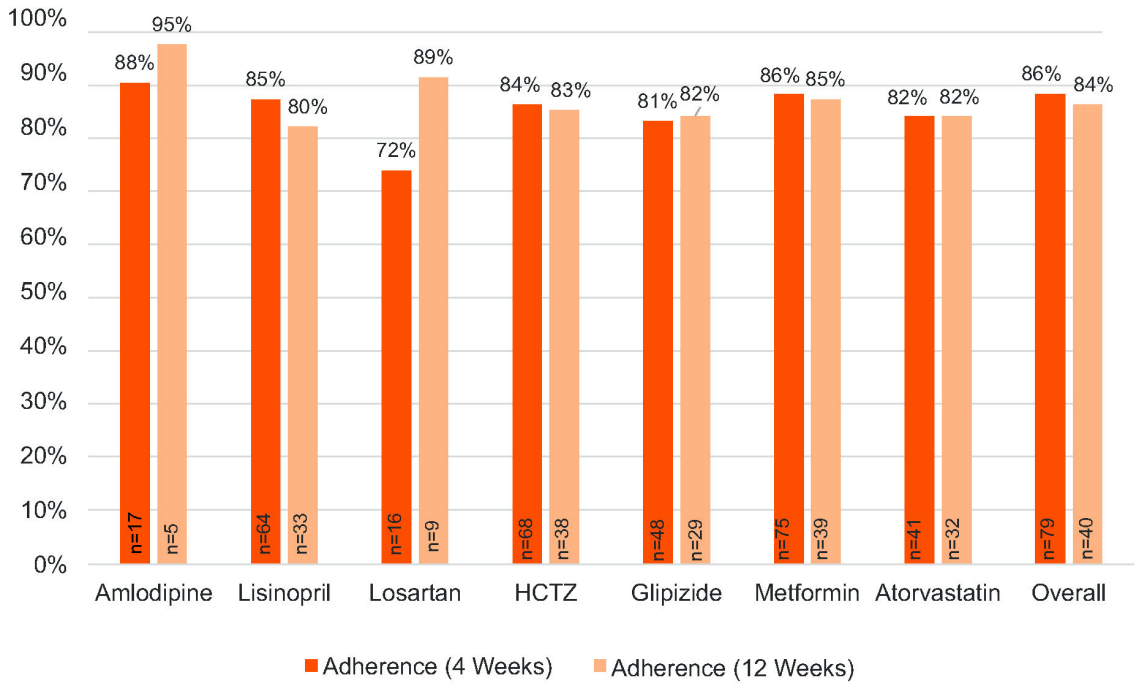
[a]Difference from usual care.

[b]N/A: Adjusted analysis was not performed.

[c]4-week DMO: n=26; 12-week DMO: n=24.

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Figure 4. Ingestion adherence for DMO subjects measured by DMO. Note adherence for the first 4 weeks includes both 4-week DMO and 12-week DMO; adherence for 12 weeks includes only 12-week DMO.



Medical Decisions

The DMO providers made approximately 3 times more medical decisions per participant (mean 6.5, SD 5.3 DMO vs mean 2.7, SD 3.3 usual care). The DMO participants received more counseling, patient education, and lifestyle coaching than usual care. The frequency of medication changes per participant was similar for DMO (mean 0.83, SD 1.49) and usual care (mean 1.00, SD 1.58). At week 4, DMO participants with uncontrolled BP, who were medication adherent (≥80%), appeared to be 4 times more likely than usual care participants to receive an antihypertensive titration. Although this suggests that greater targeting of therapy adjustments may occur in patients who utilize DMO, this finding should be interpreted with caution because the actual number of medication changes that occurred was small and the difference was not statistically significant.

Digital Medicine Offering Measurements

The mean ingestion adherence was 86% during the first 4 weeks (combined DMO) and 84% for the entire 12 weeks (12-week DMO) (see Figure 4).

Exploratory Outcomes

Among statin users, reductions in LDL-C were larger for DMO compared with usual care. These differences were even greater in participants with a baseline LDL-C of 70 mg/dL or higher. In participants with baseline LDL-C of 70 mg/dL or higher (n=54; 4-week DMO: n=6, 12-week DMO: n=28, usual care group: n=20), changes in LDL-C were mean –37.2 (SE 7.9) mg/dL at week 4 and mean –30.1 (SE 8.0) mg/dL at week 12 for DMO and mean –4.0 (4.3) mg/dL at week 4 and mean –10.9 (SE 5.9) mg/dL at week 12 for usual care. The differences in change in LDL-C between DMO and the usual care group were –33.2 (95% CI –50.6 to –15.8) at week 4 and –19.2 (95% CI –36.4 to –2.0) at week 12. These differences were statistically significant (see Table 5 for complete results).

The DMO participants had a nonsignificantly greater increase in PAM score compared with usual care; the changes were mean 7.9 (SE 3.8) for 4-week DMO, mean 7.9 (SE 3.0) for 12-week DMO, and mean 1.7 (SE 3.3) for usual care at week 12 (see Table 6).

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Table 5. Summary of total cholesterol and low-density lipoprotein cholesterol (LDL-C) outcomes for the combined digital medicine offering (DMO) group only.[a]

Outcome	Usual care	DMO (combined)		
	Value	Value	Difference,[b] (95% CI)	Adjusted difference,[b] (95% CI)
Total cholesterol (mg/dL)[c]				
Baseline, mean (SE)	174.4 (13.1)	177.4 (9.5)		
Week 4, mean change (SE)	–9.2 (7.1)	–34.8 (7.1)	–25.7 (9.7); (–44.6, –6.7)	–23.0 (7.8); (–38.2, –7.8)
Week 12, mean change (SE)	–21.9 (10.2)	–29.5 (7.4)	–7.9 (11.3); (–30.1, 14.3)	–8.1 (7.9); (–23, 7)
LDL-C (mg/dL)[c]				
Baseline, mean (SE)	99.3 (6.7)	103.9 (10.1)		
Week 4, mean change (SE)	–3.7 (3.8)	–29.7 (9.4)	–25.6 (9.4); (–44.1, –7.1)	–22.7 (6.1); (–34.6, –10.8)
Week 12, mean change (SE)	–9.5 (5.6)	–21.3 (10.0)	–11.0 (13); (–37.4, 15.4)	–10.8 (6.3); (–23.1, 1.5)
Total cholesterol with baseline LDL ≥70 mg/dL (mg/dL)[d]				
Baseline, mean (SE)	174.1 (11.6)	185.1 (8.4)		
Week 4, mean change (SE)	–7.0 (6.9)	–39.8 (7.9)	–32.9 (10.2); (–52.9, –12.9)	–26.5 (9.1); (–44.4, –8.6)
Week 12, mean change (SE)	–18.9 (9.4)	–37.7 ± 7.5	–18.8 ± 10.6; (–39.6, 2.0)	–13.9 ± 8.8; (–31.2, 3.3)
LDL-C with baseline LDL ≥70 mg/dL (mg/dL)[d]				
Baseline, mean (SE)	104.2 (7.0)	114.0 (7.1)		
Week 4, mean change (SE)	–4.0 (4.3)	–37.2 (7.9)	–33.2 (8.9); (–50.6, –15.8)	–25.3 (7.0); (–39.1, –11.6)
Week 12, mean change (SE)	–10.9 (5.9)	–30.1 (8.0)	–19.2 (8.9); (–36.4, –2.0)	–13.4 (7.1); (–27.4, 0.5)

[a]Due to small sample sizes for DMO groups, results are summarized.

[b]Difference from usual care.

[c]Includes participants on any statin therapy in usual care (n=23) and on digital atorvastatin in the DMO group (n=41).

[d]Includes participants on statin therapy in usual care (n=20) and on digital atorvastatin in the DMO group (n=34).

Table 6. Summary of Patient Activation Measure (PAM) outcomes.

Outcome	Usual care	DMO (combined)		4-week DMO		12-week DMO	
	Value	Value	Difference,[a] (95% CI)	Value	Difference,[a] (95% CI)	Value	Difference,[a] (95% CI)
Baseline, mean (SE)	70.3 (5.1)	70.6 (2.8)		73.4 (4.7)		68.0 (2.8)	
Week 4, mean change (SE)	–0.9 (1.6)	2.2 (1.9)	3.2 (3.6); (–3.9, 10.2)	2.1 (3.1)	3.0 (4.0); (–5, 11)	2.3 (2.4)	3.3 (3.4); (–3.4, 9.9)
Week 12, mean change (SE)	1.7 (3.3)	7.9 (2.4)	6.2 (4.6); (–2.8, 15.2)	7.9 (3.8)	6.2 (5.3); (–4, 17)	7.9 (3.0)	6.3 (4.7); (–2.9, 15.4)

[a]Difference from usual care.

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Table 7. Satisfaction survey results (N=75).

Survey question	Answered agree or strongly agree, n (%)
It was easy to use Proteus in my daily routine	68 (91)
It was easy to learn how to use Proteus	69 (92)
Seeing my data showed me how well I'm managing my health	68 (91)
Seeing my data motivated me to improve my health	70 (93)
Proteus helped me have more helpful conversations with my health care professionals	64 (85)
Sharing my data with my health care professionals helped me understand my care plan	68 (91)
Using Proteus improved my experience of health care service for my condition(s)	66 (88)
Proteus helped me to see how I use my medication(s) from day-to-day	66 (88)
Proteus helped me take my medication(s) more regularly	68 (91)
It was easy to use the iPad	67 (89)
It was easy to use the Proteus app	64 (85)
In general, I did not mind wearing the patch	61 (81)
Connecting and applying each new patch was easy for me to do	68 (91)

Participant Satisfaction With Digital Medicine Offering

In general, participants agreed the DMO was easy to learn (92%, 69/75) and to incorporate in their daily routine (91%, 68/75), and that using the data was useful to manage (91%, 68/75) and improved their health (93%, 70/75) and that sharing their data with their provider helped them to understand their care plan (91%, 68/75). Most (81%, 61/75) did not mind wearing the patch (see Table 7).

Safety

There were 32 of 82 DMO participants (39%) who reported 59 adverse events (AEs), of which 33 were unrelated to the DMO; 8 of 36 usual care participants (22%) reported 17 AEs. There were no serious AEs related to the DMO or the study. There were 14 device-related AEs in 11 participants, most commonly mild skin reactions to the wearable sensor (13 events in 10 participants, 12%). Additionally, 12 participants reported study medication-related AEs (14 events total) with gastrointestinal AEs (9 events in 8 participants; 7 mild, 2 moderate, 1 moderate event led to study withdrawal, 10%) being the most common. Another AE, fatigue (mild intensity), unrelated to the device or study medication, led to study withdrawal.

Discussion

In this study, participants with uncontrolled HTN and T2DM who used the DMO had significantly greater reductions in SBP within 4 weeks than the usual care group (9 mm Hg greater reduction), which was maintained at 12 weeks with a significantly greater proportion of patients achieving their BP goal. Participants using the DMO also showed lower trends in HbA_{1c} (as much as a 1% greater reduction), and LDL-C (33 mg/dL greater reduction) compared to participants who received usual clinical care. These clinical findings were maintained in analyses adjusting for age, gender, race, and baseline clinical parameters. Use of the DMO was also safe; the frequency of skin reactions is generally lower than published research on adhesive tape and patches [25-28].

These findings are relevant in the care of T2DM patients who have an increased risk of serious cardiovascular and microvascular complications. Each 2 mm Hg reduction in SBP or 1 mm Hg reduction in DBP has been associated with lowering mortality from stroke and ischemic heart disease by 10% and 7%, respectively [29]. A reduction in HbA_{1c} of 0.5% or more is considered clinically significant to reduce the risk of microvascular complications [30,31]. Statin adherence, as evidenced by LDL-C reduction, has also been associated with improved outcomes in diabetes patients [29,32,33]. However, given the short duration of this pilot study, additional longer-term evidence will be necessary to demonstrate that the changes in BP, HbA_{1c}, and LDL are durable.

We hypothesize that improved clinical outcomes with the DMO were related in part to improved self-care (medication adherence and patient activation). In the literature, average adherence to chronic medicines is approximately 50%; participants using DMO achieved a mean adherence of 86% during the first 4 weeks. The DMO also had a greater increase in PAM scores; a 1-point increase in PAM score is associated with a 1.8% increased likelihood of decreasing HbA_{1c} to less than 8% [9].

Providers could make more targeted and timely therapy optimization decisions using the objective behavioral data reported by the DMO. We found that at week 4, for participants with uncontrolled BP, investigators in the DMO arm were more likely to make therapy adjustments or give adherence counseling and/or education guided by the DMO data compared to usual care participants.

Other digital health solutions have failed to demonstrate benefit. Bloss et al [34] failed to demonstrate benefits of digital health interventions (telemonitoring devices for BP, blood glucose, or electrocardiogram rhythm) compared to usual care in a large controlled study. In that study, no instructions were given to

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providers on use of the device data; this has been shown to make blood glucose monitoring less effective in non-insulin-using diabetes patients [30,34]. There were also confounders. For example, many participants with diabetes in the control arm used insulin and likely made insulin-titration decisions based on blood glucose results. Finally, the inclusion criteria were based on cost versus level of disease control and may have enrolled participants not needing additional interventions.

In contrast, a recent study demonstrated benefits of a pharmacist case management intervention to reduce BP using a telemonitoring BP device [35]. Participants in the intervention arm spoke with pharmacists (via the phone) who reviewed BP data, provided coaching, and titrated medications. The intervention group had a statistically greater reduction in SBP at 6 months than usual care (mean difference –10.7, 95% CI –14.3 to –7.3 mm Hg), similar to the reductions in SBP observed in our pilot study on the DMO, except the pharmacist case management study only addressed hypertension, whereas this DMO study evaluated patients with both uncontrolled HTN and T2DM.

There were several limitations to this study. This study had a small sample size and included only 13 sites, which likely contributed to discrepancies noted in participant demographic and baseline characteristics. As mentioned in the Methods, this was a pilot study to measure the effect size of the DMO on SBP. The adjusted analyses suggested that these baseline differences did not affect the outcomes. However, they may have still affected the results for BP at goal. The small sample size may have also contributed to lack of power to detect differences between groups for some of the secondary and exploratory outcomes. In order to demonstrate use of the DMO in the real-world primary care clinic workflow, ambulatory BP monitoring was not used; therefore, BP fluctuations may be potentially related to the context of in-clinic measurement (outside of the participant's natural context). A comparison of adherence to treatment was not included among the goals of this study. No objective assessment of adherence to treatment was attempted in the usual care arm because there are only indirect methods of measuring adherence as an alternative to DMO and none of these methods have been established to be inherently reliable or accurate. Therefore, we cannot conclude that DMO led to higher levels of medication adherence. However, measuring an improvement in adherence was not an objective of the study.

Despite these limitations, this study demonstrates positive evidence that a digital health offering that measures and promotes medication adherence, patient self-care, and provider engagement can help patients improve their level of BP and diabetes control. The results should be generalizable given the diversity of the study population. Reducing BP, HbA_{1c}, and LDL-C in a consistent manner over a longer term through the use of DMO-like approaches may help patients decrease their overall risk for complications. Future real-world evidence can build on these results to further elucidate longer-term outcomes.

Acknowledgments

We thank all the study participants, study coordinators, and site investigators involved in this study. We are also gratefully acknowledge INC Research (Raleigh, NC) who was compensated for their efforts for management and coordination of the study, protocol and statistical analysis plan development, creation of the case report forms, data management, and part of the statistical analysis. Finally, we thank Penjit Moorhead, MS, and Maxsim Gibiansky, PhD, employees of Proteus Digital Health, for providing the bulk of the statistical analysis. This study was funded and supported by the sponsor, Proteus Digital Health.

Authors' Contributions

NV and YK had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to the study concept and design, critically revised the manuscript for important intellectual content, and supervised the conduct of the study. JF, NV, PR, and YK contributed to the acquisition, analysis, or interpretation of the data. JF, NV, and PR drafted the manuscript. YK oversaw the statistical analysis. NV, PR, YK, and GS obtained funding. NV and PR provided administrative, technical, or material support.

Conflicts of Interest

The sponsor, Proteus Digital Health, had a role in the design and conduct of the study; analysis and interpretation of the data; preparation, review, and approval of the manuscript; and decision to submit the manuscript for publication. The sponsor had no role in the collection or management of the study. JF reports consulting relationship with Proteus Digital Health, Johnson & Johnson, AstraZeneca, CeQur, and Sanofi. He also reports receiving study grants from Abbvie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Merck, Novo Nordisk, Pfizer, and Sanofi. NV, PR, YK, and GS are employed by Proteus Digital Health. GS is also a cofounder, officer, and stock owner of Proteus Digital Health. LO reports a consulting relationship with Proteus Digital Health; his contribution to this publication was as a paid consultant and was not part of his Stanford University duties or responsibilities.

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Abbreviations

AE: adverse event
BP: blood pressure
DBP: diastolic blood pressure
DMO: digital medicine offering
FPG: fasting plasma glucose
HbA1c: glycated hemoglobin A1c
HTN: hypertension
ICC: intracluster correlation coefficient
ITT: intention-to-treat
LDL-C: low-density lipoprotein cholesterol
PAM: Patient Activation Measure
T2DM: type 2 diabetes mellitus

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Edited by G Eysenbach; submitted 12.04.17; peer-reviewed by C Exeter, E da Silva, A Naik; comments to author 10.05.17; revised version received 24.05.17; accepted 10.06.17; published 11.07.17.

Please cite as:
Frias J, Virdi N, Raja P, Kim Y, Savage G, Osterberg L
Effectiveness of Digital Medicines to Improve Clinical Outcomes in Patients with Uncontrolled Hypertension and Type 2 Diabetes: Prospective, Open-Label, Cluster-Randomized Pilot Clinical Trial
J Med Internet Res 2017;19(7):e246
URL: http://www.jmir.org/2017/7/e246/
doi:10.2196/jmir.7833
PMID:28698169

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Original Paper

Using New and Emerging Technologies to Identify and Respond to Suicidality Among Help-Seeking Young People: A Cross-Sectional Study

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Related Article:

This is a corrected version. See correction statement: http://www.jmir.org/2017/10/e310/

Abstract

Background: Suicidal thoughts are common among young people presenting to face-to-face and online mental health services. The early detection and rapid response to these suicidal thoughts and other suicidal behaviors is a priority for suicide prevention and early intervention efforts internationally. Establishing how best to use new and emerging technologies to facilitate person-centered systematic assessment and early intervention for suicidality is crucial to these efforts.

Objective: The aim of this study was to examine the use of a suicidality escalation protocol to respond to suicidality among help-seeking young people.

Methods: A total of 232 young people in the age range of 16-25 years were recruited from either a primary mental health care service or online in the community. Each young person used the Synergy Online System and completed an initial clinical assessment online before their face-to-face or online clinical appointment. A suicidality escalation protocol was used to identify and respond to current and previous suicidal thoughts and behaviors.

Results: A total of 153 young people (66%, 153/232) reported some degree of suicidality and were provided with a real-time alert online. Further levels of escalation (email or phone contact and clinical review) were initiated for the 35 young people (15%, 35/232) reporting high suicidality. Higher levels of psychological distress (P<.001) and a current alcohol or substance use problem (P=.02) predicted any level of suicidality compared with no suicidality. Furthermore, predictors of high suicidality compared with low suicidality were higher levels of psychological distress (P=.01), psychosis-like symptoms in the last 12 months (P=.01), a previous mental health problem (P=.01), and a history of suicide planning or attempts (P=.001).

Conclusions: This study demonstrates the use of new and emerging technologies to facilitate the systematic assessment and detection of help-seeking young people presenting with suicidality. This protocol empowered the young person by suggesting pathways to care that were based on their current needs. The protocol also enabled an appropriate and timely response from service providers for young people reporting high suicidality that was associated with additional comorbid issues, including psychosis-like symptoms, and a history of suicide plans and attempts.

(J Med Internet Res 2017;19(7):e247) doi:10.2196/jmir.7897

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KEYWORDS

suicidal ideation; mental health; primary health care; telemedicine; health services

Introduction

Suicidal thoughts are common among young people presenting to traditional face-to-face mental health services and engaging with online mental health services [1,2]. Young people presenting to such services are also more likely to engage in suicidal behaviors (such as planning or attempts), which are among the strongest predictors of completed suicide [3-6]. Suicidal thoughts and behaviors are also associated with complex comorbid mental health problems [7], alcohol, or other substance use problems [8], as well as social and economic difficulties that contribute to greater disability [9]. Together, this highlights the need for suicide prevention and early intervention strategies that facilitate the early detection and rapid response to suicidality for those help-seeking young people [10,11].

This is a particularly pertinent issue given that almost half of those who have died by suicide had contact with a primary care provider within one month of the suicide [12], and one-quarter of those with depression who die by suicide are likely to have been in active engagement with mental health services at the time of death [13-16]. This emphasizes the challenge mental health professionals and services face when trying to identify and respond to those at high risk of engaging in harmful suicidal behaviors. This may be influenced by the relatively limited exposure to acutely suicidal patients in a clinician's daily work and a lack of systematic or organizational processes that directly address suicidal thoughts and behaviors [17].

New and emerging technologies (eg, mobile and Internet-based apps and e-tools) may be able to improve the systematic assessment and response to suicidality at a service and individual level so that those at risk can receive the appropriate care sooner [18,19]. Evidence indicates that online assessments are preferred and accurate for identifying suicidal thoughts and behaviors and other sensitive information [20,21], and online screening has demonstrated utility for facilitating access to treatment, especially when integrated with professional services [22-24]. The integration of these technologies with traditional services is crucial, and understanding how best to utilize the benefits of new and emerging technologies in terms of accessibility is an important goal for the ongoing development of effective early intervention strategies that target suicidal thoughts and behaviors.

The aim of this study was to examine the use of a suicidality escalation protocol embedded within the Synergy Online System (Textbox 1) that identifies and responds to suicidal thoughts and behaviors experienced by young people (aged 16-25 years) seeking help through primary mental health care and community settings and to identify specific predictors of suicidality.

Textbox 1. Synergy Online System.

The Synergy Online System is a personalized Internet-based resource designed to help people manage their physical, mental, and social wellbeing using a mixture of evidence-based apps, e-tools, and online and face-to-face services. One of the cornerstone principles of the Synergy Online System is a focus on the entire spectrum of health and well-being, from those who simply want to achieve goals to improve their daily habits, to those experiencing serious mental health problems. A key feature of the Synergy Online System is that it's configurable (ie, can rearrange or turn on or off different components within the system as well as tailor content), which allows it to easily adapt and thus meet the needs of end users. The System aims to transform the provision of mental health services by delivering readily accessible, affordable, and equitable mental health care through an increased focus on prevention and early intervention and improving the management of mental disorders across settings.

Methods

Participants

Participants in this study included young people aged 16-25 years who had access to the Internet and were either seeking help through primary mental health care services (*headspace*) or online in the community for the first time. Participants were recruited into one of three groups as follows:

Primary care sample 1: Participants were recruited from a group of young people presenting for the first time to *headspace* Camperdown or *headspace* Campbelltown (both in Sydney, Australia) from July 2015 to July 2016. These participants were recruited for the initial "proof of concept" trial of the Mental health eClinic (MHeC) of the Synergy Online System.

Primary care sample 2: Participants were recruited from a group of young people presenting for the first time to any *headspace* service in the Central and Eastern Sydney Primary Health Network (ie, Ashfield, Bondi Junction, Camperdown, Hurstville, and Miranda) from September 2016 to February 2017. These participants were recruited for a trial of the MHeC of the Synergy Online System embedded with primary mental health care services (*headspace*).

Community sample: Participants were recruited from three urban, regional, and rural communities in New South Wales that have a number of geographical, social, and economic vulnerabilities (ie, Central Coast, Western Sydney, and the Far West). Participants were recruited through targeted advertising in each of these communities (including posters and postcards in local businesses, paid Facebook advertisements, and advertisements on organizational social media channels) from March 2016 to June 2016. Young people were invited to participate in the study if they were currently living in one of these communities and had regular access to a mobile phone and the Internet.

Ethics

The University of Sydney Human Research Ethics Committees approved these studies and all participants gave written or online informed consent when they first accessed the Synergy Online System and before completing the initial clinical assessment.

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Measures

All participants were invited to complete an initial clinical assessment (accessed via the MHeC of the Synergy Online System). Participants from primary care sample 1 were provided with a URL to the alpha version of the MHeC and asked to complete the initial clinical assessment online before either a video visit or face-to-face appointment with a clinician. Participants from primary care sample 2 were provided with a URL to the beta version of the MHeC (with the video visit "turned off") and asked to complete the initial assessment before their scheduled face-to-face appointment with a clinician. Participants from the community sample either navigated themselves to the MHeC or were automatically directed (via an e-tool embedded within the Synergy Online System) to the beta version of the MHeC (with the video visit "turned on") if they were expressing psychological distress. For all participants using the MHeC, a "need help now" button was always displayed to provide the details of relevant emergency and helpline services for those who sought immediate help.

The initial clinical assessment assesses a range of mental health outcomes, as well as comorbid and associated risk factors. Being administered online and using smart skips, the full assessment takes approximately 45 min to complete (median, 47.5 min) and includes 14 modules (in the following order): demographics; current education and employment participation; mental health concerns; self-harm and suicidal behaviors; tobacco, alcohol, and other substance use; physical activity; sleep-wake behaviors; lifetime disorders; physical and mental health history; cognition; eating behaviors and body image; social connectedness; and puberty. Participants completed all modules. For the purposes of this study, the following measures were specifically selected and included for analysis.

Demographics

Participants' age, gender, highest level of education, and current education, employment, and training status (used to determine not in education, employment or training [NEET] status).

Mental Health

Current psychological distress was assessed using the Kessler-10 (K10) questionnaire [25] that is a well-validated measure of general psychological symptoms and distress widely used in adult and adolescent populations in both clinical and community settings. Hypomania-like symptoms over the last 12 months were assessed using a screener derived from the Altman self-rating scale [26]. Psychosis-like symptoms over the last 12 months were assessed using a screener derived from Community Assessment of Psychotic Experiences-Positive Symptoms scale [27]. Participants were also asked "Have you ever experienced a major mental health or behavioral problem that has affected your everyday life?" and this was used as a proxy for a previous mental health problem.

Suicidality

The Suicide Ideation Attributes Scale (SIDAS) is a 5-item scale assessing suicidal ideation over the past month [28]. The scale assesses frequency, controllability, closeness to attempt, distress, and interference with daily activities on a 10-point Likert scale. A score of 0 corresponds to "no current ideation", a score of 1 to 20 corresponds to "low current suicidal ideation", and a score of 21 to 50 corresponds to "high current suicidal ideation". The scale has strong internal reliability (Cronbach alpha=.91). Lifetime suicidal thoughts and behaviors (ideation, planning, and attempts) were assessed by three questions from the Youth Risk Behaviors Survey [29,30]; (1) "Have you ever seriously thought about killing yourself?" (2) (1) "Have you ever seriously thought about killing yourself?" (2) "Have you ever made a plan about how you would kill yourself?" and (3) "How many times have you actually tried to kill yourself?".

Functioning

An item from the Brief Disability Questionnaire (BDQ) was used to assess participant's inability to carry out daily tasks over the previous month [31]. Specifically, participants were asked "Over the past month, how many days in total were you unable to carry out your usual daily activities fully?" This enabled a calculation of "days out of role in the past month."

Alcohol and Substance Use

Two questions about alcohol and substance use were used to assess the presence of a current comorbid alcohol or substance use problem. Specifically, participants were asked "Have you recently thought that you should cut down on alcohol or other addictive drugs?" (derived from the CAGE questionnaire; [32]) and "Have you recently had a friend, relative or doctor suggest that you should cut down on alcohol or other addictive drugs?" (derived from the Alcohol Use Disorders Identification Test; [33]). Participants who answered "no" to one or both of these questions were categorized as "no problem", and participants who answered "yes" to both questions were categorized as "likely problem" [34].

Statistical Analyses

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS 22.0 for Windows). Group differences between the three sample groups (primary care sample 1, primary care sample 2, and community sample) were assessed using the Kruskal-Wallis H test for continuous variables and the chi-square test for categorical variables. The sample was then split by suicidality group (see Textbox 2; "no suicidality", "low suicidality", and "high suicidality") to assess group differences using the Kruskal-Wallis H test for continuous variables and the chi-square test for categorical variables. To examine the independent predictors of suicidality, two separate logistic regressions were conducted. The first model compares the "no suicidality" group with the "any suicidality" group (low and high suicidality groups combined). The second model compares the "low suicidality" and "high suicidality" groups. For both models, variables were entered using a forward forced-entry method with demographic variables (age, gender, education, and NEET status) entered in the first block, current mental health variables (K10, hypomania-like symptoms, psychosis-like symptoms, and alcohol or substance use) entered in the second block, mental health history variables (previous mental health problem, suicide plans or attempts history) entered in the third block, and functioning (days out of role) entered in the final block. To control for sample groups in the analyses, "sample" was also entered in the final block. Only models with

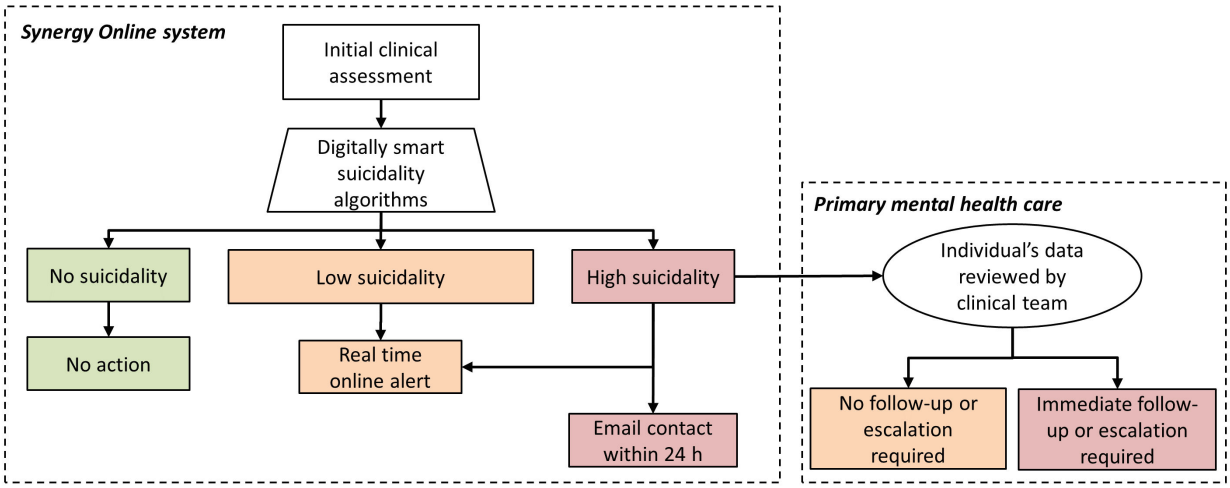
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nonsignificant Hosmer-Lemeshow goodness of fit tests were included.

Textbox 2. Suicidality escalation protocol.

The suicidality escalation protocol involves multiple levels of action, dependent on the participants' responses to the initial assessment (Figure 1). Every young person completes the initial clinical assessment, and at the end of the suicidality module the digitally smart algorithms assess current and past suicidality. The algorithm assigns them to one of the three groups: "no suicidality" (SIDAS score of 0 and no lifetime suicidal behaviors), "low suicidality" (SIDAS score of 1-20 and/or lifetime suicidal behaviors), and "high suicidality" (SIDAS score of 21 to 50). For the "no suicidality" group, no action is taken. For those in the "low suicidality" or "high suicidality" groups, an automatic real-time alert is immediately presented on the young person's screen. The alert displays information regarding both crisis and non-crisis services so the young person can access immediate support if needed. For those in the "high suicidality" group, two additional actions are initiated. First, a notification is sent to the clinical research team who initiate email contact with the participant within 24 h. This email aims to provide further information that encourages the young person to seek help and requests they inform the clinical research team how they are going by replying to the email or calling. Second, for those currently in contact with a service, the young person's data is forwarded to the clinical service for review, and a decision is made regarding further follow-up or escalation. Further follow-up or escalation involves one or more of the following: contact over the phone, rescheduling the young person's appointment or an online "video visit" within the subsequent 72 h. Importantly, this suicidality escalation protocol is designed to respond in real-time to the suicidality expressed by the young person and is not used to determine suicide risk. Formal suicide risk is determined by a health professional or a multidisciplinary team after making contact with the young person and reviewing the young person's data.

Figure 1. Suicidality escalation protocol.



Results

Sample Characteristics

The demographic and behavioral characteristics for each sample are presented in Tables 1 and 2. A total of 232 participants were included in the analyses (95 from primary care sample 1, 105 from primary care sample 2, and 32 from the community sample). The mean age of the entire sample was 20.44 years (standard deviation [SD]=2.59; median=21 years), 69% (160/232) were female, and 37% (87/232) were classified as NEET. Across all three samples, the mean K10 score was in the severe range of psychological distress (x =28.99, SD=8.86; median=30); 17% (40/232) reported no psychological distress, 13% (31/232) reported mild psychological distress, 19% (43/232) reported moderate psychological distress, and 51% (118/232) reported severe psychological distress. The mean SIDAS score was 8.25 (SD=11.52; median=2); 39% (90/232) reported no current suicidal ideation, 46% (107/232) reported low current suicidal ideation, and 15% (35/232) reported high current suicidal ideation. The only statistically significant differences identified between the three sample groups were for "days out of role" over the past month (χ^2_2=16.2, *P*<.001).

Suicidality Escalation in Primary Care—A Proof of Concept

The first use of the suicidality escalation protocol in a primary mental health care setting occurred at *headspace* Camperdown and *headspace* Campbelltown and was rolled out entirely by the clinical research team. Of the entire primary care sample 1, 33% (31/95) were identified as "no suicidality" and so no action was initiated, 51% (49/95) were identified as "low suicidality" and were presented with a real-time alert only, and 16% (15/95) were identified as "high suicidality," which initiated the real-time alert and an additional two escalation actions. All 15 individuals were contacted via email by the clinical research team and had their data reviewed. Of these 15, 7 had their entry into clinical care escalated (ie, their initial clinical assessment appointment was brought forward). Clinicians reported that the decision to escalate an individual was influenced by the following: (1) concerns over specific suicidal ideation attributes such as little of control over suicidal thoughts (5/7 participants) and closeness to making an attempt (5/7 participants), (2) concerns over the presence of hypomania or psychosis-like symptoms (1/7 participants), (3) recent plans to make an attempt that were identified upon follow-up (1/7 participants), (4) few protective factors identified upon follow-up (1/7 participants), (5) few protective factors identified at follow-up (1/7

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participants), and (6) recent self-harm (1/7 participants). All 7 participants were escalated due to one or more of these factors being present, and the clinician decided that their initial appointment for care was too long to wait. The remaining 8 participants did not have the initial assessment appointment brought forward due to most, or all of the above, factors being absent or because their clinical appointment was scheduled within a few days (range=0-5 days), which was deemed to be sufficient by the reviewing clinician.

Table 1. Demographic characteristics by sample group (N=232).

Characteristics	Primary care 1 (n=95)	Primary care 2 (n=105)	Community (n=32)	*P* value
Age, mean (SD[a])	20.39 (2.56)	20.41 (2.53)	20.66 (2.90)	.88
Gender, n (%)				.76
Female	68 (72)	71 (68)	21 (66)	
Male	27 (28)	34 (32)	11 (34)	
Education[b], n (%)				.70
Secondary	44 (46)	49 (48)	16 (55)	
Tertiary	51 (54)	54 (52)	13 (45)	
NEET[c] status, n (%)				.12
Non-NEET	62 (65)	59 (56)	24 (75)	
NEET	33 (35)	46 (44)	8 (25)	

[a]SD: standard deviation.

[b]"no formal education" and "primary education" groups were left out due to insufficient cell counts (n=5 cases missing).

[c]NEET: not in education, employment or training.

Suicidality Escalation Scaled Up for Use in Primary Care

The suicidality escalation protocol was scaled up and rolled out across all *headspace* services in the Central and Eastern Sydney Primary Health Network. Of the entire primary care sample 2, 34% (36/105) were identified as "no suicidality" and so no action was initiated, 55% (57/105) were identified as "low suicidality" and were presented with a real-time alert only, and 11% (12/105) were identified as "high suicidality," which initiated the real-time alert and an additional two escalation actions. All 12 individuals were contacted via email by the clinical research team and had their data forwarded for review to the clinical service responsible so that specific service protocols could be initiated.

Of the entire community sample, 37.5% (12/32) young people were identified as "no suicidality" and so no action was initiated, 37.5% (12/32) were identified as "low suicidality" and were presented with a real-time alert, and 25% (8/32) were identified as "high suicidality", which initiated the real-time alert and an additional two escalation actions. All 8 individuals were contacted via email by the clinical research team, and had their data reviewed.

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Table 2. Behavioral characteristics by sample group (N=232).

Characteristics	Primary care 1 (n=95)	Primary care 2 (n=105)	Community (n=32)	*P* value
K10[a] score, mean (SD[b])	29.28 (8.16)	29.75 (8.28)	25.59 (11.76)	.11
K10 category, n (%)				.08
No	13 (14)	15 (14)	12 (38)	
Mild	15 (16)	13 (13)	3 (9)	
Moderate	18 (19)	20 (19)	5 (16)	
Severe	49 (51)	57 (54)	12 (37)	
SIDAS[c] score, mean (SD)	7.93 (11.50)	7.52 (9.71)	11.59 (16.05)	.87
SIDAS category, n (%)				.34
No ideation	37 (39)	40 (38)	13 (41)	
Low ideation	43 (45)	53 (51)	11 (34)	
High ideation	15 (16)	12 (11)	8 (25)	
Hypomania-like symptoms, last 12 months, n (%)				.06
No	68 (72)	88 (84)	22 (69)	
Yes	27 (28)	17 (16)	10 (31)	
Psychosis-like symptoms, last 12 months, n (%)				.51
No	65 (68)	71 (68)	25 (78)	
Yes	30 (32)	34 (32)	7 (22)	
Days out of role in past month, mean (SD)	7.53 (7.22)	8.04 (8.47)	2.34 (2.66)	<.001
Alcohol and substance use, current, n (%)				.22
No problem	60 (73)	87 (83)	25 (78)	
Likely problem	26 (27)	18 (17)	7 (22)	
Previous mental health problem, ever, n (%)				.24
No	27 (28)	31 (29)	14 (44)	
Yes	68 (72)	74 (71)	18 (56)	
Suicide plans or attempts, ever, n (%)				.18
No	67 (71)	66 (63)	17 (53)	
Yes	28 (29)	39 (37)	15 (47)	

[a]K10: Kessler-10.

[b]SD: standard deviation.

[c]SIDAS: Suicide Ideation Attributes Scale.

Predictors of Suicidality

The overall sample was split according to “no suicidality”, “low suicidality”, and “high suicidality” to examine the demographic and behavioral differences between these groups (Tables 3 and 4). No differences were identified between the sample groups (*P*=.33) or for the demographic variables; age (*P*=.08), gender (*P*=.74), or NEET status (*P*=.29); however, significant differences were identified for highest level of education (χ^2_2=8.6, *P*=.01). In terms of behavioral characteristics, no differences were identified for days out of role (*P*=.09); however, significant differences were identified between the three suicidality groups for psychological distress (χ^2_2=48.5, *P*<.001), hypomania-like symptoms in the last 12 months (χ^2_2=12.9, *P*=.002), psychosis-like symptoms in the last 12 months (χ^2_2=29.2, *P*<.001), alcohol or substance use (χ^2_2=8.3, *P*=.02), and previous mental health problem (χ^2_2=15.8, *P*<.001). Significant differences between the “low suicidality” and “high suicidality” groups were also identified for history of suicide plans or attempts (χ^2_1=22.3, *P*<.001).

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Table 3. Demographic characteristics by suicidality group (N=232).

Characteristics	Suicidality			*P* value
	No (n=79)	Low (n=118)	High (n=35)	
Sample, n (%)				.33
Primary care 1	31 (39)	49 (42)	15 (43)	
Primary care 2	36 (46)	57 (48)	12 (34)	
Community	12 (15)	12 (10)	8 (23)	
Age, mean (SD)[a]	20.32 (2.66)	20.75 (2.52)	19.66 (2.53)	.08
Gender, n (%)				.74
Female	57 (72)	79 (67)	24 (69)	
Male	22 (28)	39 (33)	11 (31)	
Education[b], n (%)				.01
Secondary	32 (41)	53 (46)	24 (71)	
Tertiary	46 (59)	62 (54)	10 (29)	
NEET[c] status, n (%)				.29
Non-NEET	48 (61)	71 (60)	26 (74)	
NEET	31 (39)	47 (40)	9 (26)	

[a]SD: standard deviation.

[b]"no formal education" and "primary education" groups were left out due to insufficient cell counts (n=5 cases missing).

[C]NEET: not in education, employment or training.

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Table 4. Behavioral characteristics by suicidality group (N=232).

Characteristics	Suicidality			*P* value
	No (n=79)	Low (n=118)	High (n=35)	
Sample, n (%)				.33
Primary care 1	31 (39)	49 (42)	15 (43)	
Primary care 2	36 (46)	57 (48)	12 (34)	
Community	12 (15)	12 (10)	8 (23)	
K10[a] score, mean (SD[b])	24.30 (8.04)	29.92 (8.22)	36.43 (6.41)	<.001
K10 category, n (%)				<.001
No	26 (33)	14 (12)	0 (0)	
Mild	14 (18)	16 (14)	1 (3)	
Moderate	17 (21)	22 (18)	4 (11)	
Severe	22 (28)	66 (56)	30 (86)	
Hypomania-like symptoms, last 12 months, n (%)				.002
No	67 (85)	92 (78)	19 (54)	
Yes	12 (15)	26 (22)	16 (46)	
Psychosis-like symptoms, last 12 months, n (%)				<.001
No	67 (85)	82 (70)	12 (34)	
Yes	12 (15)	36 (30)	23 (66)	
Days out of role in past month, mean (SD)	6.22 (7.63)	7.18 (7.69)	8.46 (7.35)	.09
Alcohol and substance use, current, n (%)				.02
No problem	70 (89)	87 (74)	24 (69)	
Likely problem	9 (11)	31 (26)	11 (31)	
Previous mental health problem, ever, n (%)				<.001
No	34 (43)	36 (30)	2 (6)	
Yes	45 (57)	82 (70)	33 (94)	
Suicide plans or attempts, ever, n (%)				<.001[c]
No	79 (100)	67 (57)	4 (11)	
Yes	0 (0)	51 (43)	31 (89)	

[a]K10: Kessler-10.

[b]SD: standard deviation.

[c]This *P* value refers to the 2x2 comparison between the low and high groups. By definition the "no suicidality" group has 0 "yes" responses.

Further analyses using logistic regression were conducted to (1) identify predictors of "no suicidality" compared with "any suicidality" (low and high suicidality groups combined) (Model 1, Table 5), and (2) to identify predictors of "low suicidality" compared with "high suicidality" (Model 2, Table 5). Model 1 identified that higher psychological distress and a current alcohol or substance use problem were predictors of "any suicidality" compared with "no suicidality" (χ^2_{12}=57.7, *P*<.001, R^2=0.22). Model 2 identified that higher psychological distress, any psychosis-like symptoms in the last 12 months, a previous mental health problem, and a history of suicide plans or attempts were all predictors of "high suicidality" compared with "low suicidality" (χ^2_{13}=67.0, *P*<.001, R^2=0.36).

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Table 5. Logistic regression models showing predictors of suicidality (N=232).

	No suicidality versus any suicidality[a]			Low suicidality versus high suicidality[b]		
	Beta (SE[c])	OR (95% CI)	*P* value	Beta (SE)	OR (95% CI)	*P* value
Age	.05 (0.07)	1.05 (0.91-1.22)	.47	−.17 (0.15)	0.84 (0.63-1.13)	.26
Gender						
Female		1.00			1.00	
Male	.65 (0.38)	1.92 (0.92-4.02)	.08	.66 (0.64)	1.94 (0.55-6.81)	.30
Education[d]						
Secondary		1.00			1.00	
Tertiary	−.22 (0.39)	0.81 (0.37-1.75)	.58	−.91 (0.69)	0.40 (0.10-1.57)	.19
NEET[e] status						
NEET		1.00			1.00	
Non-NEET	.30 (0.35)	1.35 (0.68-2.67)	.39	.92 (0.68)	2.50 (0.66-9.51)	.18
K10[f] score	.11 (0.02)	1.12 (1.07-1.17)	<.001	.11 (0.04)	1.12 (1.03-1.21)	.01
Hypomania-like symptoms, last 12 months						
No		1.00			1.00	
Yes	.14 (0.45)	1.16 (0.48-2.76)	.75	.41 (0.60)	1.50 (0.47-4.84)	.50
Psychosis-like symptoms, last 12 months						
No		1.00			1.00	
Yes	.80 (0.41)	2.22 (1.00-4.95)	.05	1.54 (0.58)	4.68 (1.51-14.53)	.01
Alcohol and substance use, current						
No problem		1.00			1.00	
Likely problem	1.04 (0.46)	2.84 (1.15-7.05)	.02	−.12 (0.63)	0.89 (0.26-3.04)	.85
Previous mental health problem						
No		1.00			1.00	
Yes	.42 (0.35)	1.52 (0.77-3.03)	.23	2.43 (0.99)	11.34 (1.64-78.30)	.01
Suicide plans or attempts, ever						
No					1.00	
Yes	N/A[g]	N/A	N/A	2.34 (0.70)	10.41 (2.65-40.83)	.001
Days out of role, past month	−.02 (0.02)	0.98 (0.94-1.03)	.42	.01 (0.04)	1.00 (0.92-1.09)	.93
Sample						
Community		1.00			1.00	
Primary care 1	−.22 (.57)	0.80 (0.26-2.43)	.69	.25 (0.86)	1.28 (0.24-6.83)	.77
Primary care 2	−.27 (.57)	0.76 (0.25-2.30)	.63	−.51 (0.92)	0.60 (0.10-3.67)	.58

[a]Model 1 **:** R^2=0.22 (Cox and Snell), 0.31 (Nagelkerke). Model χ^2_{12}=57.7, *P*<.001.

[b]Model 2 **:** R^2=0.36 (Cox and Snell), 0.55 (Nagelkerke). Model χ^2_{13}=67.0, *P*<.001.

[c]SE: standard error.

[d]"no formal education" and "primary education" groups were left out due to insufficient cell counts (n=5 cases missing) .

[e]NEET: not in education, employment or training.

[f]K10: Kessler-10.

[g]N/A: Not applicable, this comparison is invalid since the "no suicidality" group, by definition, has no history of suicide plans or attempts and therefore was left out of the model.

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Discussion

Principal Findings

We identified that two-thirds of help-seeking young people reported some degree of suicidality, and the protocol provided these young people with a real-time alert online. Further levels of escalation (email or phone contact and clinical review) were initiated for the 15% (35/232) of young people who reported high suicidality. Higher levels of psychological distress and a current alcohol or substance use problem predicted any level of suicidality (compared with no suicidality). In addition to higher levels of psychological distress, psychosis-like symptoms in the last 12 months, a previous mental health problem, and a history of suicide plans or attempts were specific predictors of high suicidality (compared with low suicidality). These results support the use of new and emerging technologies to facilitate the systematic assessment and detection of young people experiencing suicidal thoughts with additional comorbidities and enable an appropriate and timely response from service providers.

The use of the suicidality escalation protocol of the Synergy Online System as an adjunct to traditional primary mental health care services assisted clinical decision-making about suicide risk and the need for care among those young people reporting higher levels of suicidality. Of the young people in primary care, 13.5% (27/200) had their case escalated to clinical review by a clinician or clinical team before their entry into care. Importantly, none of these young people were referred to crisis services but instead had their entry into care facilitated due to a clinically perceived higher need for immediate care. This escalation process ensured that individuals presenting to primary care services with increased suicidality were not delayed by a service waitlist, which commonly arises from a mismatch between service demand and capacity [35]. Instead, the Synergy Online System was able to deploy many immediate actions to ensure the suicidality risk is addressed in a timely and efficient manner. The use of this System has already had major implications on actual health service practices for the youth mental health services that have adopted Synergy; specifically, improving patient and workforce management through systematic assessment, automatic escalation of an individual's data, and assisting clinical team review and decision-making processes.

Importantly, the results here also highlight the benefits of offering online services to young people by allowing mental health care and the service to be brought to the young person when they need it, wherever they live, rather than relying on young people to present initially to a face-to-face service which has many barriers to overcome [36]. Notably, there were comparable levels of suicidal ideation in the community sample compared with those presenting to primary mental health care. These young people may never have presented to a face-to-face service either because of common barriers to help-seeking or because a service was not available locally [37,38]. The use of the online service meant that a service could "come to them" when they needed it and in a manner that is preferable to some young people [39]. The use of new and emerging technologies as reported in this paper is critical in reaching the high numbers of at-risk youth in the community who are not presenting to traditional face-to-face services. Importantly, with the rapid increase in new and emerging technologies for mental health care, there is a significant need for effective suicide escalation protocols that can appropriately and efficiently manage risk. A real-time mapping system to (local) mental health services might be useful for those in the community who seek help online to ensure the system effectively facilitates help-seeking behavior, which is a crucial unresolved issue for online assessment and feedback systems [40-42]. Similarly, further follow-up through partnerships with specific local or national suicide prevention organizations may be needed to increase help-seeking behavior for those identified as at-risk or in need of care in the community.

Psychological distress differentiated between each level of suicidality identified, which is consistent with the established relationship between distress and suicidality [43,44]. The only other predictor that differentiated between no suicidality and any suicidality was a current alcohol or substance use problem. This reflects the common relationship between alcohol and substance use and suicidal thoughts and behaviors, particularly among young people with mental health problems [45]. Young people reporting high suicidality were also more likely to report psychosis-like symptoms in the last 12 months, a previous mental health problem, and a history of suicide plans or attempts. Together, this confirms the significant comorbidity that help-seeking young people initially present with and reiterates the need for services to be equipped to respond to the differing individual needs a young person has when they first present to care.

The ongoing development of the Synergy Online System would benefit from employing methodologies that utilize longitudinal outcomes to improve the existing algorithms accuracy for identifying individual cases of suicidality that should be escalated and followed up immediately by a clinician and service. Machine learning methodologies are increasingly used in psychiatric research as they facilitate individual-level prediction of unseen observations, which makes them suitable for the development of clinically useful digital tools [46]. Recent evidence has demonstrated the use of these algorithms to utilize clinical and demographic variables to predict suicide attempters among a group of mood disorder patients with accuracy comparable with most breast cancer prediction algorithms [47,48], whereas another study demonstrated the utility of such algorithms to differentiate between suicidal and nonsuicidal patients [49]. Employing these approaches could improve the personalization of care beyond simple cut-off scores and include key risk factors specific to a particular individual. Similar approaches have been employed by Facebook who have developed an online tool that uses machine learning to identify users at risk of suicide by assessing their posts and comments and provides the user with a number of options for how to get help [50]. These semiautomated approaches require rigorous evaluation and validation using qualitative person-centered approaches such as user acceptance testing, in addition to more traditional quantitative methods to determine whether they are appropriate and effective. This is important for the development

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of clinically useful and scalable suicide prevention and early intervention efforts that are integrated with existing services and practices.

Limitations

For the future development of the protocol, some limitations need to be addressed. First, the initiation of the suicidality escalation protocol is dependent on when the young person completes the online assessment. So young people at-risk who don't complete the online assessment immediately cannot be identified and spend a longer period under distress and not in care. Second, the outcome for those who had their entry into care escalated is unclear, so it is difficult to determine the impact of the suicidality escalation protocol on their clinical outcome. This was beyond the scope of this particular study, but it is an important focus for future research to establish the long term impact of this protocol on engagement with services and clinical trajectory. Another key focus for this work would be to determine whether the protocol missed individuals who would become high risk or later engage in suicidal behaviors. Third, the relatively small sample size of the community sample, compared with the two primary care sample groups, means that the sample characteristics were somewhat biased toward the primary care groups and limits the generalizability of these results to young people in the community who seek help online. Finally, the use of the K10 as a measure of general psychological distress may be limited primarily to depression and anxiety symptoms and less useful for other mental health problems common in adolescence.

Conclusions

This study contributes to the research and knowledge about the use of new and emerging technologies to identify and respond to increased suicidality among help-seeking young people. Young people with increased suicidality were more likely to present with a number of comorbid issues including psychosis-like symptoms and a history of plans or attempts, which emphasizes the need for these young people to receive appropriate and timely care.

Acknowledgments

Frank Iorfino is supported by an Australian Postgraduate Award (APA). Data collected for primary care sample 1 was supported by the Young and Well CRC (2011-16), and data collected for primary care sample 2 and the community sample was supported by a Commonwealth Government of Australia investment in Project Synergy — the design, build, and evaluation of an innovative system of care that embeds new and emerging technology into Australia's youth mental health services (2014-16). This project was carried out through a partnership between the Young and Well CRC and The University of Sydney's Brain and Mind Centre. When Young and Well CRC closed on June 30, 2016, Project Synergy was novated to The University of Sydney. Thanks to the entire Youth Mental Health and Technology Team at the Brain and Mind Centre.

Conflicts of Interest

Professor Ian Hickie has been a commissioner in Australia's National Mental Health Commission since 2012. He is the co-director, Health and Policy at The University of Sydney's Brain and Mind Centre. The Brain and Mind Centre operates an early-intervention youth services at Camperdown under contract to headspace. Professor Hickie has previously led community-based and pharmaceutical industry-supported (Wyeth, Eli Lily, Servier, Pfizer, AstraZeneca) projects focused on the identification and better management of anxiety and depression. He is a member of the Medical Advisory Panel for Medibank Private, a board member of Psychosis Australia Trust, and a member of Veterans Mental Health Clinical Reference group. He is the chief scientific advisor to, and an equity shareholder in, Innowell. Innowell has been formed by The University of Sydney and PricewaterhouseCoopers (PwC) to deliver the $30m Australian Government-funded "Project Synergy." Project Synergy is a 3-year program for the transformation of mental health services through the use of new and innovative technologies. Professor Jane Burns is the CEO of, and an equity shareholder in, Innowell.

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Abbreviations

BDQ: Brief Disability Questionnaire
K10: Kessler-10 Questionnaire
MHeC: Mental health eClinic
NEET: Not in Educational, Employment or Training

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SIDAS: Suicide Ideation Attributes Scale
SPSS: Statistical Package for the Social Sciences

Edited by G Eysenbach; submitted 23.04.17; peer-reviewed by P Batterham, AE Aladağ, D Reidenberg, S MacLean; comments to author 17.05.17; revised version received 26.05.17; accepted 26.05.17; published 12.07.17.

Please cite as:
Iorfino F, Davenport TA, Ospina-Pinillos L, Hermens DF, Cross S, Burns J, Hickie IB
Using New and Emerging Technologies to Identify and Respond to Suicidality Among Help-Seeking Young People: A Cross-Sectional Study
J Med Internet Res 2017;19(7):e247
URL: http://www.jmir.org/2017/7/e247/
doi:10.2196/jmir.7897
PMID:28701290

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Original Paper

Short Text Messages to Encourage Adherence to Medication and Follow-up for People With Psychosis (Mobile.Net): Randomized Controlled Trial in Finland

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Abstract

Background: A text messaging service (short message service [SMS]) has the potential to target large groups of people with long-term illnesses such as serious mental disorders, who may have difficulty with treatment adherence. Robust research on the impact of mobile technology interventions for these patients remains scarce.

Objective: The main objective of our study was to investigate the impact of individually tailored short text messages on the rate of psychiatric hospital readmissions, health care service use, and clinical outcomes. In addition, we analyzed treatment costs.

Methods: Between September 2011 and November 2012, we randomly assigned 1139 people to a tailored text message intervention (n=569) or usual care (n=570). Participants received semiautomated text messages for up to 12 months or usual care. The primary outcome, based on routinely collected health register data, was patient readmission into a psychiatric hospital during a 12-month follow-up period. Secondary outcomes were related to other service use, coercion, medication, adverse events, satisfaction, social functioning, quality of life, and economic factors (cost analysis).

Results: There was 98.24% (1119/1139) follow-up at 12 months. Tailored mobile telephone text messages did not reduce the rate of hospital admissions (242/563, 43.0% of the SMS group vs 216/556, 38.8% of the control group; relative risk 1.11; 95% CI 0.92-1.33; *P*=.28), time between hospitalizations (mean difference 7.0 days 95% CI –8.0 to 24.0; *P*=.37), time spent in a psychiatric hospital during the year (mean difference 2.0 days 95% CI –2.0 to 7.0; *P*=.35), or other service outcomes. People who received text messages were less disabled, based on Global Assessment Scale scores at the time of their readmission, than those who did not receive text messages (odds ratio 0.68; 95% CI 0.47-0.97; *P*=.04). The costs of treatment were higher for people in the SMS group than in the control group (mean €10,103 vs €9210, respectively, *P*<.001).

Conclusions: High-grade routinely collected data can provide clear outcomes for pragmatic randomized trials. SMS messaging tailored with the input of each individual patient did not decrease the rate of psychiatric hospital visits after the 12 months of follow-up. Although there may have been other, more subtle effects, the results of these were not evident in outcomes of agreed importance to clinicians, policymakers, and patients and their families.

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Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 27704027; http://www.isrctn.com/ISRCTN27704027 (Archived by WebCite at http://www.webcitation.org/6rVzZrbuz).

(J Med Internet Res 2017;19(7):e245) doi:10.2196/jmir.7028

KEYWORDS

text messaging; psychotic disorders; randomized controlled trial; medication adherence

Introduction

Mobile technology has the potential to promote patient self-management, leading to better health behaviors, which, in turn, improve clinical outcomes among people with chronic illnesses. Short message service (SMS) text messaging on mobile telephones could address some of the chronic disease management needs. Text messaging reminders are simple, efficient options that enable direct or indirect communication between health services and patients in a time- and cost-efficient manner [1]. The majority of mHealth studies have tested basic mobile phone features, such as text messaging [2], but the effectiveness of using text messaging for supporting treatment adherence among people with serious mental disorders, such as schizophrenia, is still not clear [3].

The use of mHealth apps is expanding in various areas of health care [4], including mental health [5], and likewise, the evaluation of such apps is increasing [1]. Nevertheless, clear evidence of the value of mHealth apps in improving adherence, within of the realm of chronic disease management, is still lacking [6]. With regard to people with schizophrenia, for whom adherence is particularly an issue [7], the relevant up-to-date Cochrane review found that information and communication technology (ICT)-based prompts were not clearly beneficial: in 1 randomized controlled trial with 320 participants, the relative risk of stopping medication within 6 months was 1.11 (95% CI 0.96-1.29; moderate-quality evidence) [8]. Despite this, the number of mHealth apps promoting medication adherence has increased, including apps specifically targeted at improving mental health [9]. The potential harm that such technology can cause for people with chronic mental illnesses must also be considered [10], although very few studies have specifically addressed this issue [11]. Some patients find text messaging disturbing and discontinue reading the messages [12]. In theory, this could increase the sense of isolation among such patients, resulting in decreasing adherence [13]. The effects of SMS text messaging on mental health and health service use also remain incompletely explored. To provide precise results of the effects of text messaging on clinically relevant outcomes, high-grade, longer-term, and adequately powered studies are needed [14].

In this paper, we report the findings of a large pragmatic, multicenter, parallel-group, 12-month randomized controlled clinical trial investigating the impact of individually tailored SMS text messages on the rate of psychiatric hospital readmissions, health care service use, and clinical outcomes. We hypothesized that patients in the intervention group receiving SMS prompts would have fewer psychiatric hospital readmissions during the 12-month follow-up period, less service use, fewer coercive incidents, less medication use, fewer adverse events, higher satisfaction, higher social functioning, a better quality of life, and lower treatment costs, compared with those who did not receive SMS prompts. Our assumption behind our hypothesis was that if text message reminders lead to improved adherence to treatment—for example, to better medication intake, appointment keeping, or self-management—then we would see fewer hospital readmissions or other adverse events.

Methods

Design and Study Setting

The Mobile.Net study was initiated by the Academy of Finland to assess the effectiveness of SMS text messaging in encouraging medication compliance and self-care for people with serious mental illnesses. We assumed that when a patient is willing to take their medication frequently as prescribed, the positive results can be seen as a decreased need for health service use. Good patient medication adherence reduces the rate of relapse and hospital readmissions [15]. The rationale, design, and methods have previously been described [16]. The trial was undertaken at psychiatric hospitals in Finland. We approached the managers of the hospitals, sent them written material about the study, and allowed them up to 3 weeks to decide if they wanted their hospital to participate. Of 30 possible hospital organizations, 24 organizations (45 wards) decided to take part. The trial was approved by the Ethics Committee of the Hospital District of Southwest Finland (December 16, 2010; ETMK 109/180/2010).

Participants

Participants in the trial were adults (aged 18-65 years) at the point of discharge from a psychiatric hospital ward, for whom ongoing antipsychotic medication had been advised. Each participant had a mobile phone, was able to use the Finnish language, and gave written informed consent to participate. We did not include a formal test of capacity, but rather, we relied on the judgment of experienced health care professionals in their routine assessment of patients' understanding, retention, assimilation, and communication of information as patients were nearing the point of discharge. Formalized assessment of patient cognition is not part of routine psychiatric care in Finland. We excluded people who had a planned nonacute treatment period in a hospital ward, as well as those who were being treated in forensic psychiatric services. Participants gave written informed consent to take part in the study, complying with the Declaration of Helsinki, the World Health Organization principles of good clinical practice, and national requirements.

Randomization and Masking

We used a central randomization service at the University of Turku (the Department of Mathematics and Statistics). The study was individually randomized, open label, stratified by

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hospital, with a variable (random) permuted block length of 4 patients per block, to ensure that trial groups at each hospital were balanced. The allocation was computer generated by an independent statistician outside of the study and masked to participants. The investigators who enrolled participants could not foresee assignment. In addition, the statisticians, the outcome assessors of the survey data, the data analysts, and the National Register holder—responsible for the Finnish routine data used in this study—were kept blinded to allocation. However, after randomization, due to the type of intervention, the allocation group was unmasked to participants, the research nurses at each hospital, and the health care staff on the wards. While the Data Management Committee undertook ongoing safety surveillance, investigators running preliminary analyses for the Committee were masked to data until the database was released.

The high number of hospitals and study wards included in the trial necessitated that recruitment be undertaken in 10 waves, between September 2011 and November 2012. A research assistant, completely independent of the trial team (masked for allocation), inserted the allocation numbers into sealed envelopes. Written allocations of assignment, sealed in entirely opaque individual envelopes and marked with a study identification number, were distributed to each study ward. Research nurses on each study ward sequentially assigned the sealed envelopes in a predetermined order to people who had both fulfilled the inclusion criteria and given their written informed consent during their discharge process.

Recruitment

We used standardized, face-to-face informed consent procedures for patient recruitment during the inpatient stays, before a patient was discharged from the ward. Nurses were asked to identify potentially eligible patients from the medical records. These patients were given a short, 1-page information leaflet about the study, and then, at their time of discharge, patients were provided with more detailed written information with an invitation to participate. If willing, patients then attended appointments with a research nurse (specifically trained for this task) to discuss practical arrangements, check eligibility, and complete a baseline assessment (age, sex, marital status, vocational education, employment status, and number of psychiatric treatment periods) and study registration. Before consenting, participants were made aware that they were free to withdraw without obligation at any time and that such an action would not adversely affect any aspect of their care. We did not envisage that the intervention would interfere with routine outpatient care.

Interventions

Patients in the experimental group received semiautomated 1-way text messages for up to 12 months from the time of recruitment. To increase acceptability of the prompts and engage users, the fundamental content of the 85 text messages was designed by both service users and health care professionals [16], and then tailored with input from each individual patient at the point of randomization. Patients in the intervention group selected compulsory text messages regarding medication (eg, “Take your medication, please,” “It is important to take your medication as prescribed.”) and treatment appointments (“Remember to book a follow-up appointment,” “Please go to your follow-up appointment.”), as well as voluntary text messages related to their free time and daily management (“Are your clothes clean and tidy?”, “Be more gentle with yourself.”). Text message examples are translations from the Finnish language. The content of the text messages is described in greater detail in Kauppi et al [17].

Messages were selected in cooperation with the research nurses on each ward and were recorded in a text message booklet. Text message selection was based on patients’ preferences: each patient was able to select the exact messages he or she wanted [17]. There was no specific or predefined schedule for the messages. However, to make sure patients did not receive an overwhelming amount of text messages, and to prevent patient habituation to the text messages [18], we limited the total amount of text messages to up to 12 messages in a month. The patients were able to choose the amount (between 2 and 12 text messages per month), time (any time, day or night) and day of the week (from Monday to Sunday) of the selected messages (see Kauppi et al [17]). The messages were not personalized in any other way, to protect patient privacy. Patient names and information related to illnesses or medication were not mentioned in the messages. The text messages were not interactive (they were 1-way messages), and therefore no response was required from patients. If a patient sent a message to the research group, we reviewed it and contacted staff members responsible for that particular patient if needed. Otherwise, the patient would receive a general response, unrelated to their treatment. Text messages were sent to the patients automatically via a specific digital text message reminder system. Table 1 provides a detailed description of the intervention [19,20].

Research nurses (n=129) who worked on the study wards had 2 days of training, which covered theoretical and practical issues in randomization and intervention management, and two 1-day training updates during the trial. Each research nurse recorded the number of patients in each ward, the eligible participants, the number of those who refused, and those who gave informed consent. Every 2 weeks, Mobile.Net researchers from the research center (in Turku, Finland) made quality control assessment phone calls to each of the 45 wards to ensure that eligible patients were assessed, baseline data collected, and ethical requirements followed. These calls also monitored whether staff had received any messages from patients or their caregivers describing discomfort or harm caused by the text messages and to identify any problems in randomization. In addition, we visited the research wards at least twice during the recruitment period: we held face-to-face meetings with the research nurses and staff members to ensure high-quality data collection, maintained interest, and an *esprit de corps*. Email support for the study ward was also available during the months of patient recruitment.

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Table 1. Description of the short message service (SMS) text messaging intervention[a].

Categories	Description
Brief name	Tailored, patient-led SMS intervention.
Rationale and theory	The intervention is based on self-determination theory [20], which explains human motivation. The theory assumes that developing a sense of autonomy, competence, and relatedness is critical to processes of internalization and integration, through which an individual comes to self-regulate and maintain behaviors beneficial to health and well-being. Intrinsic forms of motivation involve engaging in behaviors for their own sake (eg, for challenge and enjoyment), while extrinsic forms of motivation involve doing an activity because it is instrumental in achieving a separate consequence. Environments that promote autonomy and support confidence are likely to enhance compliance and health outcomes.
Materials	Materials (and their users) were a computer with access to the Internet at the hospital (research nurses); mobile phone with a SIM[b] card to receive text messages (patients); a paper-format text message library, including a list of 85 text messages with the contact information of the research nurse and researchers (research nurses, patients).
Procedures	The patients selected their favorite text messages from a text message library. The research nurse input each person's preferences of text messages into an electronic semiautomated system.
Providers	The semiautomated system was managed by nurses in psychiatric hospitals.
How?	Messages continued for 12 months or until participants no longer wanted to receive the messages. The messages did not include any personal health-related content (eg, identification codes or names, diagnoses, medication, or name of health services). Participants were advised to inform researchers or research nurses if their mobile number changed, if they felt at all uncomfortable because of the received text messages, or in case of any technical problems.
Where?	Patients received SMS messages after being discharged from psychiatric hospital.
When and how much?	The timing, frequency, and conditions under which SMS messages were to be stopped were decided by the participants. The total number of messages received, free of charge to patients, was limited to a maximum of 12 per month or 4 per week (the minimum was 2 per month related to medication).
Tailoring and modifications	Patients were able to stop or change the topic, frequency, or timing of any messages by sending an email, telephoning, text messaging, or mailing researchers or staff members.

[a]Modified from the template for intervention description and replication (TIDieR) checklist and guide, Hoffmann et al [19].

[b]SIM: subscriber identity module.

All patients allocated to standard care (control group) continued with usual care after discharge from hospital at the discretion of their psychiatric and nursing team. The health professionals were able to use any resources at their disposal to offer maximum care for patients based on the existing system in Finland, which does not automatically include regular text messages. We did not restrict the use of any technological applications for these people.

Outcomes

Primary Outcome

The intervention in the experimental group involved a maximum of 12 months of SMS text messaging. We collected all of the data for the primary outcome from routine data collection by the Finnish national Care Register for Health Care (HILMO; formerly the Finnish Hospital Discharge Register) [21]. The register includes individual clinical and administrative data of all people treated in psychiatric hospitals in Finland. The completeness and accuracy of this register have been found to vary from "satisfactory" to "very good" [22]. To our knowledge, and that of those administering the register, Mobile.Net is the first trial to use these routinely collected data for outcomes for a randomized trial. The use of the register as the main outcome source was important, as the focus of the study was to illustrate the use of information on health utilization for consideration by the multiple stakeholders for whom these routine data are collected—especially health providers [23].

The primary outcome was patient readmission to a psychiatric hospital (ie, how many patients [n, %] in each study arm were readmitted to a psychiatric hospital during the 12-month follow-up). The other outcomes related to service use were (1) time to next hospitalization (how many days a patient was out of the psychiatric hospital after discharge [days]), (2) time in a psychiatric hospital during the year (total number of days admitted in a psychiatric hospital during the 12-month follow-up period), and (3) healthy time (number of days during the 12-month follow-up period when the person was not admitted in a psychiatric hospital [days]). Each participant was followed up for 12 months after discharge.

Secondary Outcomes

Secondary outcome data (also taken from routinely collected data in the national register) included type of admission (n, %), involuntary treatment (number of periods of care), general hospital treatment, length of involuntary psychiatric treatment (days), length of general hospital stay (days), use of private care (data not available), coercion used (yes, no), and type of coercive incidence according to the Finnish Mental Health Act (1116/1990; seclusion, limb restraint, forced injection, physical restraint), medication use (yes, no), type of medication (antipsychotic, antipsychotic and antidepressant), and adverse events (any [yes], death according the Statistics of Finland [yes]). We assessed other secondary outcomes, patient satisfaction with care or intervention (Client Satisfaction Questionnaire-8 [CSQ-8], self-rated) [24], and quality of life (Quality of Life Enjoyment and Satisfaction Questionnaire

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[Q-LES-Q], self-rated) [25] with a structured survey supplemented by a postal or telephone survey 12 months after randomization. Patient disability was assessed by patient functioning (Global Assessment Scale [GAS], 0-100, staff rated) [26], also taken from routinely collected data in the national register. Outcomes concerning patient engagement in the intervention (fidelity) were assessed by whether or not a patient made a "request to stop SMS" (intervention group only) or "leave the study early" (for any reason), relayed by the patient or clinical staff members and recorded by the investigators after informed consent.

We analyzed treatment-emergent adverse events, defined as any harm or adverse events occurring between randomization and when the patient completed the study, reported by anyone involved. Information was collected by emails, telephone calls, text messages (staff, patients, or relatives), and visits or face-to-face meetings with staff members and recorded using a standardized instrument originally based on the clinical research monitoring and good clinical practices network [27]. We categorized harms as unexpected or expected, at different levels (a severe adverse event or an adverse event) [28]. Severe adverse events were life-threatening (an event during which the patient was at risk of death) or fatal, required inpatient hospitalization, prolonged hospitalization, or resulted in a major disability [28]. We further categorized the adverse events into medical or psychiatric problems or substance use.

We also ascertained research nurses' and patients' perceptions regarding possible harms in using SMS ("In your opinion, have text messages caused any harm to you/to patients?", yes, no). We interviewed all research nurses by telephone and interviewed patients (in the intervention group) by telephone or postal survey [29]. We collected information on patient deaths from the national health register (causes of death register) [30]. We also surveyed patients' feedback on the intervention [29].

Cost Analysis

We examined the costs of the SMS intervention by calculating the unit costs of staff time used for the intervention and text message cost for each patient during the 12-month trial. We prospectively estimated staff time (45 minutes per patient and an additional 15 minutes to upload the messages into the system). We estimated mean salary and overhead costs for staff members (€3300 average monthly costs, including additional staff costs of 23.25%, about €21.21 per hour) as referred to in locally and nationally agreed-upon unit costs by the Union of Health and Social Care Professionals in Finland [31]. The costs of the text messages were assessed based on the total number of text messages sent to each patient during the 12 months (total 67,560); the cost of each text message to Finnish consumers in 2011 was approximately €0.0004 [32].

To assess the direct costs of patient care, we prospectively collected the treatment costs per day in a psychiatric hospital. The average treatment costs for nonspecialized care wards (€408 per day per patient) and specialized care wards (€692 per day per patient) were based on the nationally agreed-upon service costs by the Ministry of Social Affairs and Health in 2011 [33]. For indirect costs, the data were not available.

Statistical Analysis

Power

Our primary analysis was based on a comparison of two estimates between study groups at the 12-month follow-up. We identified no comparable studies to assist our calculations. To show the difference in reducing readmissions to hospitals by at least 5 percentage points (a relative risk of 0.92) with 80% power at a 5% 2-sided significance level, we estimated that we would need a total of 1511 participants in each of the 2 arms (Stata v10; StataCorp LP). In 2009, based on HILMO, there were 8339 people with schizophrenia (*International Classification of Diseases, 10th Revision* [ICD-10] block F20-29) admitted to psychiatric hospitals who used antipsychotic medication. We hoped to be able to achieve this sample size in Mobile.Net [16]. Funding limitations compelled us to have a window of 15 months for recruitment.

Analysis

We carried out the analyses using the SAS System for Windows (version 9.4; SAS Institute). The primary analysis was intention-to-treat. We did not impute missing outcome data because only 2% of the data were missing for the primary outcome. For the secondary outcomes, we did not impute the data either, even though about half of the data were missing (regarding quality of life and satisfaction). The reason was that the data were collected at only 1 time point. We summarized descriptive characteristics of patients by study group, and estimated either mean (SD), median (interquartile range), or numbers and proportions as appropriate. Descriptive statistics were used to evaluate outcomes at the end point and differences between groups. The primary and secondary outcomes were involved in the calculation of relative risk (RR), odds ratio (OR), and median differences (Hodges-Lehmann estimate) or mean differences and their corresponding 95% confidence intervals. We took dependency between periods of care, measured from the same participant, into account using generalized estimating equations. Variables with yes or no answers were analyzed with a Poisson regression model, while for other dichotomous variables, binary logistic regression was used. We compared mean differences between groups using a 2-sample *t* test and median differences using a Mann-Whitney *U* test. Using data from the primary outcome alone, we investigated the effect of the SMS messaging for subgroups of people with schizophrenia-like illnesses in comparison with all other diagnostic labels. We considered 2-sided $P<.05$ to be statistically significant.

Governance and Role of the Funding Source

The funder approved the design of the study, but had no role in the design, data collection and analyses, data interpretation, content of the manuscript, or submission for publication. A total of 4 interim reviews with the Management and Safety Committee were organized at 12, 14, 19, and 27 months after recruitment began. As expected, data were not available at those times to test the primary outcome of the hypothesis, so the Committee based their consideration of when to stop patient recruitment on analyses of recruitment speed (the number of patients recruited each day), patient allocation in each group,

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and refusal rates. The Management and Safety Committee oversaw the study. The corresponding author had full access to all data and was ultimately responsible for the decision to submit the manuscript for publication. TV and KAK also had access to raw data in the study.

The trial is registered with the ISRCTN registry (27704027; Multimedia Appendix 1 [34].

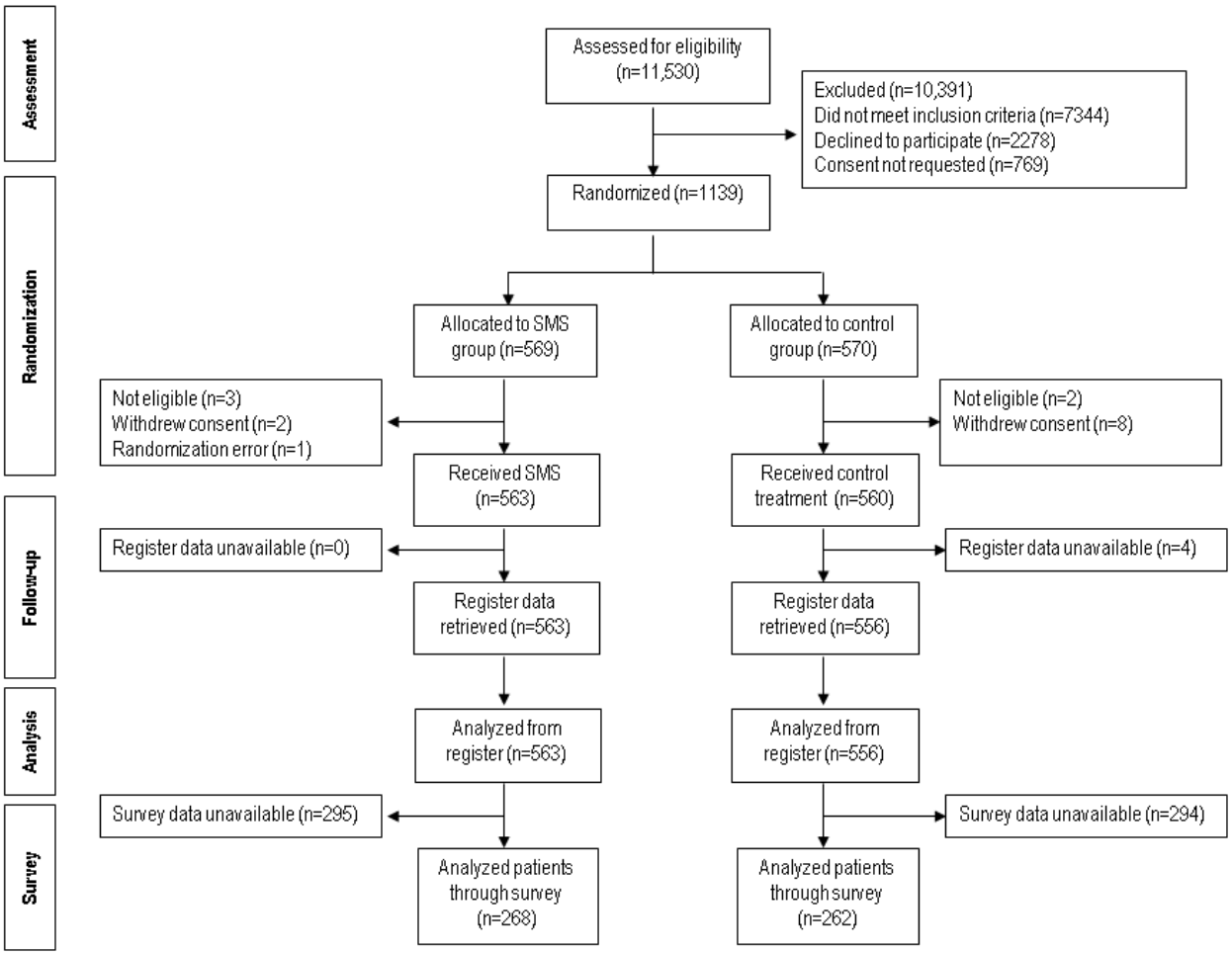
Results

During the 15 months of recruitment (September 5, 2011 to November 30, 2012) a total of 11,530 patients were admitted onto the 45 wards. Of 4186 potentially eligible patients, 3417 (81.63%) were invited to participate. The other 769 people became ineligible because either they moved to another ward before discharge or, upon further investigation, it was unclear if they had the capacity to consent and participate or refuse participation in the study (Figure 1). Key characteristics differing between eligible and noneligible participants were that eligible participants were younger and a larger proportion were women (P<.001) [35]. One ward closed during the study period, but recruited participants continued in the trial in another ward without disruption.

In total, 1139 patients were randomly assigned to either the experimental group with text messages (n=569) or the control group (n=570). We excluded 16 patients from the data because of a randomization error or because they withdrew consent or were not eligible. Of the remaining 1123 people, the follow-up was conducted with 563 (563/569, 98.9%) participants in the intervention group and 560 (560/570, 98.2%) allocated to standard care. After further quality checks of register data, we excluded 4 people because of coding errors that could not be corrected; therefore, data for these patients were not available. This left 1119 (1119/1139, 98.24%) people for analysis. For the survey-based outcomes (satisfaction, quality of life), however, the data were available for 268 patients in the intervention group (268/563, 47.6%) and 262 in the usual care group (262/560, 46.8%) (Figure 1).

Table 2 shows the main characteristics of patients at baseline and at the 12-month follow-up in the intervention (n=569) and control groups (n=570). An equal number of female and male patients participated (mean age 38 years). About half were single and most of the participants had a low level of education. Participants' mean age at the time of the first contact with mental health services was 27 years. The largest diagnosis group was F20-29 (421/1050, 40.10%, schizophrenia, schizotypal and delusional disorders, ICD-10; Table 2).

Figure 1. Flow diagram of study participants. SMS: short message service.



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Table 2. Patient characteristics.

Characteristic	SMS[a] (n=569)	Usual care (n=570)
Age in years, mean (SD)		
At trial entry	38.5 (13); n=569	38.0 (12); n=569
At first contact with services	27.4 (12); n=562	26.9 (11); n=560
Female sex, n (%)	301/569 (52.9)	278/570 (48.8)
Marital status, n (%)		
Single	277/565 (49.0)	309/569 (54.3)
Married	154/565 (27.3)	151/569 (26.5)
Divorced	120/565 (21.2)	99/569 (17.4)
Widowed	14/565 (2.5)	10/569 (1.8)
Vocational education, n (%)		
None	177/561 (31.6)	172/564 (30.5)
Vocational training courses	89/561 (15.9)	79/564 (14.0)
Primary vocational skill certificate	161/561 (28.7)	162/564 (28.7)
Secondary vocational skill certificate	80/561 (14.3)	90/564 (16.0)
University degree	54/561 (9.6)	61/564 (10.8)
Employment status, n (%)		
Employed	108/560 (19.3)	99/561 (17.6)
Retired	269/560 (48.0)	277/561 (49.4)
Self-employed	15/560 (2.7)	12/561 (2.1)
Student	60/560 (10.7)	68/561 (12.1)
Job seeker	108/560 (19.3)	105/561 (18.7)
Number of psychiatric treatment periods, n (%)		
1	9/455 (2.0)	12/387 (3.1)
≥2 treatment periods or more	446/455 (98.0)	375/387 (97.0)
Diagnosis (ICD-10[b] block), n (%)		
Organic, including symptomatic, mental disorders (F00-F09)	1/535 (0.2)	2/520 (0.4)
Mental and behavioral disorders due to psychoactive substance use (F10-F19)	31/535 (5.8)	29/520 (5.6)
Schizophrenia, schizotypal and delusional disorders (F20-F29)	212/535 (39.6)	209/520 (40.2)
Mood [affective] disorders (F30-F39)	161/535 (30.1)	163/520 (31.3)
Neurotic, stress-related and somatoform disorders (F40-F49)	48/535 (9.0)	40/520 (7.7)
Behavioral syndromes associated with physiological disturbances and physical factors (F50-F59)	1/535 (0.2)	4/520 (0.8)
Disorders of adult personality and behavior (F60-F69)	71/535 (13.3)	63/520 (12.1)
Mental retardation (F70-F79)	4/535 (0.7)	6/520 (1.2)
Disorders of psychological development (F80-F89)	3/535 (0.6)	2/520 (0.4)
Behavioral and emotional disorders with onset usually occurring in childhood and adolescence (F90-F98)	1/535 (0.2)	2/250 (0.4)

[a]SMS: short message service text message intervention group.

[b]ICD-10: *International Classification of Diseases, 10th Revision*.

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Table 3. Primary and secondary outcome analysis.

Outcomes	SMS[a] (n=563)	Usual care (n=556)	Coefficient (95% CI)	*P* value
Primary outcome, n (%)				
Readmission to psychiatric hospital	242/563 (43.0)	216/556 (38.8)	RR[b] 1.11 (0.92 to 1.33)	.28
Secondary outcomes				
Time to next hospitalization (days), median (IQR[c])	110.0 (44.0-14.0); n=242	104.5 (39.5-197.0); n=216	MdD[d] 7.0 (–8.0 to 24.0)	.37
Time in psychiatric hospital during the year (days), median (IQR)	30.0 (12.0-67.0); n=242	24.0 (10.0-67.0); n=216	MdD 2.0 (–2.0 to 7.0)	.35
Healthy time (days), median (IQR)	330.5 (285.0-350.0); n=242	338.0 (293.5=352); n=216	MdD –4.0 (–10.0 to 1.0)	.08
Type of admission (number of periods of care), n (%)				
M1[e] referral	78/442 (17.6)	77/396 (19.4)	OR[f] 0.89 (0.57 to 1.38)	.59
Mental examination	0/442 (0)	1/396 (0.3)		
Determination of treatment	0/442 (0)	0/396 (0)		
Other	364/442 (82.4)	318/396 (80.3)	OR 1.14 (0.74 to 1.77)	.54
Involuntary treatment (number of periods of care), n (%)	91/439 (20.7)	95/390 (24.4)	RR 0.85 (0.61 to 1.18)	.33
Use of private care	N/A[g]	N/A		
Length of general hospital treatment (days), median (IQR)	0.0 (0.0-0.0); n=563	0.0 (0.0-0.0); n=556	MdD 0.0 (0.0 to 0.0)	.13
Length of involuntary treatment (days), median (IQR)	18.0 (5.0-61.0); n=76	23.0 (5.0-79.0); n=67	MdD –2.0 (–13.0 to 2.0)	.35
Coercion, n (%)				
Coercive incidence (number of periods of care)	27/442 (6.1)	25/396 (6.3)	RR 0.97 (0.52 to 1.78)	.92
Type of coercive incidence (number of periods of care)				
Seclusion	20/443 (4.5)	25/396 (6.3)	RR 1.12 (0.57 to 2.20)	.75
Limb restraint	12/443 (2.7)	9/396 (2.3)	RR 1.19 (0.37 to 3.80)	.77
Forced injection	2/443 (0.5)	1/396 (0.3)	RR 1.79 (0.16 to 19.46)	.63
Physical restraint	6/443 (1.4)	4/396 (1.0)	RR 1.34 (0.38 to 4.70)	.65
Medication, by type, n (%)				
Antipsychotic	125/241 (51.9)	117/216 (54.2)	RR 0.96 (0.74 to 1.23)	.74
Antipsychotic + antidepressant	131/241 (54.4)	109/216 (50.5)	RR 1.08 (0.84 to 1.39)	.57
Adverse event, n (%)				
Any[h] (yes)	6/563 (1.1)	3/556 (0.5)	RR 1.97 (0.49 to 7.90)	.34
Death (yes)	11/563 (2.0)	16/556 (2.9)	RR 0.68 (0.31 to 1.46)	.32
Satisfaction with care/intervention/trial				
Satisfied with care (CSQ-8[i] [24]), mean (SD)	22.4 (5.0); n=268	23.1 (5.0); n=262	MD[j] –0.69 (–1.50 to 0.18)	.12
Request to stop SMS[k], n (%)	24/563 (4.3)	N/A[l]		
Left the study early[m], n (%)	295/563 (52.4)	294/556 (52.9)	RR 0.99 (0.84 to 1.16)	.91
Social functioning, n (%)				
Disability[n] (GAS[o] [26])			COR[p] 0.68 (0.47 to 0.97)	.04
46-100	106/442 (24.0)	71/394 (18.0)		
31-45	223/442 (50.5)	189/394 (48.0)		

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Outcomes	SMS[a] (n=563)	Usual care (n=556)	Coefficient (95% CI)	*P* value
1-30	113/442 (25.6)	134/394 (34.0)		
Quality of life (Q-LES-Q[q] [25] end point/change), mean (SD)	0.59 (0.18); n=268	0.59 (0.17); n=262	MD 0.00 (–0.03 to 0.03)	0.80
Economic factors, mean/median (IQR)				
Direct treatment costs[r] (€) (all)	10,103/28 (26-9410); n=563	9210/0 (0-6936); n=556	MdD 26.8 (26 to 27)	<.001
Direct treatment costs (€) (readmitted patients)	23,469/13,080 (5331-29,314); n=242	23,707/10,200 (4284-31,774); n=216	MdD 845 (794 to 3132)	0.25
Indirect cost (€)	N/A	N/A		

[a]SMS: short message service text message intervention group.
[b]RR: relative risk (Poisson regression).
[c]IQR: interquartile range.
[d]MdD: median difference (Hodges-Lehmann estimate, Mann-Whitney *U* test).
[e]M1 referral: referral for observation.
[f]OR: odds ratio (logistic regression).
[g]N/A: not available.
[h]Monitored by study investigators.
[i]CSQ-8: Client Satisfaction Questionnaire-8.
[j]MD: mean difference (2-sample *t* test).
[k]Contact with the research team.
[l]N/A: not applicable.
[m]Did not return survey questionnaire.
[n]Data from health register.
[o]GAS: Global Assessment Scale.
[p]COR: cumulative odds ratio (<1 indicates less disability in the SMS group).
[q]Q-LES-Q: Quality of Life Enjoyment and Satisfaction Questionnaire
[r]Treatment cost per patient (€1=US $ 1.13, September 2015).

Table 3 provides estimates of treatment effects on primary and secondary outcomes. Contrary to the preliminary assumption, tailored mobile telephone text messages did not reduce patients' use of health services in a psychiatric hospital (ie, readmission rate, the primary outcome). In total, there were 838 readmissions in the data. On the participant level, 40.93% (458/1119) of participants were readmitted to a psychiatric hospital during the follow-up period (242/563, 43.0% of the SMS group vs 216/556, 38.8% of the control group, RR 1.11, 95% CI 0.92-1.33). Receiving the text messages did not have any clear effect on time spent in hospital, time between hospitalizations, or number of days in the year that the person was thought to be well (healthy days).

No differences in other secondary outcomes were detected. Regarding the survey base outcome, patients' satisfaction with care (mean 22.4 for the intervention group vs 23.1 for the control, *P*=.12) or quality of life (mean 0.59 vs 0.59, *P*=.80) did not differ statistically between the groups, while the response rates dropped to 47.6% (268/563) and 46.8% (262/560) in the intervention and control groups, respectively. People who received text messages were, however, less disabled (based on GAS scores) at the time of their hospital readmission than were those who did not receive text messages (OR 0.68, 95% CI 0.47–0.97).

We analyzed patient engagement with the SMS text message intervention. In total, 35 of 1123 participants contacted researchers before the end of the 12-month follow-up to report any changes or wanting to leave the study early [35]. Patients' behavior regarding their text message selection was measured during the study [17]. In all, 5.9% (33/563) of the participants wanted to change the topic, receiving time, or frequency of the SMS text messages. The reasons for the changes included erroneously entering a message into the semiautomated system, being dissatisfied with the topic or timing of the messages, or simply wanting to stop or choose a new message [17]. Altogether, 95.2% (536/563) of the participants in the intervention group continued the SMS text message intervention throughout the entire 12 months, and 4.8% (27/563) dropped out of the intervention [35]: 3 participants dropped out before the intervention started, and 24 dropped out during the intervention period. Reasons for dropping out included (8/27) disliking the 1-way nature of the messages, finding the messages to be irritating, or no longer finding the messages to be beneficial (a more detailed description is found in Kannisto et al [35] and Kauppi et al [17]).

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Table 4. Adverse events reported during the trial.

Adverse events	SMS[a] (n=563)	Usual care (n=560)
Adverse events, n (%)		
Any	6 (1.0)	3 (0.5)
Mild	1 (0.2)	1 (0.2)
Moderate[b]	1 (0.2)	0
Severe[b]	4 (0.7)	2 (0.4)
Expected, severe	0	0
Unexpected, severe		
Life-threatening or fatal[b]	3 (0.5)	2 (0.4)
Requiring or prolonging hospitalization	0	0
Major disability[b,c]	1 (0.2)	0
Expected, less severe	0	0
Unexpected, less severe		
Medical	1 (0.2)	0
Psychiatric (paranoid thoughts)	2 (0.4)	1 (0.2)
Substance use	0	0

[a]SMS: short message service text message intervention group.

[b]Not consequence of study.

[c]Physical injury, not linked to study.

We also calculated the incremental cost of patient treatment per rehospitalization period. The cost of treatment was higher for people in the SMS group than the cost for the control group (mean €10,103 vs €9210, $P<.001$). When we calculated the cost of treatment for those who were readmitted to hospital, the statistically significant difference disappeared (mean €23,469 vs €23,707, $P=.25$).

We conducted a subgroup analysis for the primary outcome to compare people with schizophrenia-like illnesses versus those with other diagnoses. The analysis showed that people allocated to the SMS group who did not have schizophrenia-like illnesses had more psychiatric hospital days (median 26.5 vs 18.5, $P=.047$) and fewer healthy days (median 336 vs 345, $P=.02$) than patients in the control group during the 12 months. For the subgroup made up only of people with schizophrenia-like illnesses, we identified no clear differences.

During the 12-month follow-up, 9 adverse events were reported to the research staff (0.80% of 1119 participants). A total of 3 patients had paranoid experiences focused on the mobile phones (2 mild events reported by nurses and 1 moderate event reported by the patient by telephone or text messages to the researcher staff, involving 2 from the SMS group and 1 from the control group). One person in the intervention group had serious physical problems because of a stroke, and another participant wanted to stop the study. A total of 5 deaths were reported to the research staff (0.45%, 3 in the SMS group, with no discernible link to the text messages) (Table 4).

At the end of the study, we surveyed people allocated to the SMS group (n=403) to ask how they reacted to the intervention. A total of 51 participants (51/403, 12.7%) said that the text message intervention caused them harm. For example, some felt the text messages came too early in the day, others were irritated because of the interruption in work or leisure time, and some complained that the memory of the mobile phone filled up too quickly. More women than men perceived harm (35/223, 15.7% vs 16/178, 9.0%, $P=.05$). About three-quarters of the participants (274/383, 72%) were satisfied with the text message intervention. Two-thirds (247/385, 64%) were willing to receive text message intervention in the future (for more details, see Kannisto and colleagues [29]). In all, 13.8% (8/58) of the research nurses surveyed thought that the messaging caused some harm to patients by, for example, exacerbating paranoid thoughts. More female than male nurses thought that the text messages caused harm to patients (8/41, 19.5% vs 0/17, 0%, $P=.05$).

Discussion

Principal Findings

This was a pragmatic, multicenter, parallel-group randomized controlled trial, of, for this subspecialty, a large group of people with serious mental illnesses [16]. Our main assumption was that the SMS intervention, aimed at creating a higher awareness of health and well-being of individual patients, could change behavior patterns and subsequent service use. However, at the 12-month follow-up on patient service use, we did not find any advantages for the patients who used text messaging over the patients who received standard care. A Cochrane review [8] also did not find evidence that prompts increased patient adherence to treatment. The review found that ICT-based

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prompts were not clearly beneficial. There was weak evidence within this review suggesting small positive effects of SMS use on measures of the mental state, insight, and quality of life of patients, but the clinical significance of these data remains unclear. There have been few similar studies for this client group and few overlapping with Mobile.Net, and relevant trials were small with measure outcomes far upstream in the care flow. Findings from Mobile.Net serve to increase uncertainty whether SMS messaging, in this context, has any discernible effects.

Interpretation of the SMS Results

Contrary to the hopes of many that mHealth will solve problems such as limited reach and access, high costs, and low effectiveness in the delivery of health care and other conditions, this does not seem to be the case.

We had hoped that text message reminders would lead to improved adherence to treatment, which, in turn, would be seen as better medication intake, appointment keeping, or self-management and, downstream, result in fewer hospital readmissions or other adverse events. We could have overestimated the power of a simple, 1-way, tailored, minimally intrusive, technical approach to change behavior. Of course, such an intervention is not enough to solve complex problems for people with serious mental health problems. but it might have helped engagement in care. Perhaps a more personalized 2-way communication and personal support would work. We had no way of tracking patient behavior between sending a text message and the health utilization outcomes in routine data. More research into each patient's adherence level by, for example, detailed analysis of their health behavior, meetings with staff members, or medication intake, would deepen understanding of the impact of text message reminders on patient adherence and health utilization. Notwithstanding this, the simple SMS messaging we used did not work for important downstream outcomes of importance to health care providers.

We can also speculate about other reasons why the SMS intervention did not have a discernible effect on the chosen available outcomes. Although, in our study, patient engagement was high and people selected large numbers of text messages, we cannot be sure how many participants actually received, noted, or followed the content of the text messages. People may also have closed their telephone accounts or changed their prepaid systems during the intervention [36], or simply stopped reading the text messages at some point during the trial period [13]. These reasons seem improbable, though, and if they applied in this study, there would have most likely been some suggestion of one or both possibilities in our closing survey.

The one minor finding favoring the SMS intervention suggested that people allocated to the text messaging group had better global functioning scores (the Global Assessment of Functioning, collected as routine data) when readmitted to psychiatric hospital care. This is consistent with low-grade evidence from the Cochrane review, where there seemed to be some indication that ICT-based prompts had small positive effects on patient insight [8]. Our result could also have been a chance finding, as people in need of psychiatric treatment may not eagerly seek help out of fear of stigmatization [37], because they believe that treatment would be unhelpful, or as a result of poor insight [38]. Another study [39] found that around 75% (95% CI 72%-76%) of patients discontinued their medication within 18 months of follow-up. However, this should be studied in more detail, as even significant findings can also happen by chance.

In our study, the difference between groups in the lengths of involuntary treatment periods and patients' stays in a psychiatric hospital were not statistically significant. Of all patients admitted to psychiatric hospitals in Finland in 2013 (N=26,561), less than two-thirds (29%) were involuntary admitted [40]. At the same time, those admitted to Finnish psychiatric hospitals had a 2- to 3-fold higher mortality rate than the general population in Sweden and Denmark [41]. Further, the total number of care days in specialized psychiatric care came to 1,262,253 (38,384 treatment periods), and the average number of care days for patients with schizophrenia spectrum psychosis (F20-29) was 60 days in 2013. If the length of the stay for each hospitalized patient could be decreased by 1 day with any effective and less-expensive intervention, it would mean substantial savings all the way up to the Finnish annual health budget, and it would also affect the quality of life for individual patients. Therefore, in the realm of health services, small changes can have big impacts.

Strengths and Limitations

This study has several strengths. By using health registers as the main source of outcomes, the trial caused minimal extra burden for people with the illnesses and their nursing staff. The use of standardized outcome data reduced the possibility of response or dropout bias, and if there were such errors, it is unlikely that they would differ between the randomization groups. The participation rate of hospitals was high (24/30, 80%), and the participation rate for eligible patients was acceptable (around one-third), given the study population; that is, patients with serious mental illness being discharged from hospital. Randomization was successful, based on the evidence that patients in the intervention group and the usual care group were comparable on various indicators. The intervention itself was patient centered, in both its development (involving both end users and providers) and its execution (patients could choose the messages they were to receive). The duration of the follow-up period was 12 months, and the proportion of missing data gathered in the national health register was exceptionally small. When we added in our own questionnaire, outside of routine data, however, compliance with data acquisition did decrease, although it was still reasonably high (530/1123, 47.20%), considering the target population of the study. Mobile.Net allowed for the acquisition of high-grade data involving a detailed data monitoring system, which gathered information about different hospital wards using case notes, monitoring sheets, and frequent telephone calls to staff members throughout Finland, as well as the use of routine data from HILMO [21].

On the other hand, this study has its limitations. First, we did not achieve the target sample size: we estimated that we would need a total of 1511 participants in each of the 2 arms, and in this sense our study was powered as planned. With the achieved sample size, an 8-percentage-point difference in readmissions

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to hospitals between groups could be detected with 80% power at a 5% significance level. In this regard, our sample size is still adequate for drawing reliable conclusions.

Second, even though the majority of participants did not report negative effects, 12.7% (51/403) of participants in the SMS group and 13.8% (8/58) of the nurses associated with the intervention expressed beliefs that the text messages caused some harm to some participants. More women than men perceived possible harm in receiving SMS reminders [29]. We may assume here that some participants' negative perceptions may indicate a lack of tailoring of specific messages, or raise questions on the type of interaction or suitability of the intervention as experienced by the participants. For example, 2-way communication could have given valuable opportunities to the participants to communicate with their treatment team to receive support when needed. Despite some negative perceptions of text messages, about three-quarters of the participants were satisfied with the SMS text message intervention [29]. Whether our finding can be generalized to a wider population needs to be examined further.

Third, regarding the patient-focused questionnaires and outcomes, such as patient satisfaction with care and quality of life, the low follow-up rate for patient self-assessed instruments (530/1123, 47.20%), although in keeping with trials among this patient group [42], may bias our study results for these particular outcomes. Those participants who did not participate in follow-up surveys may have been dissatisfied and therefore did not answer the survey. There was also a significant statistical difference between the participants who did not answer the follow-up survey and those who did fill out the questionnaires.

Fourth, the condition of the patient may have had some effect on their attrition. For example, those with the lowest capacity level and, therefore, perhaps with the greatest need for supervision of medication intake, could have been self-excluding. However, we could not verify this, as we had no formal test to assess capacity for patients who participated or did not participate in the study. On the other hand, we recruited patients to the study at the time of their discharge process, and therefore we may assume that the patients' capacity to be discharged from the psychiatric hospital would have already been assessed by the psychiatrists responsible for the patients' treatment.

Fifth, we hypothesized that, if patient medication adherence is better after the SMS intervention, the number of readmissions might be lower in the intervention group. We measured patient adherence by service utilization rather than by counting pills [43], or examining computerized prescription refill records [44] or blood tests, which may limit the sensitivity of the measurement. We decided to measure care utilization outcomes because our focus was on these outcomes, which can offer usable information for health service providers and societies for their decision making [45] and practicality in evaluating new technology [46], and, importantly, can help to avoid using methods that are invasive and place a burden on patients. Despite potential problems in using care utilization as an indication of the impact of the intervention, these outcomes are used as indicators in the data from "real practice," for policy initiatives [46], and as proxy outcomes for economics. There is also a lack of studies addressing questions related to delivery of mental health services in randomized trials [47]. Tracking patient medication adherence would still have been highly informative about why simple SMS text messages did not work on downstream outcomes but, we suggest, greatly undermined the finding by promoting attrition. Objective investigation would have increased our certainty regarding adherence to medication, but this would have greatly threatened the pragmatic nature of the trial. A lack of close monitoring of the messages received by individual patients could therefore have hindered the fidelity of the study, and a lack of tracking of a similar type of technology in a control group should be interpreted as a study limitation. The specificity of the study may also be questioned in regard to its design, intervention, or outcomes to ascertain which of the multiple factors affected patient behavior. Each aspect of this complex intervention could then have been subsequently open to further evaluation. Perhaps the tailoring was indeed helpful, but our timing offset any positive effect. Each factor could now be tested in further trials.

Sixth, a simple semiautomated SMS text message is not at all a simple intervention. It involves the act of messaging, the nature of the message, and timing. Our study population was perhaps one of the most challenging, and also vulnerable for new interventions. At the same time, evidence for effective interventions to guide practitioners is scant, despite high levels of need and costs of care for this group of patients [48]. The selection of our study population can be defended due to its high impact on health services and costs globally [49]. We are also aware of the challenges of this particular patient group, who have capacity problems [50], are less experienced in using health technology [51], and are less motivated to engage in their treatment [52], which may further limit the use of the new technological intervention. However, it is important to test all options for care in this group, especially like the one in this study, which could be implemented without evaluation. Had such an intervention been successful, even a small improvement may have had wide repercussions in the utilization of health services.

Our results still indicate that it is feasible to provide an intervention, scalable for a wide group of people, that can be delivered by a simple technological solution. This type of intervention may make it possible to expand care provision without being limited by specific service hours, staff motivation, or availability of professionally trained health care staff. On the other hand, because this intervention did not result in absolute benefits of the service use, and yet did include possible negative effects of mHealth on patients with serious mental illness, we are compelled to draw attention to the following point. Many hopes and promises are being attached to mHealth, in that it could solve problems in health care services, such as human resources, limited access, high costs, and the difficulty of satisfying individual needs. There is also a great deal of belief and investment in mHealth technology in several service systems, conditions, and environments. Perhaps semiautomated prompting text messages, particularly, are not the answer for patients with serious mental health problems; a better alternative could be to allocate resources to investigating alternative

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mHealth solutions or other interventions to solve care utilization problems. We need to know the limitations of technology use for various user groups, and when to invest in exploring other strategies. This study also demonstrates how using routinely collected health data sets proved to be possible within randomized trials for important outcomes of clinical and public health value. This may well be possible elsewhere, and not only confined to countries known for culturally acceptable comprehensive data collection.

Lessons Learned

Here are 7 things we would do differently in the future. First, the patient inclusion criteria should be even more inclusive to ensure a very large sample size. Second, negative perceptions related to SMS interventions should be more thoroughly investigated, and such potential problems should be considered in future intervention development for different mobile apps. Third, the intervention would have to be modified in the future to include 2-way communication and collaboration with staff (although currently still problematic), and an increase of supportive, visual, or voice-based elements could offer more interesting, albeit expensive, additions to the simple approach we tested. Fourth, other patient-focused measurements, such as treatment adherence, internal motivation, or adverse events could be included to help increase understanding of the effects, if any, of SMS from the patients' point of view. Fifth, an assessment of capacity level needs to be included in a baseline assessment, at least for a random sample of the total. This would provide a means for investigating how capacity might affect results. Sixth, a random sample of the total number of patients could be followed up to help track behavior after the intervention. For this subsample, bill accounting, follow-up calls, responses to 2-way text messages, or nurse or physician assessment of patient participation in treatment would be needed. We suggest this on a random sample, as we feel that such detailed data acquisition could threaten validity by causing attrition. Seventh, to engage vulnerable patients or those living with mental health issues, collaboration with user groups or patient association should be more active, beyond just the consultations or meetings we conducted in this study.

Conclusions

Undisclosed effects could potentially be further explored in future studies. Perhaps the small suggestion that those in the SMS group were less unwell at readmission is one such upstream effect, rather than just a chance finding. However, in terms of the outcomes that we believe policymakers, clinicians, and patients and caregivers would find important, our tailored, acceptable SMS technique was ineffectual.

Acknowledgments

The study was funded by the Academy of Finland (132581), Turku University Hospital (EVO 13893), Satakunta Hospital District (EVO 81096), Foundations' Professor Pool, University of Turku, and the Finnish Cultural Foundation. The funding bodies will not gain or lose financially from the publication of this paper, neither now nor in the future. The views expressed in the paper are those of the authors and not necessarily those of the study organizations or funding bodies. We want to thank the patients who participated in the Mobile.Net study, the research nurses, and the staff of the hospital organizations, without whom the trial would not have been possible. We especially wish to thank Kaisa Kauppi, PhD; Minna Anttila, PhD; and Sanna Suni, MA, for their valuable help with conducting the trial, data collection, and data entry. We also thank the Mobile.Net Safety Committee Group for their efforts and support throughout this trial.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT EHEALTH checklist V1.6.1.

[PDF File (Adobe PDF File), 536KB - jmir_v19i7e245_app1.pdf]

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Abbreviations

CSQ-8: Client Satisfaction Questionnaire-8
GAS: Global Assessment Scale
HILMO: Care Register for Health Care
ICD-10: International Classification of Diseases, 10th Revision
ICT: information and communication technology
OR: odds ratio
Q-LES-Q: Quality of Life Enjoyment and Satisfaction Questionnaire
RR: relative risk
SMS: short message service

Edited by A Moorhead; submitted 21.11.16; peer-reviewed by H Oh, A Rotondi, S Ballesteros, P Schulz, S Lokman; comments to author 12.01.17; revised version received 23.02.17; accepted 05.06.17; published 12.07.17.

Please cite as:
Välimäki M, Kannisto KA, Vahlberg T, Hätönen H, Adams CE
Short Text Messages to Encourage Adherence to Medication and Follow-up for People With Psychosis (Mobile.Net): Randomized Controlled Trial in Finland
J Med Internet Res 2017;19(7):e245
URL: http://www.jmir.org/2017/7/e245/
doi:10.2196/jmir.7028
PMID:28701292

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Original Paper

Adolescents' Perspectives on Personalized E-Feedback in the Context of Health Risk Behavior Screening for Primary Care: Qualitative Study

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Abstract

Background: Electronic health screening tools for primary care present an opportunity to go beyond data collection to provide education and feedback to adolescents in order to motivate behavior change. However, there is limited research to guide feedback message development.

Objective: The aim of this study was to explore youth perceptions of and preferences for receiving personalized feedback for multiple health risk behaviors and reinforcement for health promoting behaviors from an electronic health screening tool for primary care settings, using qualitative methodology.

Methods: In total, 31 adolescents aged 13-18 years completed the screening tool, received the electronic feedback, and subsequently participated in individual, semistructured, qualitative interviews lasting approximately 60 min. Participants were queried about their overall impressions of the tool, perceptions regarding various types of feedback messages, and additional features that would help motivate health behavior change. Using thematic analysis, interview transcripts were coded to identify common themes expressed across participants.

Results: Overall, the tool was well-received by participants who perceived it as a way to enhance—but not replace—their interactions with providers. They appreciated receiving nonjudgmental feedback from the tool and responded positively to information regarding the consequences of behaviors, comparisons with peer norms and health guidelines, tips for behavior change, and reinforcement of healthy choices. A small but noteworthy minority of participants dismissed the peer norms as not real or relevant and national guidelines as not valid or reasonable. When prompted for possible adaptations to the tool, adolescents expressed interest in receiving follow-up information, setting health-related goals, tracking their behaviors over time, and communicating with providers electronically between appointments.

Conclusions: Adolescents in this qualitative study desired feedback that validates their healthy behavior choices and supports them as independent decision makers by neutrally presenting health information, facilitating goal setting, and offering ongoing technological supports.

(J Med Internet Res 2017;19(7):e261) doi:10.2196/jmir.7474

KEYWORDS

adolescent; screening; health behavior; motivation; primary health care; software; technology; qualitative research

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Introduction

Most of the leading contributors to adolescent morbidity and mortality are preventable health risk behaviors such as substance use, unprotected sexual activity, and unsafe driving practices [1]. Primary care visits present a promising opportunity to recognize and intervene with adolescents who engage in these behaviors. For example, in the United States, many adolescents aged 12-17 years attend a preventive medical visit annually, with estimates ranging from 37-82% [2-4]. When annual attendance is considered over the course of the adolescent years, primary care providers may have multiple opportunities to screen, counsel, and refer those at risk for negative outcomes. Primary care providers are also well-positioned to initiate behavioral counseling and referral as a result of long-term relationships they develop with adolescent patients. However, despite recommendations from professional organizations [5,6], screening and follow-up counseling in primary care remain inconsistent [3,7].

One strategy for increasing the frequency of screening and follow-up counseling for adolescent health risk behaviors in primary care is the use of electronic screening tools [8-13]. The benefits of electronic screening tools include their ability to streamline the screening process through branching logic and to generate reports to inform follow-up counseling by providers [14]. Electronic tools also provide an opportunity to deliver direct feedback to adolescents to motivate behavior change.

Whereas some electronic screening tools have incorporated feedback, educational components, or brief interventions [9,10], there remains limited data to understand how adolescent patients react to receiving such information. However, previous investigations of automated interventions for a range of age groups do provide an initial indication of specific feedback components that may effectively promote health behavior change. For adults, feedback strategies that raise awareness of health risks and promote self-efficacy to change have been shown to be effective in increasing physical activity and changing nutrition behavior [15]. Among college students, feedback that frames behavior in the context of their peers has been shown to reduce alcohol use and risky sexual behaviors [16-18]. Among adolescents, brief Web-based interventions that include elements intended to raise awareness of health risks, promote self-efficacy, and compare behavior with peer norms have produced small effects on drinking, though data suggests that reductions in alcohol use were primarily associated with raising awareness of health risks and promoting self-efficacy [19,20]. To our knowledge, few studies have examined the use of feedback for adolescent health behaviors outside of alcohol use or for multiple risk behaviors, and with some exceptions [21], few studies have sought direct adolescent reactions to receiving such information following screening.

In this study, we used qualitative methodology to better understand youth perceptions of and preferences for receiving feedback by evaluating their responses to an electronic screening tool for primary care (the "Check Yourself" tool) that incorporates immediate, personalized feedback for multiple health risk behaviors and reinforcement for health promoting behaviors. Adopting a similar approach to previous qualitative investigations of electronic health tools [22-26], we conducted individual semistructured interviews exploring youths' overall impressions of the Check Yourself tool and their perceptions regarding the types of feedback messages that most motivated them to consider healthy behaviors, as well as what additional features would be helpful. In recognition of both the strengths and limitations of qualitative methodology, we aimed not to derive generalizable conclusions about the electronic health feedback delivered by the tool but to provide general suggestions for future feedback message development. Additionally, this qualitative data will supplement future quantitative outcomes from several randomized controlled trials of the tool currently being conducted by our research group.

Methods

Recruitment and Participants

Participants were recruited primarily from an adolescent-focused, academic clinic in Seattle, WA using a purposive sampling approach [27]. We selectively approached potential participants in the waiting area of the clinic to recruit a sample with approximately equal numbers of males and females and 13-15 and 16-18 year olds. Regarding race and ethnicity, we aimed to draw a sample representative of the Seattle area. Some participants were also recruited through flyers and word of mouth. Purposive sampling is preferred in qualitative research as it promotes the collection of a range of perspectives.

Adolescents were eligible to participate if they were in the age range of 13-18 (inclusive) years and could read and speak English. For participants aged 13-17 years, both youth assent and parental consent was obtained. For participants aged 18 years, youth consent was obtained, and parental consent was not required. Recruitment continued until theoretical saturation was reached (see "Data analysis" section below).

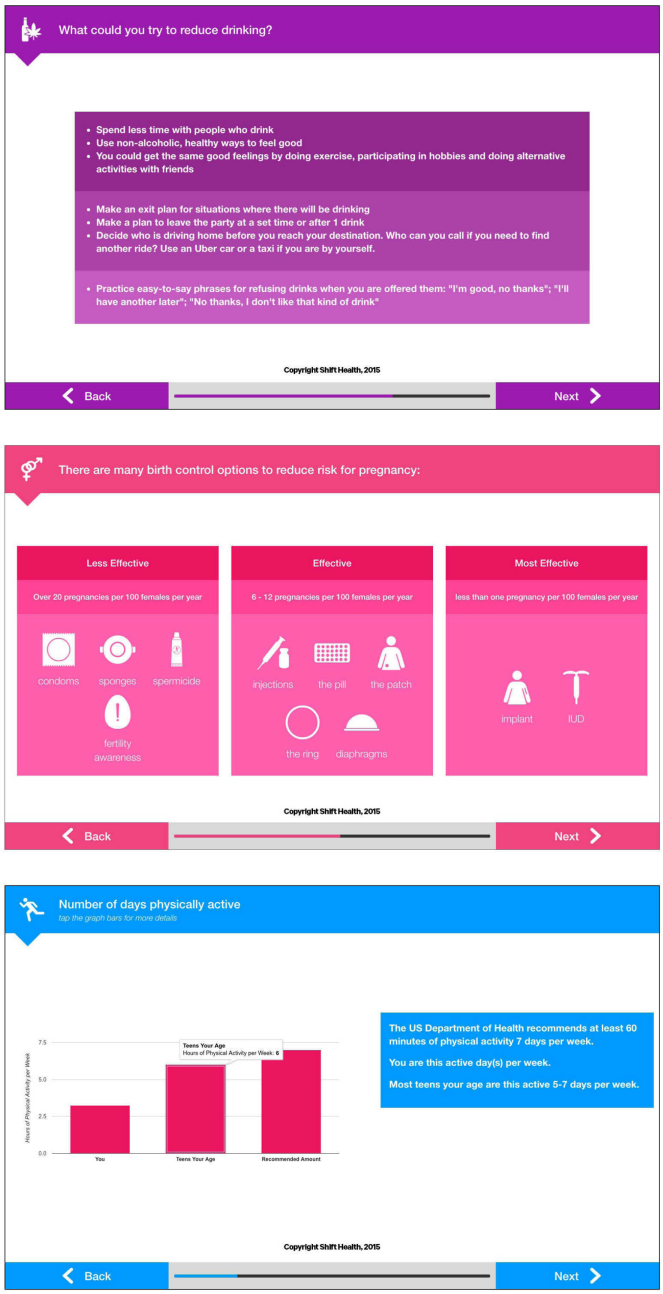
Procedure

Adolescents first completed the Check Yourself tool and subsequently participated in individual qualitative interviews. The individual interview format was used to protect confidentiality and to allow interviewers time to explore the complexities of each participant's perspectives. There were three interviewers in total (GZ, KK, and one other interviewer), all of whom completed training in qualitative methods before conducting interviews. Interviews occurred primarily in a private room in the same building as the adolescent clinic used for recruitment, at a time convenient for participants. When logistical constraints did not allow for the interview to occur at the clinic, interviewers met participants in a convenient and private location (eg, a private meeting room at a library). A majority of the interviews lasted 60 min (range: 45-90 min). Interviews occurred from February to July, 2015. Interviewers were gender-matched with participants as much as possible to promote comfort for participants in discussing sensitive health topics. Before the beginning of the interview, interviewers explained to participants that they did not personally develop the tool and that negative feedback was as valuable as positive feedback. Participants were oriented in this way to ensure that

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they did not suppress negative feedback to please the interviewer. Additionally, the interview guide contained several questions designed to elicit adolescents' suggestions regarding how the tool could be improved. Adolescents received US $30 for participating. All study procedures were approved by the institutional review board of Seattle Children's Research Institute.

Figure 1. Example screenshots from the Check Yourself tool.



The Check Yourself Tool

The Check Yourself tool is a tablet-based screening instrument developed by researchers at the University of Washington (LR and CM) in conjunction with the digital health company Shift Health [28], using TickiT, a platform for interactive patient-reported outcome measurement [29]. Designed with the goal of enhancing patient-provider communication, the tool features accessible language, colorful graphics, and integrated feedback based on screening responses. Assessment questions were developed based on screening recommendations from Bright Futures and the Guidelines for Adolescent Preventive Services [30,31], querying youth about eating and nutrition, exercise, screen time, sleep, safety behaviors (eg, wearing seatbelts and texting [short message service, SMS] while driving), drug and alcohol use, sexual behavior, and emotional health. The personalized feedback was informed by strategies shown to be effective by research on motivational interviewing

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[32] and specifically included information about (1) how adolescents' responses compared with normative peer data and national health guidelines, (2) benefits and consequences of engaging in behaviors, (3) educational information about health choices, and (4) tips and suggestions for increasing healthy behaviors. Adolescents received this feedback immediately after completing the assessment section (see Figure 1 for example screenshots). The Check Yourself tool requires approximately 15 min to complete.

Interview Content

Semistructured interviews were conducted using an interview guide that covered three areas (Textbox 1). As previous work has supported the usability of the screening segment of the tool [29,33], the interview guide for this study aimed primarily to elicit adolescent's perspectives regarding the content of the feedback messages.

Textbox 1. Items from qualitative interview guide by topic.

Overall impressions of the Check Yourself tool

- What was your overall experience with the tool?
- When you used the tool, did you find any parts confusing? Which parts?

Perceptions of motivational feedback

- Which health messages made the biggest impression on you?
- How did using the tool make you feel about your own health?
- Was there anything you thought you would want to change after using the tool?
- Which messages made you feel motivated to change?
- What additional information could have helped you feel more motivated?

Desired expansions of tool

- Are there other things you think we should add to the tool that would be helpful?
- Do you think it would be helpful if the tool sent you follow-up resources and websites? What would be most helpful to send?

Data Analysis

Interviews were audio recorded and transcribed. Interview transcripts were uploaded to Dedoose, a Web-based qualitative analysis platform [34] and independently coded by two analysts. Coding discrepancies were resolved by consensus. A codebook was developed based on the interview guide and iteratively refined as transcripts were coded. When necessary, transcripts were recoded to reflect the current state of the codebook. Following the method of thematic analysis [35], the authors collaboratively reviewed all text excerpts within each code to identify both themes expressed across participants and key quotes which best illustrated each theme. An inductive approach was taken in the thematic analysis as the authors did not investigate prespecified themes but rather let participants' responses guide the identification of themes. When selecting illustrative quotes, we prioritized quotes that (1) gave a full and articulate expression of a theme, and (2) which remained easily interpretable without the context of the full interview transcript. When data saturation occurred, defined in this study as no new themes being generated across three consecutive interviews, participant recruitment was discontinued.

Following Hill et al [36], themes are presented below with regular terms to indicate the level of agreement between participants. "All participants" or "in general" indicates agreement across all or almost all participants. "Many participants" indicates agreement across approximately half of participants. "Some participants" indicates agreement across a few participants.

Results

Participant Recruitment and Characteristics

In total, 26 participants were recruited from the waiting area of the clinic, 5 through word of mouth, and 1 via flyer. In total, 32 interviews were conducted, though 1 interview was not analyzed as the participant provided predominantly single-word responses that were not felt to enhance understanding of the youth's perspective. The final sample therefore consisted of 31 adolescents. Participants' demographic data are displayed in Table 1.

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Table 1. Participant demographic data (n=31).

Characteristic	Value	Participants
Age (years), mean (SD[a])		15.2 (1.4)
Age (years), n (%)		
	13	5 (16)
	14	5 (16)
	15	6 (19)
	16	10 (32)
	17	4 (13)
	18	1 (3)
Gender, n (%)		
	Male	13 (42)
	Female	18 (58)
Ethnicity, n (%)		
	Hispanic	6 (19)
	Non-Hispanic	25 (81)
Race, n (%)		
	African American	2 (7)
	Asian	3 (10)
	White	20 (65)
	Multiracial	2 (7)
	Race not specified	4 (13)

SD: standard deviation.

Qualitative Results

Themes are presented below and grouped by the three topic areas of the interview guide: (1) overall impressions of the Check Yourself tool, (2) reactions to the personalized feedback, and (3) desired expansions of the tool. These topic areas are not themes themselves but rather broader categories of themes.

Overall Impression of the Check Yourself Tool

In general, participants reported that the Check Yourself tool was easy to use and that colorful images and interactive content increased their interest in the health information that was presented:

> *Teenagers, we like color...Bright colors make it fun, make it not like your filling out paperwork at a hospital or a clinic.* [Female, 18]

> *The true and false questions at the end, or at least it was when I did it. Which was a good memory thing because when I went through it...there I had to answer those things so I actually remembered them.* [Male, 15]

All participants indicated that they would prefer the Check Yourself tool to pencil-and-paper screening. Some adolescents particularly appreciated that questions were presented one at a time such that responses to previous questions were not visible. They felt this feature would help conceal their responses from family members in a waiting area:

> *I didn't want anyone else to see [my responses] because my sister was sitting here, and my mom was sitting here...but this way like I said before was kind of like, you can answer the question and quickly move on and no one will see your answer if you do it fast enough.* [Female, 16]

Some participants also noted that not displaying responses to previous questions would make it less upsetting to endorse risk behaviors since they didn't have to continue to see their responses as they waited to see their provider.

Adolescents described distinct ways that they felt the Check Yourself tool could enhance their interactions with doctors. Some thought the tool could function as a "warm up before the main event" of an appointment by priming them to identify their questions and concerns to discuss during the visit. Many participants found it easier and less awkward to disclose health risk behaviors on the tool than face-to-face, and perceived the tool as helpful in reducing providers' need to ask patients about sensitive topics during the appointment:

> *I like the idea of having [the tool] because a lot of people, like I know a lot of times I would go to the doctor ready to say something and then get scared and not say it. This way, it's a little bit impersonal, but at least I'm getting it down and so the doctor, I wouldn't have to make eye contact with him, but he will know because I put it in there.* [Female, 16]

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Responses to the Personalized Feedback

Adolescents commented on several aspects of the personalized feedback provided by the Check Yourself tool. In general, participants stated that the tool provided new information including education, tips for health improvement, and information on how their behavior compared with peer norms and national guidelines for adolescent health. Nearly all youth appreciated the presentation of information in a nonjudgmental manner:

> *It wasn't super forceful. It was kind of like here's an amount that you eat, and here's the amount that people your age normally eat, and here's the recommended amount...I like how it wasn't super forceful like black screen, red words, eat more fruits and vegetables.* [Female, 18]

The most commented on feedback components were the graphs which compared the participants' own responses with peer norms and national health guidelines. Many reported that they found these comparisons to be motivating:

> *When I saw the graph of the physical activity, I was way below, and I was just thinking, "Wow, I really should do something about that.*" [Male, 14]

However, some youth felt that the comparisons were not helpful. The most common concern regarding comparisons to peer norms was that the statistics were not accurate or relevant as they were not consistent with what participants encountered in their close friend groups:

> *When I was looking at some of the numbers I was like, 'This doesn't seem right' because—or at least my high school it might seem different from what I see around me. I felt like some of those [numbers] might have been a little low, the numbers of the average teen.* [Female, 17]

> *Even if no one else in the school [used marijuana] but my friends, it wouldn't exactly matter to me because people I know do—that's what's relevant.* [Female, 14]

Regarding comparisons with national health guidelines, some adolescents disagreed that recommendations for certain behaviors (eg, screen time) were any healthier than what they were already doing. Participants typically voiced this objection if they had not yet experienced any consequences from their behaviors:

> *Personally, I'm happy with what I do right now. I have a little bit too much screen time, but I sleep eight hours every night, I do cross country, track, and winter running club...The consequences that [the tool] mentioned were loss of sleep, less time to do athletic stuff, and things like that which were all things that it previously said I was great with.* [Male, 15]

Sometimes, even if participants recognized that following the health guidelines would be beneficial, they perceived the recommendations as "unreasonable" in the context of modern adolescent lifestyles. This objection was voiced primarily in relation to screen time and exercise recommendations (<2 hours/day and 1 hour, 7 days/week, respectively). Lastly, some participants found the comparisons too stark and suggested that it would be helpful to add validating phrases to soften the message:

> *The slides that were specifically around nutrition and exercise, especially when you're not meeting it, it's very jarring to be like, "You're not meeting it," and there's no kind of soft landing that you get when you talk to a person and they're like, "Well, you're doing a pretty good job," and some of the little changes you need to make to get there.* [Male, 17]

In addition to normative comparisons, many participants reported that they were motivated by learning about the benefits of healthy behaviors:

> *When I did see that cause and effect thing it kind of made me think, "Well, that effect would be nice.*" [Female, 17]

Some others felt that learning about the consequences of risk behaviors was more motivating and specifically requested more alarming statistics. It is worth noting, however, that those endorsing this view tended to not be engaging in risk behaviors themselves and were more often reflecting on what they felt would be motivating for their peers who were.

Many adolescents also perceived value in aspects of the feedback which aimed to promote self-efficacy for and commitment to behavior change, including practical tips to change behaviors. Many were interested in getting tips regardless of whether they were engaging in risk behaviors, as the tips might be useful in the future:

> *Back to the sexual activity and stuff it gave a feedback, like stages of what is better to use like for birth control-wise...Eventually I'm going to be sexually active and I want to plan what happens and what I should use and I want to be safe.* [Female, 15]

Participants reported that the tips regarding how to increase and sustain healthy behaviors, as well as how to stay safe if engaging in risk behaviors (eg, ways to drink alcohol responsibly) were all useful. Finally, many adolescents appreciated validation for healthy behaviors:

> *I think just affirming the fact that—for instance, I put down that I always wear seat belts...It's nice to be like "Yeah, that's the right thing to do.*" [Male, 17]

Desired Expansions of the Tool

Participants expressed interest in four potential expansions for the Check Yourself tool: receiving follow-up information, goal-setting, tracking of behaviors over time, and communication with providers in between visits. Regarding follow-up content, many desired more information about specific health behaviors for personal research and learning and thought that it would be helpful if the tool would provide a targeted set of links and resources for areas of interest. Many adolescents were also interested in additional resources for changing behaviors, especially practical "tips" (eg, for how to start going to bed earlier).

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Many adolescents commented that they would like to have the opportunity to set goals based on the feedback they received from the Check Yourself tool. In talking about goal setting, participants expressed the importance of being able to determine their own goals and desired a process that emphasizes small steps and integrates with follow-up information:

> *Maybe there could be an option for their goal in each section like at the end of [the tool]...I think if it's a goal that could help with sent out information—so if they say their goal is to get two more hours of sleep every night, we could get information about the best ways to do that.* [Female, 14]

> *I would say have little steps in there to getting better. Take steps—baby steps—to getting better.* [Male, 15]

Many participants also wanted to expand the tool to include tracking health behaviors over time and in relation to goals. Some thought that tracking systems would ideally be more integrated and able to recognize and alert them to patterns across health behaviors (eg, relationships between physical activity and eating). As a part of ongoing tracking, some participants indicated an interest in receiving electronic reminders and ongoing motivational messaging about goals that they had set:

> *I guess [it would be useful to send] just how often I should do it just as a reminder and also encouragement as to why I wanted to do it in the first place.* [Female, 14]

Notably, some participants indicated a preference for electronic reminders over reminders from parents or other adults, particularly in the context of goals that they had set for themselves:

> *Those things where your parents would probably remind you, but your parents are like, "Hmm," but then [with electronic reminders] it's like oh maybe I should do it because it's good for me and it's me doing it, not my parent to be like "Go do it."* [Male, 17]

Some adolescents described a desire for their providers to be involved in the behavior tracking process, specifically wanting doctors to view their progress in between visits and to provide encouraging comments.

Discussion

Principal Findings

In this qualitative study, we examined adolescents' perspectives on an electronic health screening tool for primary care settings that provides personalized feedback. Overall, the tool was well-received by participants, who strongly preferred electronic screening over paper-and-pencil forms. Youth appreciated the colorful and interactive content, valued aspects of the tool that enhanced privacy, and indicated that they would disclose more health risk behaviors to the tool than to paper-and-pencil forms, consistent with prior research on electronic health screening [29,37-41]. Importantly, and also consistent with prior research on electronic screening, participants perceived the tool as a way to enhance—but not replace—interactions with providers by helping them to identify questions and concerns before an appointment [41,42]. To date, studies regarding screening instruments have focused primarily on the frequency of provider counseling and referral [8-12]. However, our data suggest that electronic screening with feedback could be used to impact adolescent behavior during the appointment. For example, screening and feedback may increase adolescent interest in discussing health concerns with providers. Patient communication behaviors such as these have been linked with positive health outcomes [43,44]. Future research should investigate the possibility that electronic screening with feedback influences adolescent behavior during the appointment.

Adolescents thought that the feedback delivered by the tool was generally useful and motivating. They appreciated that the feedback was presented with nonjudgmental language and responded positively to a variety of specific feedback components including information regarding the benefits of healthy behaviors, risks of negative behaviors, tips for behavior change, and the reinforcement of good choices.

Whereas many found the comparisons with peer norms and national health guidelines interesting and helpful, a small but noteworthy minority of participants dismissed the peer data as not real or relevant and guidelines as not valid or reasonable. The perspectives expressed by this minority suggest that adolescents are discerning consumers of peer normative data and that peer comparisons should be presented in a way that enhances the perceived relevance and credibility of the information. Additionally, participants in this study could have responded more truthfully about their health risk behaviors than adolescents in national survey research, spuriously making participants' behaviors appear worse than the national averages. Whereas more data is needed to evaluate the possibility that adolescents respond more honestly to electronic health screening tools than to anonymous national survey research, future interventions including normative feedback should consider the limitations of comparing self-reported health data gathered through different modalities.

In any case, when presenting normative feedback, it may be important to select comparison groups as similar as possible to individual adolescents (eg, with respect to age, gender, and school) and to clearly cite data sources to increase perceptions of relevance and credibility. Notably, the two studies which have investigated Web-based interventions, including normative feedback for adolescent alcohol use, either did not present school specific norms or did not present age and gender specific norms, and did not find a connection between normative feedback and reductions in alcohol use [19,20]. In contrast, electronic normative feedback interventions for college students that have incorporated norms specific to age, gender, and campus have been associated with significant reductions in alcohol use and risky sexual behavior [16-18]. In sum, normative misperceptions are prevalent among adolescents and contribute to a variety of health risk behaviors in addition to alcohol and drug use [45]. In order to correct these misperceptions, targeted data presentation techniques are needed to ensure that adolescents trust and believe normative feedback offered to them.

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Regarding comparisons with national health guidelines, some participants specifically found the recommendations for screen time (<2 hours/day) and exercise (1 hour, 7 days/week) unreasonable in the context of their daily lives. The media guidelines used in the Check Yourself tool were based on the 2013 guidelines from the American Academy of Pediatrics [46] that were recently updated in recognition of the increasing integration of technology into modern adolescent lifestyles [47,48]. The 2016 guidelines emphasize individualized family planning of appropriate media use and lean away from strict quantitative cutoffs [49]. Future studies should examine if the new guidelines are more acceptable to youth. Whereas the exercise recommendations were also viewed as difficult to achieve by adolescents in our study, these guidelines are based on extensive empirical evidence [50]. However, our data suggest that presenting what adolescents may perceive as stringent exercise guidelines may not promote motivation to change unless paired with strategies to promote self-efficacy such as practical tips and suggestions to set small achievable goals.

When prompted with possible adaptations to the tool, adolescents expressed interest in receiving follow-up information about health risks, opportunities to set goals and track health behaviors, receiving reminders of planned changes, and communicating with providers electronically between appointments. Participants' enthusiasm for these additional features suggests that adolescents may envision an ongoing role for technology in health behavior change, and specifically technological supports that enhance their ability to self-regulate behaviors and include the option of seeking professional input if desired. These findings corroborate results from other recent qualitative studies investigating adolescents' preferences for text messaging-based preventive interventions, which have documented high youth interest in receiving brief, personalized advice and reminders of reasons to change on an ongoing basis [26,51]. Taken together, adolescents' interest in highly personalized content lends additional support to increasing evidence that Web-based interventions incorporating tailored information yield stronger effects than generic interventions [52]. Whereas such technological supports should address the needs and preferences of adolescents, care must also be taken to ensure that busy primary care providers have tools and methods to rapidly interpret and utilize adolescent-generated data. Future research could address this issue.

Limitations

The qualitative design of this study entails both strengths and limitations. Though we were able to examine nuanced perspectives not easily accessible to quantitative research, it is possible that adolescents' opinions regarding effective types of feedback expressed during a qualitative interview may not reflect what would actually have an impact if tested using quantitative methodology. For this reason, results from this study should function to inform hypothesis generation rather than generalizable knowledge. An additional limitation stems from our recruitment from primarily one clinic in Seattle, WA, which resulted in a sample largely representative of this geographic region but whose perspectives may not describe those of adolescents in other areas and health care settings.

Conclusions

With the opportunity to create screening tools that go beyond collecting information from adolescent patients by providing education and feedback, it is useful to seek youth input in order to design content that is acceptable and effective for this population. Adolescents in this qualitative study were specific about their preferences for electronic, personalized feedback on their health behaviors. They expressed engagement with and enthusiasm for the process of receiving feedback in general and were appreciative of new health information and tips, while at the same time they offered some critiques and suggestions regarding specific feedback messages. Participants desired feedback that validates healthy behavior choices and supports them as independent decision makers by neutrally presenting relevant information. Additionally, participants valued feedback that enhances their ability for self-management by facilitating goal setting and offering ongoing technological supports. Future quantitative outcome research should test screening tools that incorporate these suggestions.

Acknowledgments

This research was supported by the Agency for Healthcare Research and Quality (AHRQ 5R01HS023383-02; PI: McCarty). The granting agency which 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. No additional financial inputs (eg, honorariums or other forms of payment) aside from those of the granting agency supported the writing of the manuscript. Publication made possible in part by support from the Berkeley Research Impact Initiative (BRII) sponsored by the UC Berkeley Library.

Authors' Contributions

LR and CM designed the study. GZ and KK collected the data. All the authors contributed to the analysis and interpretation of the data. GZ wrote the manuscript with guidance from the other authors. All the authors approved the final version of the manuscript.

Conflicts of Interest

SW serves as medical director and co-owner of Shift Health, the company that hosted the electronic intervention examined in this study.

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Edited by G Eysenbach; submitted 14.02.17; peer-reviewed by S Bradford, L Chernick, L Thompson; comments to author 23.03.17; revised version received 23.04.17; accepted 25.05.17; published 20.07.17.

Please cite as:
Zieve GG, Richardson LP, Katzman K, Spielvogle H, Whitehouse S, McCarty CA
Adolescents' Perspectives on Personalized E-Feedback in the Context of Health Risk Behavior Screening for Primary Care: Qualitative Study
J Med Internet Res 2017;19(7):e261
URL: http://www.jmir.org/2017/7/e261/
doi:10.2196/jmir.7474
PMID:28729236

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Original Paper

Development and Use of Health-Related Technologies in Indigenous Communities: Critical Review

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Abstract

Background: Older Indigenous adults encounter multiple challenges as their age intersects with health inequities. Research suggests that a majority of older Indigenous adults prefer to age in place, and they will need culturally safe assistive technologies to do so.

Objective: The aim of this critical review was to examine literature concerning use, adaptation, and development of assistive technologies for health purposes by Indigenous peoples.

Methods: Working within Indigenous research methodologies and from a decolonizing approach, searches of peer-reviewed academic and gray literature dated to February 2016 were conducted using keywords related to assistive technology and Indigenous peoples. Sources were reviewed and coded thematically.

Results: Of the 34 sources captured, only 2 concerned technology specifically for older Indigenous adults. Studies detailing technology with Indigenous populations of all ages originated primarily from Canada (n=12), Australia (n=10), and the United States (n=9) and were coded to four themes: meaningful user involvement and community-based processes in development, the digital divide, Indigenous innovation in technology, and health technology needs as holistic and interdependent.

Conclusions: A key finding is the necessity of meaningful user involvement in technology development, especially in communities struggling with the digital divide. In spite of, or perhaps because of this divide, Indigenous communities are enthusiastically adapting mobile technologies to suit their needs in creative, culturally specific ways. This enthusiasm and creativity, coupled with the extensive experience many Indigenous communities have with telehealth technologies, presents opportunity for meaningful, culturally safe development processes.

(J Med Internet Res 2017;19(7):e256) doi:10.2196/jmir.7520

KEYWORDS

Indians, North American; Canada; telemedicine; self-help devices; needs assessment; aging

Introduction

The Canadian population is aging rapidly. In July 2015, Statistics Canada reported that people aged above 65 years outnumbered children below the age of 14 years. The trend of an aging Canada is projected to continue: by the year 2024, over 20% of the total population will be over the age of 65 years [1]. National bodies such as the Canadian Medical Association have expressed concern about increasing demands on Canadian health care systems due to the aging of the population, which will result in an increase in age-related disorders such as dementia [2]. Within the Canadian population, Indigenous populations now exceed one million and are growing at a rate 6 times greater than that of the population as a whole [3]. The number of

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Indigenous adults aged 60 years and above is projected to increase 3.4 times from 2006 to 2031, resulting in over 184,000 older Indigenous adults [4]. Aging within Indigenous communities interacts with social inequities; consequently, older Indigenous adults may be more likely to require regular and specialized health care. For example, First Nations communities in Canada have higher rates of chronic conditions such as diabetes and heart disease [5], impacting quality of life and need for health services. These same communities often have insufficient financial resources to address growing health concerns and may be geographically disadvantaged in terms of access to facilities and providers [6]. This geographic concern is compounded by findings that the majority of older Indigenous adults prefer to grow older in their own homes, known as "aging in place" [7]. Aging in place is also more cost effective than long term care for both families and governments [8] and aligns with recent findings suggesting that family caregiving models in Indigenous communities are preferred. Indigenous caregiving models are not only more robust than those of the general population but are culturally grounded and present unique health and social service needs [9].

Literature concerning technological innovations for aging in place has developed significantly over the past several years, and meaningful user involvement has been identified as critical to adoption [10-12]. Comparable Indigenous-specific literature is scarce, despite the fact that the development of novel assistive technologies has potential to support health care delivery and aging in place in Indigenous communities [13]. User needs exploration is important to promote any end-use adoption of technology, but it is particularly important for Indigenous populations where user needs may differ from those espoused by older adults from the majority culture or other marginalized cultures, and all information technology is culturally bound [14]. Development of culturally safe, useful technology can only be developed by collaborative participation with Indigenous end users [15]. Consequently, the purpose of the paper was to explore the current state of the available literature concerning use, adaptation, and development of assistive technologies for health purposes by Indigenous individuals and communities.

Methods

Methodology

Initially, the research team endeavored to systematically review available literature concerning older Indigenous adults and their use of technology for health purposes. Informal searches presented keyword possibilities such as "assistive technology" and indicated that there may not be sufficient literature specific to older Indigenous adults available for systematic review. Age parameters within our chosen population were expanded to accommodate this concern, and the research question was finalized within a critical review framework for the purposes of best highlighting gaps in the literature. Working within Indigenous research methodologies also affected the search method. Research centering Indigenous voices and experiences was prioritized, and Indigenous-centered, nonacademic literature was evaluated and accepted as equal to academic sources. This practice is drawn from Indigenous research scholarship and is sometimes referred to as "choosing the margins" [16]. Indigenous cultures also uniquely experience colonization, a lived reality distinct from racism or discrimination experienced by other groups; consequently, articles about adaptation with other marginalized groups were not included. Due to the paucity of published literature meeting the search criteria, sources were sought on multiple platforms and practices such as hand searching were employed to ensure that all relevant studies were captured.

Search Strategy

Searches of peer-reviewed, academic literature and gray literature on assistive technologies and Indigenous people and communities were completed in February 2016. In the academic literature search, keywords related to Indigenous ("Aboriginal," "Indigenous," "Inuit," "Métis," "First Nation," "Native American," and "American Indian") and assistive technologies ("assistive technology," "assistive devices," "ehealth," and "mHealth") were combined and the search was conducted on several databases: MEDLINE, PubMed, PsycInfo, AMED, EMBASE, CINAHL, Social Work Abstracts, Social Services Abstracts, ProQuest Health, and the Cochrane Database of Systematic Reviews. Based on findings from this search, hand searching was also completed in both references of found articles and in the following journals: Telemedicine and Ehealth, Journal of Circumpolar Health, Rural and Remote Health, Journal of Assistive Technologies, and Journal of Social Work in Disability & Rehabilitation . Due to an overabundance of articles regarding telehealth use and development in Indigenous communities, articles captured in the search focused on telehealth were limited to Canadian and post-1990. To capture the diversity of available technologies beyond telehealth, international sources are included, primarily from the United States, New Zealand, and Australia; countries with similar colonial histories to Canada.

Gray literature was searched using the method from "Grey Matters: A Practical Search Tool for Evidence-Based Medicine" produced by the Canadian Agency for Drugs and Technologies in Health. This method was used to search the websites of the following parties: Alberta College of Family Physicians, Alberta Health and Wellness, Canadian Agency for Drugs and Technologies in Health, McGill University Health Centre, Newfoundland and Labrador Centre for Applied Health Research, Therapeutics Initiative, Australian Government Department of Health and Ageing, Australian Government Department of Health and Ageing Medical Services Advisory Committee, Monash Health Centre for Clinical Effectiveness, Institute of Technology Assessment, Agency for Healthcare Research and Quality, California Technology Assessment Forum, Centers for Medicare and Medicaid Services, Institute for Clinical and Economic Review, Alberta Medical Association, British Columbia Ministry of Health Services, Canadian Medical Association, University of Ottawa School of Rehabilitation Science, Academy of Medicine of Malaysia, Haute autorité de santé, and Alzheimer Society of Canada.

From these searches, 107 articles appeared to meet the search criteria and were selected for more detailed review. Upon detailed examination, 73 were excluded as they did not meet the search criteria, presenting no insight into Indigenous-specific

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use, adaptation, or development of technologies for health purposes. A total of 34 sources were indexed and summarized using bibliographic management software and content was coded to emergent themes.

Results

Data Analysis

There were few published studies on assistive technology use, development, or adaptation in Indigenous populations, globally. Disease-specific studies were limited (n=9), as were studies concerning older Indigenous adults (n=2). Results originated primarily in Canada (n=12), Australia (n=10), and the United States (n=9). Some studies originating in the United States found that assistive technology use in Indigenous communities was high compared with the wider American population [17,18], providing needed insight into experiences of use by this population. Studies also addressed different products: telehealth (n=8), mobile health [mHealth] (n=12), Web-based interventions (n=3), and assistive devices (n=7). The remaining 4 articles addressed considerations for development generally. Results were presented thematically: meaningful user involvement and community-based processes in development, the digital divide, Indigenous innovation in technology, and health technology needs as holistic and interdependent.

Meaningful User Involvement and Community-Based Processes in Development

Several studies detailed the importance of developing technology with, as opposed to for, Indigenous communities. The purpose of developing with is not only to ensure that technology is relevant and useful but also to decolonize the development process [14,15,18-21]. This means involving users, caregivers, health professionals, and elders or original knowledge keepers (as appropriate) at the conception of the design and throughout all development and testing phases. Within studies considering development of technology, some researchers presented models or recommendations for meaningful engagement around technology with Indigenous communities, whereas others discussed challenges.

Maar and colleagues (2010) discussed the development of eHealth (also known as telehealth) with Indigenous communities in Canada. In their study, a participatory action research (PAR) approach was blended with Indigenous research methods to identify priority areas for Indigenous health research. The research team emphasized the often negative impacts that research and expert positioning have had on Indigenous communities, reminding readers that these impacts have contributed significantly to the historic and ongoing colonization of Indigenous peoples. They suggested the engagement of individuals with real-world understanding and meaningful, lived connections to Indigenous communities rather than those coming from outside the community. Also emphasized was the importance of communities, not researchers, developing research priorities and that researchers should take the time needed to hear all voices to achieve consensus. Their conceptual model places community advisory councils at the center of the research process [15].

Community advisory councils were also at the center of a study by Davies and colleagues (2015) on the development of a culturally appropriate mobile phone app for the prevention and management of hepatitis B for Indigenous Australians. The app was piloted in a community of just over 2100 people with overcrowded homes and limited amenities. Researchers used storyboarding to present ideas and seek feedback from an advisory council after initial interviews. They took the time to ensure community needs were accurately reflected, with some storyboards undergoing more than 20 versions before approval. The app was then developed and translated into the local Indigenous language, which required a significant investment in time involving back translation and testing with fluent community members. When researchers felt the app was finally ready for market, prototypes were launched in the community and feedback was sought. This process was repeated 4 times before the app was correctly tailored to community needs [14]. Another study for the adaptation of a model of remote monitoring for use by American Indian veterans with post-traumatic stress disorder described a similar engagement process and suggests employing a cyclical model in which user feedback continually informs cultural adaptation, rather than a linear process [20].

Similarly, Ratliffe and colleagues (2012) reported on a series of case studies conducted in the Pacific Islands and presented best practices and barriers for adaptation. Best practices included establishment of support networks for users, employing creativity when adapting the home environment, resource sharing when possible, and accepting an iterative change process [22]. Furthermore, multiple studies recommended meaningful involvement of the community in the development stages for successful adoption [15,21,23].

The Digital Divide

Despite the best practices presented by these participatory approaches, significant challenges remain present for communities and for those developing “with.” Often identified was the “digital divide,” wherein some individuals and communities have greater access to the Internet, broadband, and cell towers than others. This is a continuing problem in Indigenous communities in Canada [15]. Morey (2007) suggests an expansion of this definition to include pronounced lack of Web-based content specific to the cultures and languages of marginalized communities and promotes the concept of “cultural usability” as a development concept to counteract this divide. Questions to consider under the cultural usability umbrella include whether content is relevant to the community, if the illnesses featured are concerns to the users, and whether or not suggestions for prevention and management are realistic given geographic location and socioeconomic status [24]. This definition can be further expanded to include affordability of technologies for individuals and community, a barrier that was cited in multiple studies [13,18,22].

A key aspect to the digital divide is remoteness or rurality, a concept explored in greater detail in 3 studies [13,15,19]. Arnold (2009) demonstrates this reality for remote and rural Aboriginal and Torres Strait Islander communities in Australia. She suggests considerations for development and implementation

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include being aware of distance to nearest maintenance personnel and part stores, as this will determine cost and convenience for the user. Arnold also notes that environmental factors that impact the use and implementation of the technology need to be considered. For example, the roads may not be paved, the user may spend time in the bush, and coastal areas will accelerate rusting of technology and communication infrastructure. Furthermore, older community members often live with extended family, and as such, the technology needs to adapt to not only the user's need, but also to any family members who are sharing the same living spaces. Further data on the importance of adaptation was detailed by Reisinger and Ripat (2014) who conducted a series of talking circles with US-based Navajo users and assistive device providers. Best practices identified by users included adapting assistive devices to their environment, especially with consideration to frequent outdoor use and overcrowded housing. This same community also expressed concerns regarding insufficient infrastructure to support new technologies [18]. Recommendations were varied, but a top suggestion was to employ lengthy and rigorous trial periods for new devices [18]. Primarily, working with the user during as many stages of implementation as possible is advised. Maar and colleagues (2010) reemphasize the complexity and diversity of Indigenous communities and the importance of a good engagement model as vital to managing adaptation and adoption of technology challenges.

Telehealth has been recommended for years as a technological solution to mitigate Indigenous health care disparities: health care providers do not always live where service users do, particularly if users live on reserve or in remote locations [21,25]. Nevertheless, research in telehealth use with Indigenous populations produces mixed results. One study found telehealth and remote monitoring to be as effective as conventional care [26], whereas another cautioned that telehealth should only ever be used as a complement to conventional care and that some service users should not even be considered for remote services due to the severity of their conditions [27]. Furthermore, although many participants were pleased with increased access to health care [23,28], one Ontario, Canada study found that almost a third of patient participants felt negatively about telehealth services as a whole, with most patients describing concerns about the cultural appropriateness and the privacy of the service [28], indicating poor cultural usability. Another challenge presented in the literature is a lack of training for health care providers using telehealth; Gibson and colleagues (2011) found that only 16% of providers had received any training on the technology they were using. This may contribute to a finding by Sidhu (2012) in which 45 cancer care professionals in British Columbia, Canada, were surveyed regarding perceptions of telehealth; most felt it less beneficial than conventional care. Finally, the digital divide presented as a physical challenge in some Ontario communities where broadband networks were actually insufficient to support the technology [15,23,28]. Despite these challenges, use remains fairly widespread. Factors found to contribute to more successful implementation and use of telehealth services were identified in 2 studies. Mah (2011) found that patients were more likely to engage in telehealth for the management of a specific illness than for general health care. Also, if technology was perceived as easy to use, successful uptake was also more likely [29].

Unlike telehealth, mHealth is a relatively new platform for the delivery of health care interventions. The term "mHealth" is used to describe mobile phone technologies used for health purposes. However, recommendations for enhanced cultural usability remain relevant. Emerging rural and Indigenous research suggests that the landscape of the digital divide is changing rapidly. Whereas Morey (2007) cites the digital divide as a challenge facing communities, other researchers view it as an opportunity to study innovation. In Canada, Maar and colleagues (2016) are completing the DREAM-GLOBAL project, in which they are developing culturally safe text messages (short message service, SMS) for hypertension management in Indigenous populations. A major finding was that messages should adapt to local socioeconomic and geographic conditions. They also concluded that cultural safety is essential to success [30]. Similarly, 2 Australian studies provided recommendations to occupational therapists working with Aboriginal and Torres Strait Islander people, such as accessing Indigenous health workers and seeking out cross-cultural training [19,31].

Indigenous Innovation in Technology

Brusse and colleagues (2014) describe the enthusiastic uptake of mobile technology and social media among Indigenous peoples in Australia, stating that "In the past 5 years, affordable mobile phones with camera and messaging functions have spawned a 'mobile phone culture' in some remote areas, where messages, pictures, and video clips flow freely among and between communities, often in culturally unique and creative ways" [31]. Surveys of health care consumers in New Zealand indicate similar enthusiasm in Maori communities. Interest in mHealth interventions for weight loss was higher among rural Maori and young people compared with the general population [32]. Interest in a text messaging-based intervention for alcohol abuse was also viewed favorably by Maori participants, provided there were considerations for cultural relevance [33]. Culturally safe text-based interventions for retention in a clinical trial were found to be effective with Maori participants by other researchers [34]. Similar results have been found in Indigenous communities near La Paz, Bolivia; most participants texted regularly and were open to mHealth interventions, provided Indigenous language preferences were taken into account [35]. Indigenous language use was mentioned as a key factor for successful distribution and uptake in 3 other studies [14,36,37]. Other factors for success include the use of real people and stories to market and guide the user through the product, the use of more visuals than text, considerations for gender differences, and making the product free and available on multiple platforms [14,38].

Health Technology Needs as Holistic and Interdependent

A major finding of the review is that Indigenous users of technology for health were not concerned with enhancing independence but rather interdependence. This includes recognizing that Indigenous perceptions of health may differ greatly from Western perceptions. In some instances,

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community-based, decision-making processes may be preferred to individualized systems [13,19], and independence may not be the ultimate goal of the user [19,39]. Users readily adopted technologies that included family and community in their health care, as well as technologies that fostered closer relationships with health care providers. For example, researchers in Nigeria have piloted a tool that does real-time machine translation between patients speaking Yoruba, an Indigenous language, and English-speaking doctors during remote consultations. Patients also have the option of selecting symptoms from a designated list, which prompts memory. Both medical personnel and patients demonstrated high levels of satisfaction with the service [37]. Recently, researchers in Australia evaluated the new AIMhi Stay Strong app, which is a mental health evaluation tool for health care providers to use on home visits with Aboriginal and Torres Strait Islander patients. Providers interviewed felt the app encouraged them to have more in-depth conversations with patients. Some noted that it helped even out the power relationship between provider and patient, as the patient could see what the provider was doing on the app and felt involved in the assessment process [36]. In Nain, Newfoundland, researchers studied a remotely controlled robot that could assess and provide some treatment. The robot was always with a nurse and an interpreter. Futhermore, 95% of patients indicated that they would use the robot again. Researchers recommended the robot be used full time, managed by nurses on site [40].

Another example of this relationship-based view of health and technology was found in the 3 studies regarding Web-based interventions for the management of diabetes by Native American users. All 3 studies found increases in self-management behavior [41-43], whereas 2 found improvements in blood glucose levels and other physical measures of health status as a result of the intervention [42,43]. Robinson and colleagues (2011) also determined that the more frequently and personally the users interacted with their health care providers via the website, the more carefully they monitored and managed their blood glucose levels. Jernigan and Lorig (2011) included a qualitative component to their study, and participant feedback indicated that the most valued aspect of the program by users was the culturally specific peer support. Many users described a feeling of safety derived from being among other Native American participants, pointing out that they did not need to watch their language or explain concepts specific to the Native American experience.

Furthermore, many Indigenous communities viewed health as more than simply physical, and this was reflected in their diversification of existing technologies. Recommendations for successful adoption of telehealth include the inclusion of traditional practices and beliefs in telehealth care [13,23]. Molyneaux and O'Donnell (2009) further suggest that the use of the technology be diversified and cite communities that are using the technology for a variety of purposes such as connecting loved ones for hospital visits, providing elders with social visits, staff training, health literacy education, programs for youth, and language sharing initiatives. One community discussed in their study had even invented the term "telespirituality" to describe consultations related to traditional medicine or ceremonial practices. They argue that this diversification demonstrates the value of the product to communities, which makes successful uptake more likely and involves multiple parties, establishing long term sustainability. The need for interdependence and holism was reflected in another American study where users wanted to see more frequent visits from community health representatives, peer support groups, and programs for assistive devices designed by and for users. Many mentioned the need for services to be provided in the Navajo language and with an understanding of traditional practices and ceremony [18].

Discussion

Principal Findings

Throughout the review, a number of pressing recommendations and major gaps were identified in the literature, providing insight into future research activities, policy change needed to address barriers, and positive innovation by Indigenous communities. Within each theme, the research team developed specific recommendations and identified concerns and gaps in knowledge. A pressing recommendation within the development theme emphasizes the importance of meaningful user involvement. Of note is that in spite of, or perhaps because of the digital divide, Indigenous communities are enthusiastically developing and adapting mobile technologies and social media to suit their needs, often in creative, culturally specific ways. This enthusiasm and creativity, coupled with the extensive experience many Indigenous communities have with technologies such as telehealth, presents an opportunity for meaningful, culturally safe development processes, as evidenced in recent work by Maar and colleagues [30]. Future research in this area should support these strengths and seek opportunities for culturally safe development, advocacy, and policy change.

Outside of Canada, mHealth apps appear to be emerging as a well-adopted technology in Indigenous communities, particularly within Australia and New Zealand. Canadian research in this area is significantly underdeveloped, perhaps also due to the above mentioned digital divide. Further study of perceptions of mHealth in Canadian Indigenous communities is needed. Web-based interventions were similarly not visible in the Canadian literature but presented good results in the few American studies in which they featured, particularly in the areas of social and emotional support for individuals living with chronic illnesses.

On a related note, the extensive experience with telehealth provides many lessons for researchers seeking to develop, or health care providers seeking to use, technology to reduce the distance between providers and users. Privacy concerns featured in most studies, with communities citing serious concerns about the social and legal impacts of potential confidentiality breaches. A further issue communities faced was lack of infrastructure; in some cases, the technology that had been developed could not be implemented due to insufficient broadband networks. Finally, major recommendations for continued use of telehealth and similar technologies emerged. First, that health care providers and users receive adequate training on the operation of the system, and second, that uses for the system be diversified

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beyond health to ensure maximum uptake. With a similarly small sample, the 5 studies concerning assistive devices presented some very real, practical concerns facing Indigenous users of assistive technology. Users expressed several access issues: remoteness impacted maintenance of the device, cost was prohibitive in many cases, and there was often stigma around using the devices. Mentioned as a key concern in 4 of 5 studies was the failing of devices to be sufficiently durable for the frequent and prolonged outdoor activity that remains essential to the lives of many older Indigenous adults.

Limitations

Despite a review of the published and gray literature, there remained several gaps. Research on the prevalence, policy context, and perception of assistive technology use, particularly mHealth, by Indigenous peoples in Canada was still in early stages. Notably, Inuit and Métis perceptions were not captured in the search. There was also no literature on assistive technology development to support Indigenous caregivers of older adults. Finally, there was no Indigenous-specific research on assistive technology for people with cognitive impairments such as memory loss, an emerging subset of mainstream assistive technology. In particular, further study should be conducted on culturally rooted perceptions of surveillance technologies used to support older adults with dementia, as this technology has the potential to replicate cycles of oppression and colonization.

There is also a considerable gap in evaluated products [39]. In Australia, researchers partnered with the Metro North Hospital have adapted a cardiac rehabilitation app for use by Aboriginal and Torres Strait Islander patients using similar principles, though they caution that the technology remains new and an evaluation has not yet been conducted [38]. Similarly, Brusse and colleagues (2014) caution that further evaluation is needed before conclusions can be drawn, and Shand et al (2013) have published a protocol to determine effectiveness of suicide intervention apps for Indigenous Australian youth [44].

Conclusions

Overall, technology use, adaptation, and development by Indigenous users existed prominently in the context of colonial legacy. Users had high health needs related to early onset of age-related conditions, multiple comorbidities, and a long history of inadequate health service delivery. Of the studies included in the review, those that empowered communities to direct technology development processes and those that built on existing strengths were most successful. The results also suggest that technology that is highly adaptable to task, context, or culture appear to show the greatest acceptance by Indigenous communities across the globe. Although minimization of the digital divide is also a critical factor, the ability for adaptation of technology may underlie the clear superiority of mHealth versus telehealth. The mHealth initiatives were all specifically adapted for use with Indigenous communities, many with meaningful user consultation. Telehealth, in contrast, was a platform developed for majority culture users and attempted with Indigenous users. Molyneaux and O'Donnell (2009) underscore the need for telehealth use to be diversified beyond use merely for health care within a community to maximize adoption and increase perceptions of cultural safety [13].

This review underscores the importance of exploration of the needs of unique populations, such as Indigenous communities. Technology development in collaboration with Indigenous communities rather than dissemination in those communities is critical for uptake. The incorporation of community-based participatory research methods as a means to inform technology develop met with the greatest success. mHealth platforms codeveloped with Indigenous communities offer a model for future technology development, and we suggest this is an area for future research. Moreover, mHealth platforms can capitalize on large corporate Mobile phone interests to develop a distributed infrastructure, at least with larger and urban centers. Nevertheless, cell tower networks need to be significantly expanded to encompass Canada's most vulnerable and remote communities. We suggest government policy needs to address mobile phone inequities in low density populations to further reduce the digital divide for Indigenous users of mHealth.

Acknowledgments

This research was supported by the AGE-WELL National Centre of Excellence Inc. We would like to thank Dr. Melissa Blind, Research Associate, Centre for Rural and Northern Health Research, and Dr. Wayne Warry, Director, Centre for Rural and Northern Health Research for their support and guidance in the development of this review.

Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health
PAR: participatory action research
SMS: short message service

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Edited by G Eysenbach; submitted 15.02.17; peer-reviewed by A Astell, A Billis; comments to author 23.03.17; revised version received 17.05.17; accepted 06.06.17; published 20.07.17.

Please cite as:
Jones L, Jacklin K, O'Connell ME
Development and Use of Health-Related Technologies in Indigenous Communities: Critical Review
J Med Internet Res 2017;19(7):e256
URL: http://www.jmir.org/2017/7/e256/
doi:10.2196/jmir.7520
PMID:28729237

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Original Paper

Evaluating a Web-Based Coaching Program Using Electronic Health Records for Patients With Chronic Obstructive Pulmonary Disease in China: Randomized Controlled Trial

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is now the fourth leading cause of death in the world, and it continues to increase in developing countries. The World Health Organization expects COPD to be the third most common cause of death in the world by 2020. Effective and continuous postdischarge care can help patients to maintain good health. The use of electronic health records (EHRs) as an element of community health care is new technology in China.

Objective: The aim of this study was to develop and evaluate a Web-based coaching program using EHRs for physical function and health-related quality of life for patients with COPD in China.

Methods: A randomized controlled trial was conducted from 2008 to 2015 at two hospitals. The control group received routine care and the intervention group received routine care with the addition of the Web-based coaching program using EHRs. These were used to manage patients' demographic and clinical variables, publish relevant information, and have communication between patients and health care providers. Participants were not blinded to group assignment. The effects of the intervention were evaluated by lung function, including percent of forced expiratory volume in 1 second (FEV1%), percent of forced vital capacity (FVC%), peak expiratory flow (PEF), maximum midexpiratory flow; St George's Respiratory Questionnaire (SGRQ); Modified Medical Research Council Dyspnea Scale (MMRC); and 6-Minute Walk Test (6MWT). Data were collected before the program, and at 1, 3, 6, and 12 months after the program.

Results: Of the 130 participants, 120 (92.3%) completed the 12-month follow-up program. There were statistically significant differences in lung function (FEV1%: F1,4=5.47, *P*=.002; FVC%: F1,4=3.06, *P*=.02; PEF: F1,4=12.49, *P*<.001), the total score of SGRQ (F1,4=23.30, *P*<.001), symptoms of SGRQ (F1,4=12.38, *P*<.001), the activity of SGRQ (F1,4=8.35, *P*<.001), the impact of SGRQ (F1,4=12.26, *P*<.001), MMRC (F1,4=47.94, *P*<.001), and 6MWT (F1,4=35.54, *P*<.001) between the two groups with the variation of time tendency.

Conclusions: The Web-based coaching program using EHRs in China appears to be useful for patients with COPD when they are discharged from hospital into the community. It promotes the sharing of patients' medical information by hospital and community nurses, and achieves dynamic management and follow-up analysis for patients' disease. In addition, this program can postpone the decreasing rate of lung function, improve quality of life, decrease dyspnea, and increase physical capacity.

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(J Med Internet Res 2017;19(7):e264) doi:10.2196/jmir.6743

KEYWORDS

chronic obstructive pulmonary disease; electronic health records; Web-based coaching program

Introduction

Chronic obstructive pulmonary disease (COPD) is a major cause of morbidity and mortality, and is the fourth leading cause of death worldwide [1]. Because of the complex and progressive trajectory of COPD, interventions are needed that slow disease progression and prevent hospital readmissions [2]. However, longitudinal follow-up interventions can be costly, time consuming, and burdensome for health providers and study participants [3]. Computer-tailored intervention strategies have been shown to be more cost effective than standard care [4].

Electronic health records (EHRs) are scientific computerized systems that replace and expand on functions previously provided by paper medical records. EHRs can maintain and update millions of electronic records of patients and are easily transferable. They can also store, manage, and deliver information more efficiently than people can and permit multiple clinicians to simultaneously access the same patient records from different locations [5]. Beyond this, EHRs allow better communication between patients and clinicians. Using EHRs can expand the role of current health surveillance efforts and can help bridge the gap between public health practice and clinical medicine [6]. In addition, EHRs are a major component for current studies in health informatics, but different approaches should be applied [7].

In the United States, health care system EHRs have been widely adopted [8], and in primary care in the United Kingdom. Within these, there is a combination of diagnostic and therapy codes for COPD [9]. These EHRs play a beneficial role in the care of patients with chronic illness [10] and improve the quality and efficiency of health care [11]. In some developed countries, health care systems are encouraged to combine behavioral and medical health care and apply EHRs for health information exchange and quality improvement [12]. Various studies have examined the positive effect of using EHRs for ophthalmological patients [13,14].

In the United States, the implementation of EHRs has shown to improve the quality of life of patients in pulmonary rehabilitation [15], decrease medical error [16], reduce hospitalization costs [17,18], and contribute to the establishment of standardized evidence-based nursing. Moreover, EHRs have played an important role in the follow-up of patients with chronic illness and postpartum patients [19,20]. In 2010, the United States spent US $2.6 trillion on health care [21], and more than 76% of hospitals had adopted a basic EHR system by the end of 2014 [22]. In northern Europe, EHRs have been used widely and many clinics have adopted the clinical record and information system approach. This approach allows the combination of work on medical sciences and medical informatics and the improvement of the technical level of community hygiene and family medicine [23]. Studies on the prevalence of EHR use have not been completed in China.

Despite the widespread application of EHRs, policies to support health information exchange and to increase patients' active participation still require improvement [24]. Of note, one qualitative study showed that EHRs were viewed as having adverse effects on physician workflow and team communication [25]. However, EHRs have many functions and include several kinds of data, and the aim to develop EHRs and the content of EHRs are the focus of research in the future [26].

Data for EHRs include personal medical records that consist of information related to the individual and family health history, results of physical examinations, immunization status, health care service use, and demographics. It has been suggested that placing this technology in patients' homes may have an impact on patient involvement in self-monitoring, decision making, and self-care [27]. However, to our knowledge, no research has been published about clinical outcomes after using EHRs in a COPD setting. We developed EHRs based on the aim of our study, which involved the enrollment of health care providers and patients, enabling patients to access their own health records, exchange health information, and obtain a referral between tertiary and primary care. The main aim of this study is to develop EHRs as a hospital and community referral platform and to accomplish seamless nursing and transitional care. The secondary aim is to describe a prospective design to assess the feasibility and efficacy of implementing EHRs among patients with COPD in order to promote larger studies of the application of EHRs in China and the management of COPD in primary care.

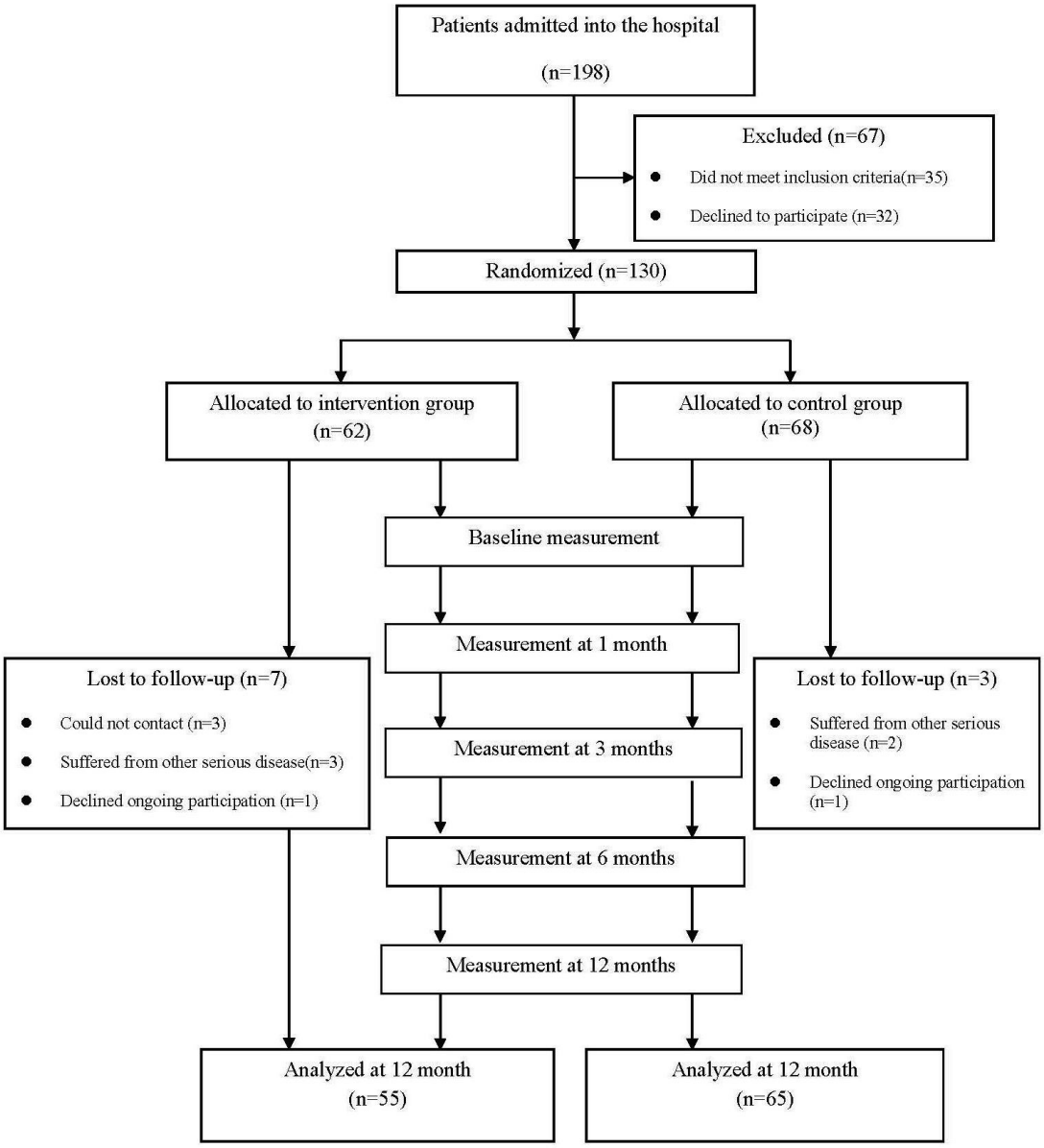
Methods

Study Design

This was a randomized controlled trial, which compared an intervention group that received a Web-based coaching program using EHRs with a control group that did not receive the intervention after discharge from hospital. All participants received usual care before discharge, including medication guidance, lifestyle education, and regular reviews in order to help them manage their disease. Data were collected before the program and at 1, 3, 6, and 12 months after the program. Figure 1 illustrates the Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

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Figure 1. CONSORT flow diagram.



Web-Based Coaching Program Using Electronic Health Records

The trial was developed by the research team, which included a clinical nurse, a head nurse, a community nurse, two respiratory physicians, and two nursing students (data collector). The clinical nurse taught disease-related information in the predischarge phase. The community nurse was responsible for the postdischarge follow-up using EHRs.

The EHRs were divided into two separate fields (Figures 2 and 3). There were two user spaces, one dedicated to the participants in the study (the front end) and the other one dedicated to the administrators of the platform (the back end). The patient-accessible personal health records were activated by the administrator logging into the system and inputting a username and code. Each participant received a unique identifier code generated by the system. The system was constructed to allow the input of the patient's demographic information, record of admission, discharge, and community information. The system build included a statistical analysis function so that a curve graph could be produced of data variation that visually informed medical staff and patients of the trajectory of the disease. Once registered, the individual participant record was retrieved by entering the unique participant identifier. When the appropriate record was retrieved from the system, the administrator could add new information to the record. After the administrator assigned the username and code for the particular participant, the participant could access information about their disease and also health education content entered by the administrator, which now appeared in the participant field. The participant could connect with the community administrator through the EHR's system. This communication is similar to email function. Medical practitioners and nurses could write suggestions to the participants in the system and, when the patients logged in, they could view the message. Participants could also ask questions directed to the medical team using the same messaging function.

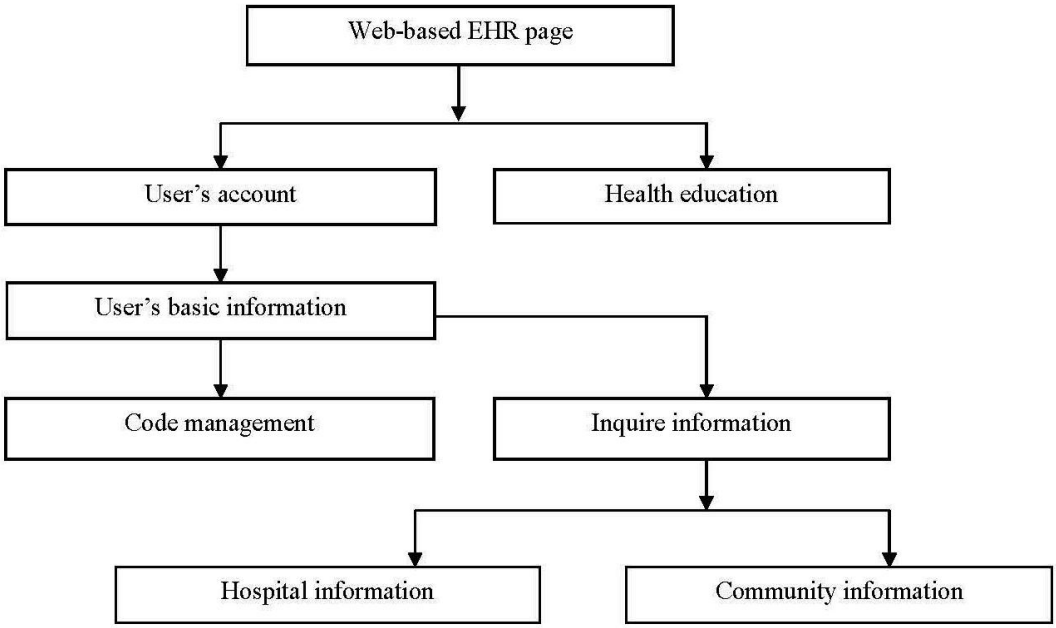
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The implementation of the Web-based coaching program was based on sharing information within EHRs. All relevant data were recorded in the EHRs to allow the participants and administrators to refer to particular information at their convenience by Internet. There were two main information sets in these particular EHRs. One was related to health education and provided a resource for participants that included information about COPD and pulmonary rehabilitation instructions. The information related to COPD consisted of the cause of the disease, development, acute exacerbation, prognosis, medication information (name, route, dosage, and adverse reactions), oxygen therapy, and diet. Pulmonary rehabilitation instructions consisted of abdominal contraction and lip breathing, respiratory muscle exercise, aerobic exercise, and the importance of smoking cessation. The second information set was the participant's particular management based on the progress of the disease. Tailored contents that match a user's preference are more useful to motivate behavioral change [28].

The EHRs could store all the patients' health information from hospital to community care. In this particular project, the individual also had control of their own records and managed their files. The records could be packaged and sent electronically. Because the participant had control of the records, they could supply their own health information to their health practitioners. Participants could read all their information and discuss it with the administrators by Internet within the EHRs.

The research team telephoned the participants every two weeks and made home follow-up visits at 1, 3, 6, and 12 months after discharge to promote adherence to the provided intervention methods and to collect data. The participants could telephone the community administrators when they had problems.

Figure 2. Participant log-in process.

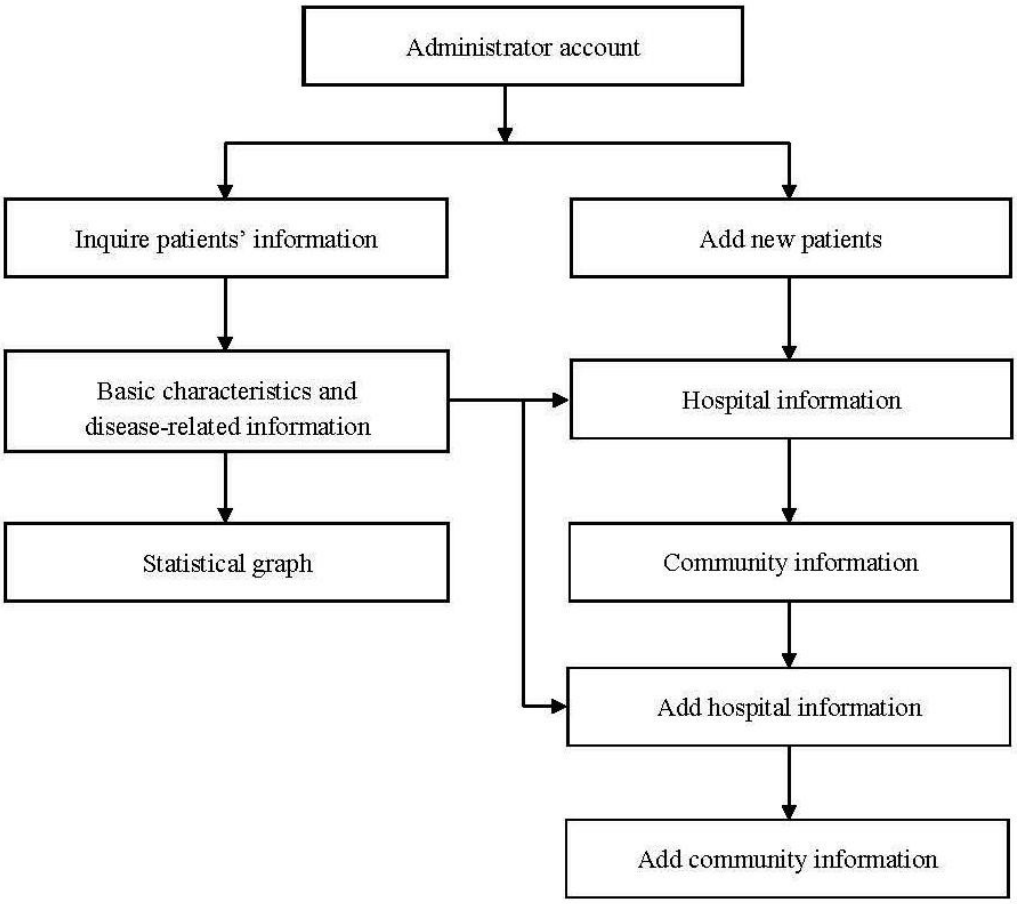


Participants

Approximately 198 patients with COPD were asked to participate in the study from September 2008 to November 2014. A convenience sample of 130 participants agreed to participate and were recruited from two tertiary hospitals in Tianjin, China. The inclusion criteria were as follows: (1) a medically confirmed diagnosis of COPD based on the Chinese Medical Association Diagnostic Criteria, including percentage forced expiratory volume for 1 second (FEV_1%)≤80% and forced expiratory volume for 1 second divided by forced vital capacity (FEV_1/FVC)≤70%; (2) clear consciousness, able to speak Mandarin, and able to communicate; (3) discharged to a home where Internet and computer have been installed; and (4) able to be reached by telephone postdischarge. The exclusion criteria included the presence of comorbidities, such as allergic rhinitis, myocardial infarction, severe heart failure, and malignant tumor; living outside Tianjin; and no access to a computer and Internet at home.

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Figure 3. Administrator log-in process.



The patients who consented to participate were assigned to the intervention or control group using a computer-generated randomized table. Permission to carry out the study was granted by Tianjin Medical University Ethics Committee. The study was conducted in accordance with the Declaration of Helsinki. All participants completed an informed consent form before entering the study.

Data Collection

Patients who were definitively diagnosed with COPD were contacted the day after their admission to hospital. The questionnaires and clinical variables were collected the day before the patient's discharge from the hospital and at 1, 3, 6, and 12 months after discharge.

Measures

Demographics

The demographic variables included gender, age, education, career, history of cigarette smoking, whether it was the first admission, and disease classification.

Lung Function

A portable MicroLoop Spirometer (Jaeger, made in Germany) was used to test lung function. The index included FEV_1%, the percent of forced vital capacity (FVC%), FEV_1/FVC, peak expiratory flow (PEF), and maximal midexpiratory flow ($MMEF_{25\%-75\%}$). These data were measured in the hospital ward using calibrated spirometers and the results were assessed in accordance with American Thoracic Society criteria. Participants were seated comfortably, the device was placed in the mouth, and the nose was blocked by hand to prevent nose ventilation. Then, the patient was instructed to make an explosive, fast, deep breath to generate the maximal expiratory flow volume (MEFV) curve; this was repeated three times [29].

St George's Respiratory Questionnaire

St George's Respiratory Questionnaire (SGRQ) was used as a respiratory disease-specific measurement of health status [30]. The SGRQ is a disease-specific instrument designed to measure the impact of respiratory symptoms on overall health, daily life, and perceived well-being. The instrument has shown good validity and reliability, with Cronbach alpha >.8. The questionnaire is divided into two sections. Section 1 includes frequency and severity of symptoms and section 2 covers activities that cause or are limited by breathlessness and impact social functioning and psychological well-being resulting from airway disease. Responses in the first section are given on a five-point Likert scale and in the second section as dichotomous variables (yes/no). Results are reported in four sections: symptoms, activities limited by breathlessness, psychosocial impact, and overall impact as a basis for the assessment of quality of life. Each section is presented as a weighted score. Scores range from 0 to 100, with higher scores indicating poorer

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health. A change of 4 units or more in the total score represents a clinically relevant change [30].

Modified Medical Research Council Dyspnea Scale

The degree of dyspnea was measured using the Modified Medical Research Council (MMRC) Dyspnea Scale [29]. This is a four-point visual analog scale: 0=dyspnea occurring only in intense activity, 1=dyspnea only when walking in a hurry or on ramp, 2=dyspnea identified by walking more slowly than others or needing pause for breath when moving at normal pace on flat ground, 3=dyspnea identified needing to pause for breath when walking on flat ground for 100 meters or several minutes, and 4=dyspnea identified as unable to leave the house or shortness of breath when dressing.

Six-Minute Walking Test

The 6-minute walking test (6MWT) has demonstrated validity and reliability to assess changes in functional capacity following pulmonary rehabilitation in patients with chronic obstructive lung disease [31]. Referring to the American Thoracic Society application guidelines, the researchers selected a 30-meter level and straight corridor in the ward marked on two sides. Patients started moving at normal speed from the start to the end point and returned, then repeated the process. The total time was 6 minutes. At the end of the 6MWT, the participant was asked to stop and the distance walked was recorded.

Analysis

Data were analyzed using SPSS for Windows version 19.0 software (SPSS Inc, Chicago, IL, USA), with the level of statistical significance set at $P<.05$. We used descriptive statistics to analyze the participants' characteristics. Repeated variant analysis was performed to test the data from the two groups collected predischarge and at 1, 3, 6, and12 months after discharge. Differences between the two groups were evaluated by *t* tests.

Expecting a difference between the groups at follow-up equivalent to an effect size of approximately 0.8, with a power of .80 and alpha at $P=.05$, the number of participants needed in each group was estimated to be 33.

During the intervention, seven of 62 participants (11%) in the study group dropped out (three changed addresses, two had cerebral infarction, one had a fracture, and one declined ongoing participation). Three of 68 participants (4%) in the control group were lost to follow-up (one had a cerebral infarction, one had myocardial infarction, and one declined ongoing participation). Therefore, 120 participants completed the study. The number of participants in the intervention group was 55 and in the control group was 65 (Figure 1).

Participants' Characteristics

The mean age of the 120 participants (47.5%, 58/120 men) was 70.6 (8.0) years. The severity of disease was evaluated as Global Initiative for Chronic Obstructive Lung Disease (GOLD) II (23.3%, 28/120), GOLD III (47.5%, 57/120), GOLD IV (29.2%, 35/120). There were no statistical differences between the intervention and control group in the main sociodemographic characteristics at baseline (Table 1).

Comparison of Lung Function Between the Two Groups

The variation of lung function in the intervention and control groups is described in Table 2.

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Table 1. Comparison of demographics characteristics between two groups

Characteristics	Intervention group (n=55)	Control group (n=65)	χ^2 (df)	*t* (df)	*P*
Gender, n (%)			3.5 (1)		.06
Male	21(38%)	36(55%)			
Female	34(62%)	29(45%)			
Age	69.33 (7.82)	71.85 (8.07)		–1.813 (1)	.07
Education, n (%)			0.5 (4)		.97
Higher education	7(13%)	9(14%)			
High school	8(15%)	8(12%)			
Middle school	22(40%)	24(37%)			
Primary school	17(31%)	22(34%)			
None	1(1%)	2(3%)			
Career, n (%)			8.4 (3)		.08
Worker	29(53%)	47(73%)			
Manager	12(22%)	4(6%)			
Officer	10(19%)	8(12%)			
Farmer	2(3%)	4(6%)			
None	2(3%)	2(3%)			
Smoke, n (%)			2.6(1)		.11
Yes	21(38%)	16(25%)			
No	34(62%)	49(75%)			
First admission, n (%)			1.1 (1)		.30
Yes	28(51%)	27(41%)			
No	27(49%)	38(59%)			
Disease classification, n (%)[a]			1.0 (3)		.23
GOLD II	15(27%)	13(20%)			
GOLD III	27(49%)	30(46%)			
GOLD IV	13(24%)	22(34%)			

[a] GOLD: Global Initiative for Chronic Obstructive Lung Disease; FEV_1/FVC: forced expiratory volume in 1 second/forced vital capacity; GOLD II: FEV_1/FVC <70%, 50% ≤FEV_1<80% predicted; GOLD III: FEV_1/FVC <70%, 30% ≤FEV_1<50% predicted; and GOLD IV: FEV_1/FVC <70%, FEV_1<30% predicted.

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Table 2. Variation tendency of lung function in the two groups.

Index of lung function[a]	$F_{2,4}$	*P*
FEV_1%		
Time	11.235	.30
Group	8.220	.01
Time*group	5.474	.002
FVC%		
Time	6.314	<.001
Group	8.355	.01
Time*group	3.055	.02
FEV_1/FVC		
Time	1.636	.17
Group	0.430	.52
Time*group	1.088	.37
PEF		
Time	8.432	<.001
Group	15.427	<.001
Time*group	6.733	<.001
$MEF_{75\%}$ FVC		
Time	1.393	.24
Group	5.404	.02
Time*group	2.621	.04
$MEF_{50\%}$ FVC		
Time	0.145	.93
Group	3.783	.05
Time*group	2.701	.05
$MEF_{25\%}$ FVC		
Time	5.172	<.001
Group	2.039	.16
Time*group	0.409	.77
MMEF		
Time	3.754	.01
Group	2.944	.09
Time*group	1.241	.29

[a] FEV_1%: The percent of forced expiratory volume in 1 second in prediction; FEV_1/FVC: forced expiratory volume in 1 second / forced vital capacity; FVC%: the percent of forced vital capacity in prediction; $MEF_{25\%}$ FVC, $MEF_{50\%}$ FVC, $MEF_{75\%}$ FVC: midexpiratory flow; MMEF: maximal midexpiratory flow; PEF: peak expiratory flow.

There was a tendency to change in FVC% (*P*<.001), PEF (*P*<.001), $MEF_{25\%}$ FVC (*P*<.001), MMEF (*P*=.01) in a year, and FEV_1% (*P*=.01), FVC% (*P*=.01), PEF (*P*<.001), $MEF_{75\%}$ FVC (*P*=.02) were significantly different in the two groups. The intervention method and time had an interaction effect in FEV_1% (*P*=.002), FVC% (*P*=.02), PEF (*P*<.001), and $MEF_{75\%}$ FVC (*P*=.04). The variation of variables is shown in Table 3.

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Table 3. Comparison of lung function between the two groups before and after intervention with repeated data analysis of variance.

Item and group	Baseline	After intervention (month)				$F_{2,4}$	*P*
		1	3	6	12		
FEV_1%							
Intervention, mean (SD)	0.38 (1.16)	0.41 (0.18)	0.41 (0.18)	0.41 (0.19)	0.42 (0.20)	2.324	.08
Control, mean (SD)	0.33 (0.14)	0.33 (0.16)	0.32 (0.16)	0.31 (0.15)[b]	0.30 (0.15)[a,b,c,d]	4.863	.01
t_1	1.881	1.486	2.811	2.872	3.622		
P	.06	.14	.01	.01	<.001		
FVC%							
Intervention, mean (SD)	0.50 (0.17)	0.55 (0.18)[a]	0.56 (0.18)[a]	0.57 (0.18)[a]	0.56 (0.18)[a]	5.509	.001
Control, mean (SD)	0.47 (0.19)	0.50 (0.16)[a]	0.48 (0.16)	0.47 (0.16)[b]	0.46 (0.14)[d]	3.533	.01
t_1	1.730	1.486	2.934	3.191	3.507		
P	.32	.14	.004	.002	.001		
PEF							
Intervention, mean (SD)	0.32 (0.16)	0.39 (0.19)[a]	0.41 (0.20)[a]	0.43 (0.20)[a,b]	0.41 (0.19)[a]	12.486	<.001
Control, mean (SD)	0.28 (0.13)	0.27 (0.16)	0.29 (0.18)	0.29 (0.17)	0.27 (0.16)	0.686	.56
t_1	1.766	3.680	3.614	4.228	3.680		
P	.08	<.001	<.001	<.001	<.001		
$MEF_{75\%}$ FVC							
Intervention, mean (SD)	0.22 (0.17)	0.23 (0.19)	0.25 (0.21)	0.25 (0.19)	0.25 (0.19)	2.397	.06
Control, mean (SD)	0.17 (0.13)	0.19 (0.17)	0.18 (0.17)	0.17 (0.15)	0.15 (0.12)	0.606	.18
t_1	1.669	1.341	2.103	2.468	3.369		
P	.10	.18	.04	.01	.001		
$MEF_{50\%}$ FVC							
Intervention, mean (SD)	0.18 (0.17)	0.19 (0.15)	0.19 (0.14)	0.19 (0.15)	0.21 (0.16)	1.809	.15
Control, mean (SD)	0.15 (0.15)	0.14 (0.13)	0.15 (0.15)	0.14 (0.13)	0.13 (0.10)	0.932	.42
t_1	0.941	1.737	1.601	1.812	3.230		
P	.35	.08	.11	.07	.002		
$MEF_{25\%}$ FVC							
Intervention, mean (SD)	0.18 (0.15)	0.22 (0.17)[a]	0.23 (0.16)[a]	0.21 (0.15)[a]	0.22 (0.16)[a]	2.861	.04
Control, mean (SD)	0.16 (0.13)	0.18 (0.13)	0.20 (0.18)[a]	0.17 (0.12)[c]	0.17 (0.12)	2.611	.048
t_1	0.865	1.388	0.913	1.418	1.789		
P	.39	.17	.36	.16	.08		
MMEF							
Intervention, mean (SD)	0.18 (0.15)	0.20 (0.16)	0.21 (0.15)[a]	0.20 (0.15)	0.22 (0.15)[a,d]	3.180	.03
Control, mean (SD)	0.15 (0.12)	0.16 (0.14)	0.18 (0.17)	0.16 (0.13)	0.15 (0.12)	1.766	.16
t_1	1.275	1.395	1.187	1.577	2.621		
P	.20	.17	.24	.12	.01		

[a] Significant compared to baseline.

[b] Significant compared to 1 month.

[c] Significant compared to 3 months.

[d] Significant compared to 6 months.

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For FEV_1%, there were no statistically significant differences in the intervention group (*P*=.08). However, there were significant differences in the control group (*P*=.01). From 3 months to 12 months, the intervention group had higher values than the control group (*P*=.01, *P*=.01, and *P*<.001, respectively).

For FVC%, there were statistically significant differences in the intervention group (*P*=.001) and the control group (*P*=.01). From 3 to 12 months, the intervention group had higher values than the control group (*P*=.004, *P*=.002, and *P*=.001, respectively).

There were statistically significant differences in the intervention group (*P*<.001) for PEF and no significant differences in the control group (*P*=.56). From 1 to 12 months, the intervention group had higher values than the control group (*P*<.001).

For maximal midexpiratory flow in $MMEF_{25\%-75\%,}$ there were statistically significant differences in $MEF_{25\%}$ FVC between the intervention (*P*=.04) and control group (*P*=.048), and there were statistically significant differences in the intervention group (*P*=.03) for MMEF.

Comparison of Quality of Life Between the Two Groups Before and After Intervention

The variation of SGRQ between the intervention and control group is described in Table 4.

There was a tendency to change in overall impact (*P*<.001), symptoms (*P*<.001), activities (*P*=.03), and psychosocial impact (*P*=.047) in a year. The intervention method and time showed an interaction effect in each variable. The variation of variables is shown in Table 5.

For overall impact, there were statistically significant differences in the intervention and control groups (*P*<.001). From 1 month to 12 months, the intervention group had higher values than the control group (*P*=.01, *P*<.001, *P*<.001, and *P*<.001, respectively).

There were statistically significant differences in symptoms in the intervention and control groups (*P*<.001). From 3 months to 12 months, the intervention group had lower values than the control group (*P*=.02, *P*<.001, and *P*<.001, respectively).

For activities, there were significant differences in the intervention group (*P*<.001). However, there were no significant differences in the control group. From 1 month to 12 months, the intervention group had lower values than control group (*P*=.002, *P*=.001, *P*<.001, and *P*<.001, respectively).

There were statistically significant differences in impact in the intervention (*P*=.02) and control groups (*P*<.001). From 1 month to 12 months, the intervention group had lower values than the control group (*P*=.03, *P*<.001, *P*<.001, and *P*<.001, respectively).

Table 4. Variation tendency on the St George's Respiratory Questionnaire (SGRQ) in the two groups.

Item and group	Total		Symptom		Activity		Psychosocial impacts	
	$F_{1,4}$	*P*	$F_{1,4}$	*P*	$F_{1,4}$	*P*	$F_{1,4}$	*P*
Time	7.607	<.001	20.859	<.001	2.871	.03	2.477	.047
Group	21.894	<.001	8.781	.004	20.400	<.001	18.413	<.001
Time*group	23.300	<.001	12.384	<.001	8.351	<.001	12.259	<.001

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Table 5. Comparison of quality of life between the two groups before and after intervention.

Item and group	Baseline	After intervention (month)				$F_{1,4}$	P
		1	3	6	12		
Total							
Intervention, mean (SD)	47.20 (18.73)	37.95 (20.89)[a]	35.02 (20.42)[a]	34.45 (19.95)[a]	31.35 (20.53)[a,b]	20.364	<.001
Control, mean (SD)	51.22 (18.53)	47.95 (19.60)	51.03 (21.46)[b]	55.69 (20.90)[a,b,c]	57.92 (21.41)[a,b,c,d]	10.001	<.001
t_1	–1.177	–2.705	–4.163	–5.663	–6.904		
P	.24	.01	<.001	<.001	<.001		
Symptom							
Intervention, mean (SD)	61.87 (19.75)	41.04 (27.30)[a]	38.56 (24.71)[a]	38.84 (23.60)[a]	35.82 (21.32)[a]	16.194	<.001
Control, mean (SD)	57.74 (19.77)	47.95 (19.60)[a]	49.95 (25.85)[a]	54.98 (23.48)[b,c]	58.03 (23.71)[b,c]	5.905	<.001
t_1	1.142	–1.355	–2.454	–3.745	–5.353		
P	.26	.18	.02	<.001	<.001		
Activity							
Intervention, mean (SD)	58.24 (23.16)	51.09 (24.38)[a]	50.13 (24.89)[a]	47.15 (25.43)[a]	43.96 (24.66)[a,b]	7.101	<.001
Control, mean (SD)	65.49 (20.19)	64.58 (21.37)	65.02 (23.27)	68.77 (22.19)	69.00 (22.45)	1.996	.12
t_1	–1.834	–3.231	–3.382	–4.974	–5.818		
P	.07	.002	.001	<.001	<.001		
Impacts							
Intervention, mean (SD)	34.85 (21.01)	29.18 (20.31)[a]	26.00 (20.93)[a]	26.80 (21.04)[a]	22.89 (22.12)[a]	3.279	.02
Control, mean (SD)	40.42 (20.10)	37.48 (20.97)	41.02 (22.43)[b]	44.49 (22.06)[b]	48.48 (22.88)[a,b,c,d]	7.851	<.001
t_1	–1.479	–2.191	–3.767	–4.470	–6.198		
P	.14	.03	<.001	<.001	<.001		

[a] Significant compared to baseline.

[b] Significant compared to 1 month.

[c] Significant compared to 3 months.

[d] Significant compared to 6 months.

Table 6. Variation tendency of the Modified Medical Research Council (MMRC) Dyspnea Scale and 6-Minute Walk Test (6MWT) for the two groups.

Item and group	MMRC		6MWT	
	$F_{1,4}$	P	$F_{1,4}$	P
Time	21.090	<.001	0.394	.09
Group	56.522	<.001	9.631	.004
Time*group	47.940	<.001	35.541	<.001

Comparison of Modified Medical Research Council Dyspnea Scale and Six-Minute Walk Test Between the Two Groups Before and After Intervention

The variation of the MMRC and 6MWT for the intervention and control groups are described in Table 6. There is a tendency to change in MMRC (P<.001) and 6MWT (P<.001) in a year. The intervention method and time had an interaction effect in MMRC. However, there was no significant difference in the intervention time in the 6MWT. The variation of MMRC and 6MWT are shown in Table 7.

For the MMRC, there were statistically significant differences in the intervention (P=.01) and control groups (P=.001). From 1 month to 12 months, the intervention group had lower values than the control group (P<.001).

The 6MWT was only tested at baseline, 6 months, and 12 months when the participants were required to be reexamined in the outpatient service. There were significant differences between the intervention (P<.001) and control groups (P<.001). From 6 months to 12 months, the intervention group had higher values than the control group (P=.002 and P<.001, respectively).

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Table 7. Comparison of the Modified Medical Research Council (MMRC) Dyspnea Scale and 6-Minute Walk Test (6MWT) between the two groups before and after intervention.

Item and group	Baseline	After intervention (month)				$F_{1,4}$	P
		1	3	6	12		
MMRC							
Intervention, mean (SD)	2.27 (1.01)	1.49 (1.05)[a]	1.35 (1.09)[a]	1.22 (0.91)[a,b,c]	1.13 (0.98)[a,b,c,d]	36.306	.01
Control, mean (SD)	2.54 (0.89)	2.63 (0.86)	2.62 (0.90)	12.71 (0.88)	2.86 (0.79)[a,b,c,d]	4.859	.003
t_1	1.537	6.537	6.996	8.626	10.728		
P	.13	<.001	<.001	<.001	<.001		
6MWT[e]							
Intervention, mean (SD)	267.40 (121.09)	—	—	286.63 (125.38)[a]	297.28 (113.22)[d]	12.932	<.001
Control, mean (SD)	224.07 (102.31)	—	—	210.18 (101.20)[a]	198.89 (98.84)[a,d]	37.951	<.001
t_1	1.804			3.133	4.321		
P	.07			.002	<.001		

[a] Significant compared to baseline.

[b] Significant compared to 1 month.

[c] Significant compared to 3 months.

[d] Significant compared to 6 months.

[e] The 6MWT was only tested at baseline, 6 months, and 12 months when the participants were at the hospital because this test must be taken in the hospital.

Discussion

Principal Results

This study examined the effects of a Web-based coaching program using EHRs for patients with COPD. The intervention group had a statistically significant better pulmonary function measured by FVC% and PEF, physical capacity measured by 6MWT, health-related quality of life measured by SGRQ, and lower dyspnea degree measured by MMRC during the 1-year follow-up.

The EHRs are databases that health care providers use to record patient-related information to track care [32,33]. The effects of EHRs have been validated effectively in a pharmacogenetic study and also in a study of asthma exacerbation among school-aged children [34,35]. However, one qualitative study found that participants' low technological issues resulted in low satisfaction with the technology [36]. Because of several factors associated with high or low compliance with Web-based interventions [37,38], we recommend the use of a combination of Internet and non-Internet engagement to enhance follow-up of all participants.

The EHRs have contributed to the health management of people with chronic illness. Provision of patient-centered advice including personal diet and alimentary advice and personal intervention methods based on gender, age, health, environment, employment, and medical service can make a difference. The EHRs in our study were a continuous, comprehensive, individualized, health information database. The system had a large capacity to store content, was low cost, occupied a small amount of computer memory, and enabled a convenient reference point related to COPD. Patients could navigate their own records at any time at home.

This study was consistent with other studies which demonstrated that comprehensive therapy methods, such as medication, oxygen, respiratory exercise, diet, and health education could not change the decline of FEV_1% altogether. However, our program could postpone the decreasing speed of FEV_1%. The FEV_1% of the control group began to decline at the end of 3 months and patient quality of life also declined as identified by SGRQ. The rate of decline in FEV_1% is representative of the natural history of COPD [39]. With the aggravation of airway obstruction, FEV_1% has a declining trend and an irreversible pathological process. Although the decline of FEV_1% could not change, a study by Garcia et al [40] demonstrated that respiratory muscle exercise could increase FVC%, which was a way to judge airway obstruction and had a relationship with trachea resistance and conformance of pulmonary tissue. Our study also showed that the Web-based EHR coaching program was correlated with an increase in FVC%. Our intervention taught patients how to make a complete expiration through a breathing technique that can increase FVC%.

The program improved the quality of life for patients with COPD compared to the control group, whose quality of life declined. The SGRQ, an index predicting quality of life with COPD, was an effective and sensitive score to evaluate quality of life with COPD. This result shows the opposite finding compared to a recent study on the long-term effects of an Internet-mediated pedometer-based walking program in the United States that only reported there were no significant differences between the intervention and control groups [41].

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Therefore, the content in the program made a big impact on patient quality of life. Our study showed that although quality of life in the intervention group improved notably, the intervention could not reverse airway obstruction, only postpone the ingravescence rate of airway obstruction. Although the irreversibility of airway obstruction was closely related with quality of life, the SGRQ is not a good indicator of irreversibility, which is related to the mortality and frequency of acute exacerbation [42,43].

The intervention contributes to a decrease in the degree of dyspnea. This program includes Web-based EHRs containing considerable information regarding prevention, treatment, pulmonary rehabilitation, and disease variation, which could encourage patients to actively engage in healthy behaviors and increase adherence to medication, oxygen therapy, and respiratory exercise. Consequently, this may improve patient endurance by decreasing systematic oxidative stress and decrease the dyspnea level by decreasing oxygen consumption and physiological dead space [44].

In our study, the program was related to an extended 6-minute walking distance, which strengthened endurance and improved quality of life. Physical capacity refers to a person's overall ability to function and "undertake the physically demanding activities of daily living" [45]. Relevant studies have tested that different types of interventions, such as telephone support, a mobile telephone program, computer-based program, or diary-recorded home-walking intervention, could increase physical capacity for patients with COPD compared to standard care [46-49]. However, one study showed that telephone mentoring for home-based walking demonstrated no benefit to the exercise capacity measured by the 6MWT [50]. Therefore, this Web-based coaching program using EHRs gives patients more confidence to control dyspnea and is recommended for use in the hospital, community, and home setting. During the study period, the researchers found that the 6MWT was not an instrument currently used in hospitals in China for patients with COPD and only the participants who were recruited in this study used this measure. We had hoped that respiratory physicians would use this instrument more regularly as a necessary examination that they must consider to assess patients' adaptation to exercise.

Limitations

Our study had several limitations. First, we were not able to evaluate selection bias because we could not differentiate between participants who enrolled versus those who declined participation. Second, many participants were elderly and unable to use EHRs by themselves, needing help from their family members. This condition may have limited the participants' ability to navigate the EHRs when their families were not present. Third, we could not control the frequency of computer use by participants or coaching compliance, which could influence the effect of the intervention. Finally, our study setting was limited to Tianjin and did not include those with mild severity of COPD (GOLD I), limiting the generalizability of our results in all the patients with four disease classifications of COPD in China.

Conclusion

The study established a Web-based coaching program using EHRs, which included Internet and non-Internet as a valuable component of intervention for COPD management in China. The program contributed to improved quality of life for people with COPD through better respiratory function and physical capacity. It also promoted hospital and community nurses sharing patients' medical information, and achieved dynamic management and follow-up analysis.

Acknowledgments

This work was supported to Yaogang Wang by grants from the National Natural Science Foundation of China (71473175; 71673199), the Key Project Scientific of Tianjin Science and Technology Commission of China (15ZCZDSY00500), and Lan Wang by grants from Philosophy and Social Sciences projects of Tianjin in China (Grant No TJSR13-006). The authors would like to express thanks to all the participants who kindly took part in this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V1.6).

[PDF File (Adobe PDF File), 677KB - jmir_v19i7e264_app1.pdf]

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Abbreviations

COPD: chronic obstructive pulmonary disease
EHR: electronic health record
FEV1%: percent of forced expiratory volume in 1 second
FEV1/FVC: forced expiratory volume in 1 second/forced vital capacity
FVC%: percent of forced vital capacity
GOLD: Global Initiative for Chronic Obstructive Lung Disease
MMEF25%-75%: maximal midexpiratory flow
PEF: peak expiratory flow

Edited by G Eysenbach; submitted 06.10.16; peer-reviewed by D Paolotti, I Mircheva; comments to author 15.01.17; revised version received 17.01.17; accepted 29.05.17; published 21.07.17.

Please cite as:
Wang L, He L, Tao Y, Sun L, Zheng H, Zheng Y, Shen Y, Liu S, Zhao Y, Wang Y
Evaluating a Web-Based Coaching Program Using Electronic Health Records for Patients With Chronic Obstructive Pulmonary Disease in China: Randomized Controlled Trial
J Med Internet Res 2017;19(7):e264
URL: http://www.jmir.org/2017/7/e264/
doi:10.2196/jmir.6743
PMID:28733270

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Original Paper

Nurse-Moderated Internet-Based Support for New Mothers: Non-Inferiority, Randomized Controlled Trial

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Abstract

Background: Internet-based interventions moderated by community nurses have the potential to improve support offered to new mothers, many of whom now make extensive use of the Internet to obtain information about infant care. However, evidence from population-based randomized controlled trials is lacking.

Objective: The aim of this study was to test the non-inferiority of outcomes for mothers and infants who received a clinic-based postnatal health check plus nurse-moderated, Internet-based group support when infants were aged 1-7 months as compared with outcomes for those who received standard care consisting of postnatal home-based support provided by a community nurse.

Methods: The design of the study was a pragmatic, preference, non-inferiority randomized control trial. Participants were recruited from mothers contacted for their postnatal health check, which is offered to all mothers in South Australia. Mothers were assigned either (1) on the basis of their preference to clinic+Internet or home-based support groups (n=328), or (2) randomly assigned to clinic+Internet or home-based groups if they declared no strong preference (n=491). The overall response rate was 44.8% (819/1827). The primary outcome was parenting self-competence, as measured by the Parenting Stress Index (PSI) Competence subscale, and the Karitane Parenting Confidence Scale scores. Secondary outcome measures included PSI Isolation, Interpersonal Support Evaluation List–Short Form, Maternal Support Scale, Ages and Stages Questionnaire–Social-Emotional and MacArthur Communicative Development Inventory (MCDI) scores. Assessments were completed offline via self-assessment questionnaires at enrolment (mean child age=4.1 weeks, SD 1.3) and again when infants were aged 9, 15, and 21 months.

Results: Generalized estimating equations adjusting for post-randomization baseline imbalances showed that differences in outcomes between mothers in the clinic+Internet and home-based support groups did not exceed the pre-specified margin of inferiority (0.25 of a SD) on any outcome measure at any follow-up assessment, with the exception of MCDI scores assessing children's language development at 21 months for randomized mothers, and PSI Isolation scores at 9 months for preference mothers.

Conclusion: Maternal and child outcomes from a clinic-based postnatal health check plus nurse-moderated Internet-based support were not inferior to those achieved by a universal home-based postnatal support program. Postnatal maternal and infant support using the Internet is a promising alternative to home-based universal support programs.

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Trial Registration: Australian New Zealand Clinical Trials Registry Number (ANZCTR): ACTRN12613000204741; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=363712&isReview=true (Archived by WebCite at http://www.webcitation.org/6rZeCJ3k1)

(J Med Internet Res 2017;19(7):e258) doi:10.2196/jmir.6839

KEYWORDS

public health informatics; community health services; Internet

Introduction

Universal home-based support for mothers and infants has been a core component of health system outreach since the mid-late 19th century in the United Kingdom, and since the 1930s in European welfare states such as Denmark, Finland, and the Netherlands [1-3]. Postnatal home-based support designed to engage the entire newborn population is used to screen for the presence of maternal and infant problems and to offer support using principles of proportionate universal service delivery—more support for those with greater need [4]. In contemporary Australia, as well as checking maternal and infant health, nurses providing home-based support promote parent knowledge and positive attitudes relevant to child rearing and refer mothers and infants who require additional help to appropriate specialist services, including more intensive nurse home-visiting programs [5,6]. There are clearly advantages to home-based nurse support. It allows nurses to observe the conditions in the home and surrounding area and may feel like a more convenient, natural, and comfortable method of support for mothers. On the other hand, home visits are an expensive way to deliver nurse-led programs to whole populations and involve substantial transport and travel time costs, especially in more geographically dispersed urban and rural environments.

In the past, home-based support provided by community nurses was a key source of information and professional support for mothers of young children. However, the Internet now provides a convenient and private source of health information, the opportunity to exchange information with other mothers, and access to interactive treatment programs designed to address problems such as depression or anxiety [7-10]. Use of the Internet among women of child-bearing age in Australia and many other countries is now ubiquitous [7,11]. This offers health systems new opportunities to better support mothers in an equitable and potentially cost effective manner.

Increasing use of the Internet by mothers to obtain information and support has encouraged the development of numerous Websites and "mobile phone apps" by non-government and commercial organizations [12,13]. However, a concern for professionals and mothers is the variable quality of information provided on Internet websites and their lack of connection with local health services [9,13,14]. For example, it has been reported that health-related information on the Internet can be misleading and occasionally, "utterly wrong" [9,15,16]. In contrast, offering information within the context of professional evidence-based nurse support to mothers via the Internet has the potential to help address concerns about the quality of information and advice provided. Furthermore, if support is offered in a nurse-led group-based format it provides mothers with access to both professional and peer support during the immediate postnatal period. We know of no other interventions that use the Internet as a source of information and social support in combination with professional nurse support.

A recent systematic review of studies between 1998 and 2012 that compared outcomes for postpartum home-based with clinic-based support (without an Internet component) for mothers and infants drew attention to the paucity of studies and inconsistency of results in this area [17]. Conclusions of this review suggested that mothers preferred traditional home-based support to clinic-based care, and those receiving home-based support may persist longer with breastfeeding. Other studies have reported that mothers receiving home-based support have fewer acute care visits, re-hospitalizations and missed well-baby visits than those receiving either no follow-up or telephone follow-up post-delivery [18,19]. However, information in the area is very limited and no previous studies to our knowledge have compared home-based support to clinic-based care combined with Internet-based support provided by community nurses.

In close collaboration with the South Australian Child and Family Health Service (CaFHS), we devised a clinic+Internet intervention that would be achievable by nurses, feasible within current service delivery, and consistent with clinical governance models. As this is the first study of its kind, we utilized a non-inferiority design because of the strong clinical, social, and political support for home-based support programs, and concern that a clinic-based postnatal health check plus Internet-based support may generate inferior outcomes to that achieved by home-based support [20]. Thus, the first research task was to test whether similar outcomes could be achieved with clinic+Internet support versus traditional home-based support. We additionally included a preference trial arm to examine whether there were differences among those who would choose either the home-based or clinic+Internet service. This preference trial arm is essentially an observational study run in parallel with the randomized controlled trial (RCT). The design facilitates greater external validity of results than those based only on participants willing to be randomized, who may differ from those who have a strong preference for one or other of the interventions offered during the consent process.

This study compares maternal and infant outcomes for those who received the new Internet-based intervention versus outcomes for those who received standard postnatal home-based support from a community nurse, routinely offered to all mothers in South Australia (Australian New Zealand Clinical Trials Registry ACTRN12613000204741). We have previously reported intervention mothers' level of engagement with the website [21].

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Methods

Participants, Recruitment, and Randomization

Participants were new mothers referred by their birthing hospital to 1 of 6 CaFHS community clinics in Adelaide, South Australia, for their initial postnatal health check. During March to December, 2013, when CaFHS administrative officers from these clinics telephoned mothers to arrange their health check, they informed mothers about the study and sought verbal consent for the research team to contact mothers. The approach used by administration officers was scripted and the text is available elsewhere [22]. The research team then telephoned consenting mothers to provide further details about the study and to arrange for a research assistant to visit mothers in their home or at another location chosen by the mothers. At that visit a written description of the study was provided to mothers, their written informed consent was obtained, and the pre-intervention assessment was completed.

Full details of the research design are provided in the trial protocol [22]. In brief, the trial utilized a pragmatic, preference, randomized, non-inferiority design in which service preferences were elicited from mothers at the time of their recruitment [20,23]. Mothers were informed that the aim of the study was to test whether the new clinic+Internet support program was helpful to mothers and babies. Those who expressed a "strong preference" for clinic+Internet support or for standard home-based support were allocated to their preferred intervention, whereas those without strong preferences were randomly assigned to one of the two conditions. Randomization was based on the service identification number (odd vs even) serially assigned to all infants when they are referred to CaFHS from their birthing hospital (assignment of this number is done by central administrative CaFHS staff who had no involvement in the recruitment of mothers, delivery of the intervention or the analysis of results for the study).

The inclusion of the preference trial arm and randomized arms enabled us to examine whether outcomes were not inferior amongst both those who would "choose" a particular mode of service delivery (home-based or clinic-based+Internet) and those willing to be randomized in the study. These lower and higher preference populations may be different and analyzing outcomes from all the groups provide valuable information regarding applicability of the intervention in practice as it indicates more closely what the effects would likely be in real world circumstances [23]. The research team was unable to contact 68 of the 1895 eligible mothers identified. Of the 1827 contacted, 819 agreed to participate (response rate=44.8% (819/1827); see Figure 1). This response rate is consistent with that commonly reported for randomized controlled trials, especially those that are attempting to recruit from almost the entire eligible population, as is the case in this study [24]. Mothers were excluded from participation in the study if (1) they did not have access to the Internet, (2) they required an interpreter, or (3) their nurse or clinician recommended that they not participate due to the presence of problems such as infant ill health, domestic violence or substance abuse [22].

Clinic+Internet Support

CaFHS aims to complete postnatal health checks within one month of infant births. Mothers in the clinic+Internet group received their postnatal health check at CaFHS community health clinics before being assigned to an online mothers' group. On average each group was comprised of 12 mothers (range 9-12). Groups were moderated by 1 of 7 qualified CaFHS nurses experienced in facilitating face-to-face mothers' groups, who had completed a 3-day training program on managing Internet-based mothers' groups. Groups took place from the time infants were aged approximately 1 month until they were 7 months old [22].

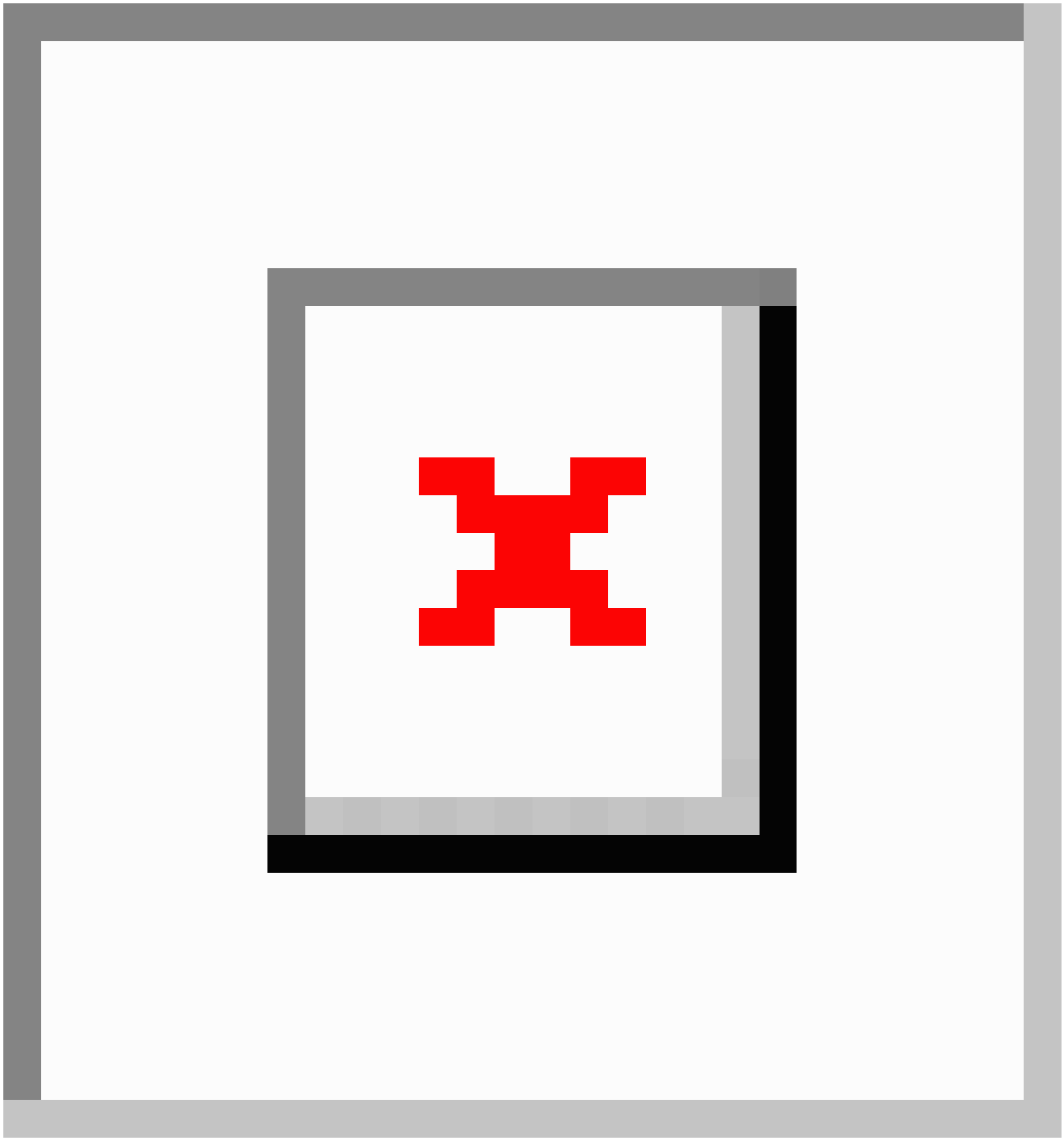
The Internet-based intervention used in the study was developed and implemented by the authors in close collaboration with staff at CaFHS. The aim was to leverage the potential of the Internet to develop a new service model that could provide ongoing professional support to mothers without the need for postnatal home-based help. The website for the intervention was built by independent Web application developers [25] and focus groups were utilized pre-trial to ensure its usability. Intellectual property ownership was based on organizational agreements between the South Australian Department of Health and Ageing and The University of Adelaide and included neither the authors nor the website developers. The affiliations for both organizations were displayed on the login screen.

Mothers could login to the intervention website via computer or mobile device and employed asynchronous text-based communication to exchange information, provide mutual support, and seek help from their nurse facilitator [26]. The "chat" page of the website was designed to be similar to "chat rooms" found on many other websites, including "Facebook," with the important difference that content was moderated and enhanced by an experienced maternal and child health nurse. This format was utilized instead of the threaded discussion trees common in discussion forum websites because it was more likely to be familiar and hence easier for mothers to use.

Information provided about other mothers in each group was initially limited to first names. Additionally, mothers were told that all members of their group had delivered an infant within a few weeks of each other and all had been enrolled in the group when their infants were approximately one month old. This approach of providing only limited information in the first instance is consistent with the approach used in face-to-face mothers' groups and addresses issues of privacy and confidentiality. However, also consistent with face-to-face groups, after the groups commenced nurses encouraged mothers to share additional information about themselves on the chat page, which many mothers did.

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Figure 1. Flow diagram of participants through each stage of the RCT.



During the intervention, nurses followed a curriculum that addressed 11 broad topic areas relevant to mothers and infants (eg, sleeping and settling, breastfeeding, and infant development). However, the chronological order in which the topic material was presented to groups in the chat page was flexible and could be varied depending on the nature of the discussions taking place between mothers. Mothers asked questions about a wide range of issues relevant to maternal and infant health including approaches to address maternal tiredness, settling infants, and breast feeding. Mothers also discussed these issues among themselves and offered encouragement to each other when having difficulties in these areas. About 29.9% (114/381) of mothers took up an option to be notified if there was activity on their group's online chat page. Nurses reviewed all posts twice each week. While doing this they would acknowledge mothers' comments, encourage discussion between mothers, and provide evidence-based information to support parenting skills. They would also correct misinformation and redirect mothers to relevant online resources both within the intervention website and externally. If necessary, nurses could follow-up with individual participants via email, text messaging, telephone calls, or appointments for face-to-face contact. However, this was rarely necessary.

The online groups functioned in a comparable fashion to face-to-face mothers' groups that typically took place weekly in community clinics in South Australia. A key issue for both types of mothers' groups was to ensure that the mothers understood that such interventions are not designed to provide

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urgent or emergency support. Information about sources of help for the latter was provided on the website and also by nurses during online discussions. Mothers could also access additional parenting information and relevant support telephone numbers (eg, parent helplines) through the intervention website (see Multimedia Appendix 1 for screenshots of the website).

The intervention content did not change during the trial and participants had continual access to the website during the 6 month intervention. There were no scheduled downtimes and the server was monitored in case of outages. Mothers reported any technical difficulties to their nurse moderator or to the research team. Nurses reported problems to the research team. Problems were rare and were resolved either by the research team or by the website developers. A feature allowing mothers and nurses to report problems directly to the website developers was deployed to the website approximately 5 months prior to the end of the trial. The intervention website received some minor updates during the trial such as color changes to website features to enhance visibility, and improved website compatibility with older Web-browsers and mobile devices.

Home-Based Support

Mothers in the home-based support group received their postnatal health check in their home. This included a health check for mothers and infants, and provision of booklets and pamphlets about maternal care of infants and relevant community-based resources. Home-based support visits by CaFHS nurses were scheduled to last 60-90 minutes.

Measures

Trained research assistants took written self-assessment questionnaires to mothers in their homes or at another location chosen by the mother. Mothers completed questionnaires when they enrolled in the study, mean age of the child in weeks post randomization being 4.1(SD 1.3) and again when their child was aged 9, 15, and 21 months.

Maternal Outcomes

Outcomes were chosen according to their priority as outcome goals for the standard CaFHS support program for new mothers in South Australia [22]. The primary outcome was parenting self-competence, which was assessed using two different measurements: the Parenting Stress Index (PSI) Competence subscale (excluding two items assessing parental education, 11 items; range 11-55) [27] and the Karitane Parenting Confidence Scale (15 items; range 0-45) [28,29]. We chose two measures to assess self-competence because different measures focus on somewhat different aspects of the construct of parenting self-competence. Inclusion of two measures made it possible to determine the consistency of the results in the study, regardless of the particular measure used. The analysis of results was undertaken independently for each measure.

The secondary outcomes were maternal social support assessed using PSI Isolation subscale (6 items; range 6-30) [27], the Interpersonal Support Evaluation List – Short Form (ISEL-SF; 16 items; range 0-48) [30], and the Maternal Support Scale, adapted from the Diabetes Support Scale [31] (12 items; range 12-84; Cronbach alpha=.92). Additional secondary analyses examining mother-infant attachment, maternal well-being, and spousal support are reported in Multimedia Appendix 2.

Child Outcomes

Children's socioemotional development was assessed at 9, 15, and 21 months using the Ages and Stages Questionnaire–Social-Emotional (ASQ-SE) [32]. The version of the ASQ-SE appropriate for the child's age was administered at each assessment (9 months: 22 items; range 0-220; 15 and 21 months: 26 items; range 0-380). Children's verbal development was assessed at 21 months using the MCDI-SF [33]. This measure included a vocabulary checklist that yields a composite score for each checked word (100 items; range 0-100). Minor adaptations were employed with permission from the authors to replace some uncommon American words with equivalent Australian words (eg, candy was changed to lolly).

All questionnaires except for the MCDI-SF [33] utilized Likert-type response options. Higher scores indicate a higher level of problems on the PSI subscales [27] and the ASQ-SE [32], and a lower level of problems on the other questionnaires.

Demographic information included children's gender, maternal age (in years), education, prenatal employment, housing, and family characteristics (eg, single-parent or two-parent; number of children).

Ethics Approval

Ethics approval was received from the Women's and Children's Health Network Human Research Ethics Committee (REC2368/4/17).

Missing Data

Although 91.9% (753/819) mothers completed the final assessment, 3.1% (25/819) mothers were missing one or two baseline demographic items, and 36.9% (302/819) mothers were missing one or more outcome measures across the four assessments. To reduce potential bias from missing data, we used multiple imputation by chained equations [34]. We generated 20 data sets that were identical for complete data but could differ for imputed values [35,36]. We used the method of chained equations, randomly sampling the imputed values from the posterior predictive distribution of the missing data [37,38]. Datasets were imputed separately for the clinic+Internet and home-based support groups for randomized and preference participants. Due to non-convergence of imputation models, parental living situation was imputed separately to outcomes and was not utilized in statistical analyses. Subsequent analyses utilized imputed data and adjusted coefficients and variance estimates for variability between datasets according to Rubin's rules [39].

Statistical Analysis

All analyses were intent-to-treat. At each assessment point and for each measure, the adjusted mean clinic+Internet group outcome score was compared with the adjusted mean home-based support group outcome score.

The clinic+Internet score on each measure was considered to be "non-inferior" to the home-based support score if the difference between them was less than the score equivalent to

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0.25 of the SD of the overall baseline score for the particular measure. This non-inferiority margin is considered a small effect and was established a priori [22,40]. An example of the inferiority margin calculation is as follows. The overall baseline PSI Competence mean (SD) score among all randomized participants was 22.61 (SD 5.24). The non-inferiority margin for this measure was therefore 0.25 x 5.24 (SD 1.31).

We estimated that a sample size of 200 per randomized group would provide 80% power at alpha=.05 to detect a difference of this magnitude [41]. For outcomes in which higher scores indicate more problems, such as the PSI subscales, the clinic+Internet group was considered to be non-inferior to the home-based support group if the upper 95% CI of the difference between the adjusted group means was less than the non-inferiority margin for that measure [42,43]. Outcomes for which higher scores indicate less problems, such as the Karitane Parenting Confidence Scale, non-inferiority was concluded if the lower 95% CI was greater than the relevant non-inferiority margin [42].

The MCDI-SF was completed on a single occasion and outcome data analyzed using multiple linear regression. For all other measures, adjusted mean outcome scores at each assessment were identified using linear generalized estimating equations (GEE) employing exchangeable within-group correlation structures and the Huber-White sandwich estimator [44]. In the models, predictor variables were group (clinic+Internet vs home-based support), time (baseline, 9, 15, 21 months), group by time interaction, and baseline maternal age, highest level of education, employment status and housing, and child's gender and first child status. Subsequently, a second GEE analysis (with time and group by time interaction variables) was used to identify the size of the difference between adjusted group mean (95% CI) outcome scores at each assessment [42]. All analyses were conducted using Stata 14.1 [34].

Two sensitivity analyses were conducted. The first adjusted for possible clustering according to online group membership by including a dummy variable coding for online-group in the generalized estimating equation used to identify adjusted mean scores (95% CI) for clinic+Internet mothers. The second was a complete case analysis. Results from these sensitivity analyses were very similar to those reported in the manuscript (see Multimedia Appendices 3 and 4).

Results

The demographic characteristics of mothers in each study group are shown in Table 1. Across the four groups, 47.3% (387/819) of mothers were first-time mothers. However, as previously reported, being a first-time versus experienced mother had little impact on mother's level of engagement with the intervention [21].

Information about the use of social media, online forums, and parenting websites was collected from all participants at enrolment and again at the 9 month follow-up assessment. At enrolment, on average across the study groups, 38.8% (312/804) of mothers reported frequently (ie, "most days or many times") using social media to obtain parenting information, 25.7% (210/818) frequently used online forums, and 19.2% (153/795) frequently used parenting websites. At the 9 month follow-up assessment, 42.2% (313/742) of mothers frequently used social media, while only 11.1% (84/760) frequently used online forums and 7.0% (51/733) frequently used parenting websites (see Multimedia Appendix 5 for the frequencies in each study group).

As part of the standard support offered to all mothers in South Australia, during the 6 months following their initial home-based or clinic-based postnatal review, mothers in both study groups could receive additional support from nurses in either or both settings. This additional support could be initiated by nurses or mothers. Table 2 shows that among those randomly assigned to their groups, 1.8% (4/224) of mothers in the clinic+Internet group and 11.4% (28/246) in the home-based support group received 1-2 additional home visits. Also, 37.1% (83/224) of mothers in the clinic+Internet group and 28.5% (70/246) in the home-based support group attended 1-2 additional clinic appointments. In all groups a small percentage of mothers completed more than 4 additional home visits or clinic appointments (Table 2). It is likely that these were mothers or infants who had significant health or psychosocial problems, or had problems in both areas. In general, the patterns of service use were similar for the randomized and preference groups.

The adjusted mean (SE) outcome scores in the clinic+Internet and home-based support groups at each assessment point, the mean (95% CI) difference between these scores, and the non-inferiority cut-off for each measure are shown in Tables 3 and 4. In all groups, all mean outcome scores at baseline were in the "normal range" (Tables 3 and 4).

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Table 1. Participants' baseline demographic characteristics.

Characteristic	Randomized		Preference	
	Clinic+Internet (n=240)	Home-based (n=251)	Clinic+Internet (n=141)	Home-based (n=187)
First child, n (%)	103 (42.9)	116 (46.2)	63 (44.7)	105 (56.1)
Male child, n (%)	125 (52.1)	126 (50.2)	79 (56.0)	90 (48.1)
Two-parent household, n (%)	232 (96.7)	237 (94.4)	137 (97.2)	183 (97.9)
Mother's education[a], n (%)				
University degree	122 (51.0)	123 (49.0)	80 (56.7)	95 (51.0)
Trade or technical school	65 (27.1)	69 (27.6)	N/A[b]	N/A
Some or all years of high school	53 (21.9)	59 (23.4)	N/A	N/A
Mother's employment, n (%)				
Full-time paid employment	136 (56.5)	134 (53.4)	72 (51.1)	108 (57.8)
Part-time paid employment	72 (30.0)	74 (29.5)	55 (39.0)	60 (32.1)
Other	32 (13.5)	43 (17.1)	14 (9.9)	19 (10.2)
Housing, n (%)				
Rental	75 (31.3)	83 (33.1)	53 (37.9)	36 (19.3)
Own home	165 (68.8)	168 (66.9)	88 (62.1)	151 (80.7)
Maternal age, mean (SD)	32.7 (4.7)	32.3 (5.3)	32.5 (5.0)	33.2 (4.5)

[a]Mother's highest completed education. This was a dichotomous variable (completed university vs no university degree) for preference participants as the three category variable failed to converge during multiple imputation. Complete case distributions of all categories are reported in Multimedia Appendix 4.

[b]N/A: not applicable.

Table 2. Proportion of participants receiving additional services during the 6 months following their postnatal review.

Number of services	Randomized		Preference	
	Clinic+Internet (n=224)	Home-based (n=246)	Clinic+Internet (n=121)	Home-based (n=177)
Home, n (%)				
0	214 (95.5)	208 (84.6)	114 (94.2)	153 (86.4)
1-2	4 (1.8)	28 (11.4)	2 (1.7)	17 (9.6)
3-4	0 (0.0)	4 (1.6)	0 (0.0)	2 (1.1)
> 4	6 (2.7)	6 (2.4)	5 (4.1)	5 (2.8)
Clinic, n (%)				
0	105 (46.9)	138 (56.1)	62 (51.2)	102 (57.6)
1-2	83 (37.1)	70 (28.5)	34 (28.1)	40 (22.6)
3-4	23 (10.3)	25 (10.2)	15 (12.4)	17 (9.6)
> 4	13 (5.8)	13 (5.3)	10 (8.3)	18 (10.2)

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Table 3. Randomized participants: adjusted mean (SE), and difference between mean (95% CI) outcome scores. All scores adjusted for child's gender, number of children, maternal education, maternal employment prior to the birth of her baby, housing situation, and maternal age (years) at baseline.

Outcome assessment	Clinic+Internet (n=240)	Home-based (n=251)	Difference (95% CI)	Non-inferiority criterion[a]
Maternal confidence				
Parenting Stress Index – Competence[b]				
Baseline	22.64 (0.04)	22.59 (0.04)	0.05 (−0.07 to 0.17)	
9 months	20.82 (0.04)	20.59 (0.04)	0.23 (0.11 to 0.35)	Upper CI < 1.31
15 months	20.22 (0.04)	20.21 (0.04)	0.01 (−0.11 to 0.13)	Upper CI < 1.31
21 months	20.33 (0.04)	19.86 (0.04)	0.47 (0.35 to 0.59)	Upper CI < 1.31
Karitane Parenting Confidence Scale				
Baseline	40.13 (0.02)	40.08 (0.02)	0.05 (−0.01 to 0.11)	
9 months	41.79 (0.02)	41.83 (0.02)	−0.04 (−0.10 to 0.02)	Lower CI > −1.05
15 months	41.83 (0.02)	41.80 (0.02)	0.02 (−0.04 to 0.08)	Lower CI > −1.05
21 months	42.07 (0.02)	42.22 (0.02)	−0.15 (−0.21 to −0.09)	Lower CI > −1.05
Maternal social support				
Parenting Stress Index – Isolation[b]				
Baseline	11.24 (0.02)	11.13 (0.02)	0.11 (0.05 to 0.17)	
9 months	11.89 (0.02)	11.49 (0.02)	0.39 (0.33 to 0.45)	Upper CI < 0.85
15 months	11.77 (0.02)	11.74 (0.02)	0.03 (−0.04 to 0.09)	Upper CI < 0.85
21 months	11.79 (0.02)	11.77 (0.02)	0.01 (−0.05 to 0.08)	Upper CI < 0.85
Interpersonal Support Evaluation List – Short Form				
Baseline	40.50 (0.07)	40.74 (0.07)	−0.25 (−0.44 to −0.06)	
9 months	38.96 (0.07)	39.43 (0.07)	−0.47 (−0.66 to −0.28)	Lower CI > −1.38
15 months	38.84 (0.07)	38.64 (0.07)	0.20 (0.01 to 0.39)	Lower CI > −1.38
21 months	38.55 (0.07)	39.28 (0.07)	−0.74 (−0.92 to −0.55)	Lower CI > −1.38
Maternal Support Scale				
Baseline	74.98 (0.08)	75.85 (0.09)	−0.88 (−1.11 to −0.64)	
9 months	75.11 (0.08)	76.04 (0.09)	−0.92 (−1.16 to −0.69)	Lower CI > −2.26
15 months	75.61 (0.08)	75.56 (0.09)	0.05 (−0.18 to 0.28)	Lower CI > −2.26
21 months	75.65 (0.08)	76.30 (0.09)	−0.65 (−0.89 to −0.42)	Lower CI > −2.26
Child outcomes				
Ages and Stages Questionnaire – Social-Emotional[b]				
9 months	22.09 (0.20)	21.36 (0.22)	0.73 (0.15 to 1.31)	Upper CI < 3.38
15 months	24.14 (0.20)	23.74 (0.22)	0.40 (−0.18 to 0.98)	Upper CI < 3.91
21 months	23.63 (0.20)	22.36 (0.22)	1.27 (0.69 to 1.85)	Upper CI < 3.98
MacArthur Communication Development Inventories				
21 months	29.69 (0.32)	34.45 (0.33)	−4.76 (−5.67 to −3.85)	Lower CI > −5.30[c]

[a]Non-inferiority is found when the 95% CI of the difference between the means meets the non-inferiority criteria. Non-inferiority is not applicable to baseline scores.

[b]Higher scores indicate more problems.

[c]Failed to achieve non-inferiority.

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Table 4. Preference participants: adjusted mean (SE), and difference between mean (95% CI) outcome scores. All scores adjusted for child's gender, number of children, maternal education, maternal employment prior to the birth of her baby, housing situation, and maternal age (years) at baseline.

Outcome assessment	Clinic+Internet (n=141)	Home-based (n=187)	Difference (95% CI)	Non-inferiority criterion[a]
Maternal confidence				
Parenting Stress Index – Competence[b]				
Baseline	22.55 (0.02)	22.83 (0.02)	−0.28 (−0.35 to −0.21)	
9 months	20.43 (0.02)	20.48 (0.02)	−0.05 (−0.11 to −0.02)	Upper CI < 1.40
15 months	20.57 (0.02)	20.51 (0.02)	0.06 (−0.01 to 0.13)	Upper CI < 1.40
21 months	20.31 (0.02)	20.13 (0.02)	0.18 (0.11 to 0.25)	Upper CI < 1.40
Parenting Stress Index – Isolation				
Baseline	39.97 (0.05)	40.19 (0.03)	−0.21 (−0.32 to −0.10)	
9 months	41.29 (0.05)	41.92 (0.03)	−0.62 (−0.73 to −0.51)	Lower CI > −1.08
15 months	41.63 (0.05)	42.14 (0.03)	−0.51 (−0.62 to −0.40)	Lower CI > −1.08
21 months	41.71 (0.05)	42.35 (0.03)	−0.64 (−0.75 to −0.53)	Lower CI > −1.08
Maternal social support				
Parenting Stress Index – Isolation[b]				
Baseline	11.46 (0.08)	11.12 (0.07)	0.34 (0.14 to 0.54)	
9 months	12.05 (0.08)	11.21 (0.07)	0.83 (0.64 to 1.03)	Upper CI < 0.96[c]
15 months	12.33 (0.08)	11.71 (0.07)	0.62 (0.42 to 0.82)	Upper CI < 0.96
21 months	12.20 (0.08)	11.56 (0.07)	0.65 (0.45 to 0.85)	Upper CI < 0.96
Interpersonal Support Evaluation List – Short Form"				
Baseline	40.41 (0.10)	40.93 (0.09)	−0.52 (−0.78 to −0.25)	
9 months	38.77 (0.10)	39.53 (0.09)	−0.76 (−1.02 to −0.49)	Lower CI > −1.58
15 months	38.29 (0.10)	39.22 (0.09)	−0.94 (−1.20 to −0.67)	Lower CI > −1.58
21 months	38.38 (0.10)	39.23 (0.09)	−0.85 (−1.11 to −0.58)	Lower CI > −1.58
Maternal Support Scale				
Baseline	73.93 (0.13)	77.09 (0.11)	−3.16 (−3.49 to −2.82)	
9 months	74.74 (0.13)	75.72 (0.11)	−0.99 (−1.32 to −0.65)	Lower CI > −2.42
15 months	74.37 (0.13)	76.30 (0.11)	−1.94 (−2.27 to −1.60)	Lower CI > −2.42
21 months	75.11 (0.13)	76.69 (0.11)	−1.58 (−1.92 to −1.25)	Lower CI > −2.42
Child outcomes				
Ages and Stages Questionnaire – Social-Emotional[b]				
9 months	22.25 (0.37)	21.42 (0.27)	0.83 (−0.07 to 1.72)	Upper CI < 3.34
15 months	23.69 (0.37)	22.00 (0.27)	1.69 (0.80-2.58)	Upper CI < 3.87
21 months	24.72 (0.37)	22.08 (0.27)	2.64 (1.75-3.54)	Upper CI < 4.21
MacArthur Communication Development Inventories				
21 months	32.38 (0.74)	33.33 (0.62)	−0.95 (−2.84 to 0.94)	Lower CI > −5.61

[a]Non-inferiority is found when the 95% CI of the difference between the means meets the non-inferiority criteria. Non-inferiority is not applicable to baseline scores.

[b]Higher scores indicate more problems.

[c]Failed to achieve non-inferiority.

As noted earlier, for each measure we compared the size of the difference between the mean clinic+Internet and home-based support group scores with the a priori non-inferiority cut-off score identified for the particular measure. For example, Table 3 shows the difference between the PSI Competence scores at 9 months was 0.23 (95% CI=0.11-0.35). Since the upper CI for

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this difference is less than this measure's non-inferiority cut-off score of 1.31, the outcome for the clinic+Internet group was considered to be non-inferior to that of the home-based support group at this assessment.

For randomly assigned participants, at each follow-up assessment, all maternal outcome scores and all ASQ-SE scores in the clinic+Internet group were non-inferior to the corresponding scores in the home-based support group (Table 3). However, the difference between the MCDI-SF adjusted mean scores was −4.79 (95% CI=−5.66 to −3.92) with the lower 95% CI extending beyond the non-inferiority cut-off of −5.30.

Results for mothers in the preference groups were similar to those for randomly assigned mothers with two exceptions (Table 4). First, in the preference groups the adjusted mean MCDI-SF score in the clinic+Internet group was not inferior to the score in the home-based support group. Secondly, the adjusted mean PSI Isolation score in the clinic+Internet group, for which higher scores indicate more problems, was inferior to the home-based support group mean score at 9 months (adjusted mean difference = 0.80; upper 95% CI=0.99, exceeding the non-inferiority cut-off of 0.96). However, the clinic+Internet group score on this measure was not inferior to the home-based support score at 15 and 21 months (Table 4).

Discussion

Principal Findings

When infants were aged 9, 15, and 21 months, outcomes for mothers and infants who received a clinic-based health check+Internet support were generally not inferior to those who received home-based support. The primary outcome of parenting self-competence was not inferior on scores for both the PSI Competence scale and the Karitane Parenting Confidence Scale. There were two exceptions to the general pattern of non-inferiority. First, children of mothers randomly assigned to receive clinic+Internet support, but not those assigned on the basis of their preference, had inferior MCDI scores assessing their verbal development at 21 months. However, the difference was not inferior for randomized and preference groups in the complete case analyses (see Multimedia Appendix 4). Second, for mothers assigned to the clinic+Internet group on the basis of their preference, but not those randomly assigned, PSI Isolation scores assessing maternal social isolation were inferior at 9 months. At all other time points, non-inferiority was met for all outcomes in both randomized and preference groups.

The results suggest that clinic-based support combined with a nurse-moderated Internet-based group intervention delivered when infants are aged 1-7 months can achieve comparable outcomes for mothers and infants to those achieved by universal home-based support. This is important because Internet delivery has the potential to allow nurses to provide ongoing support services without the need to travel to mothers' homes, reduce costs of 'no-show' visits, and allow one nurse to work with more families during a single day. For mothers, Internet delivery enables access to reliable, evidence-based "just-in-time" information and nursing support without the need to attend fixed-time appointments in clinics that may be geographically distant from their homes. With regards to engagement in the present study, randomized mothers logged into the website a median of 9 times (IQR=1–25) during the first 6 weeks of the intervention, and a median of 10 times (IQR=0–39) during the remaining 19 weeks. The median time to mothers' last login was 4.9 months [21].

Qualitative feedback provided by mothers at follow-up assessments showed that the intervention components most valued by mothers were access to helpful advice and information when needed, contact with their nurse moderator, and support from other new mothers with similar experiences. It was notable that mothers accepted and valued the regular presence of an experienced nurse in the forum. This was evident in mothers' comments when advice was offered from one mother to another and they reflected on whether their nurse would agree with the advice being offered, much as occurs in discussion between mothers in face-to-face groups moderated by nurses. Importantly, it did not appear that the presence of a nurse moderator inhibited mothers in their discussions with each other but rather provided reassurance that advice being shared was consistent with what would be suggested by a professional in the area. In this context, 'misinformation' tended to be one of emphasizing one approach over another or a recommended style of handling a problem rather than being grossly incorrect advice.

The clinic+Internet program has the potential to improve and maintain population reach, help ensure quality control of the information provided, and facilitate access to support services during an infant's first year. In contrast to home-based support with its focus on helping individual mothers in their homes, group-based online support programs also have the potential to provide ready access for new mothers to nurse-moderated peer support.

Delivering nurse support to mothers and infants via the Internet has three other potential benefits. First, it provides the opportunity for nurses to readily track mothers' level of engagement with different components of a support program. Second, by using simple quizzes and other feedback from mothers, nurses can gauge mothers' ongoing knowledge acquisition. This could enable nurses to more accurately target services to mothers and infants most in need of support. Third, the provision of easily accessible information about developmental milestones and early childhood health problems has the potential to facilitate mothers' early recognition of their child's developmental or health problems. In the past, developmental screening was undertaken in health services or community clinics at fixed intervals according to the age of infants and children. However, current evidence in child health and development emphasizes the importance of replacing fixed age reviews with a more continuous approach sensitive to developmental variability of children, and combining this with increased awareness of developmental issues at a population level [45]. This poses an enormous challenge for current methods of universal service provision.

Strengths and Limitations

One of the main strengths of the study was its pragmatic nature. The entire RCT was conducted within a routine service setting using existing administrative infrastructure to allocate

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participants and deliver the intervention as part of normal service delivery. Other strengths include the "preference" design which showed the results were similar for mothers randomly assigned to their study groups and those assigned on the basis of their preference. This similarity increases the likelihood that results would apply generally to mothers utilizing a similar nurse-moderated Internet-based group intervention during the post-natal period [23]. Potential limitations include evidence that participating mothers were from a somewhat more socially advantaged group. However, the Australian Bureau of Statistics shows that 42.0% of Australian women aged 25-34 have university qualifications compared with 51.4% (421/819) of participants in this study, suggesting that participating mothers may not be greatly more advantaged than the general female population [46]. Finally, a cost-effective analysis lies outside the scope of this manuscript but will be reported in the future.

Conclusion

Results from the study suggest that clinic-based support combined with a nurse-moderated Internet-based group intervention delivered to new mothers can achieve comparable outcomes to those achieved by universal home-based support. Improving early childhood outcomes has been recognized as a policy priority internationally [47,48]. Achieving this requires cost-effective interventions with wide population reach, which can enhance early childhood health and well-being at a population level. In many countries, including Australia, population-level maternal and infant services are provided via relatively expensive home-based nurse support programs. However, it is possible that for many carers, population-wide services could be just as effectively provided by clinic-based nurses supported by Internet-based programs, especially among lower risk groups who may comprise up to 70% of the population [49]. This could assist the better targeting of home-based programs toward carers and infants who need this more intensive level of support.

Acknowledgments

This research is supported by a National Health and Medical Research Council – Partnership Project (1016281) and South Australia Department of Health and Aging. John Lynch was supported by an Australia Fellowship from the National Health and Medical Research Council of Australia (570120). Alyssa Sawyer and Murthy Mittinty were supported by funds from the Australia Fellowship awarded to John Lynch. These researchers are independent of the funding bodies. The other authors have no financial relationships relevant to this article. The funders did not play a role in the design and conduct of the study; collection management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

Authors' Contributions

MGS and JWL conceptualized and designed the study, analyzed and interpreted results from the study, and drafted and revised the manuscript. CER, ACPS, and MM helped analyze and interpret results from the study, draft and revise the manuscript. KB, and DJ helped conceptualize and design the study, draft and revise the manuscript. All authors approved the final manuscript as submitted.

Conflicts of Interest

Kerrie Bowering was the Director of Child and Family Health Services (CaFHS) until February 2016 and Debra Jeffs is the Nursing Director of CaFHS. The intervention website was built by independent Web application developers Portal Australia [25]. Intellectual property ownership was based on organizational agreements between the South Australian Department of Health and Ageing and The University of Adelaide and did not include the authors or the website developers.

Multimedia Appendix 1

Screenshots of the intervention website.

[PDF File (Adobe PDF File), 1MB - jmir_v19i7e258_app1.pdf]

Multimedia Appendix 2

Analyses of additional secondary outcomes (mother-infant attachment, maternal well-being, and spousal support).

[PDF File (Adobe PDF File), 38KB - jmir_v19i7e258_app2.pdf]

Multimedia Appendix 3

Analyses of maternal confidence and social support, and of the child outcomes, adjusting for possible online-group clustering in the clinic+Internet group.

[PDF File (Adobe PDF File), 122KB - jmir_v19i7e258_app3.pdf]

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Multimedia Appendix 4

Complete case analyses of maternal confidence and social support, and of the child outcomes.

[PDF File (Adobe PDF File), 203KB - jmir_v19i7e258_app4.pdf]

Multimedia Appendix 5

Mothers' use of online resources for parenting information.

[PDF File (Adobe PDF File), 71KB - jmir_v19i7e258_app5.pdf]

Multimedia Appendix 6

CONSORT-eHEALTH V1.6.

[PDF File (Adobe PDF File), 1MB - jmir_v19i7e258_app6.pdf]

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Abbreviations

ASQ-SE: Ages and Stages Questionnaire–Social-Emotional
CaFHS: Child and Family Health Service
MCDI: MacArthur Communicative Development Inventories
N/A: not applicable
PSI: Parenting Stress Index
ISEL-SF: Interpersonal Support Evaluation List–Short Form

Edited by G Eysenbach; submitted 19.10.16; peer-reviewed by J Cole, N Yonemoto; comments to author 21.01.17; revised version received 23.02.17; accepted 02.06.17; published 24.07.17.

Please cite as:
Sawyer MG, Reece CE, Bowering K, Jeffs D, Sawyer ACP, Mittinty M, Lynch JW
Nurse-Moderated Internet-Based Support for New Mothers: Non-Inferiority, Randomized Controlled Trial
J Med Internet Res 2017;19(7):e258
URL: http://www.jmir.org/2017/7/e258/
doi:10.2196/jmir.6839
PMID:28739559

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Original Paper

Improving Employee Well-Being and Effectiveness: Systematic Review and Meta-Analysis of Web-Based Psychological Interventions Delivered in the Workplace

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Abstract

Background: Stress, depression, and anxiety among working populations can result in reduced work performance and increased absenteeism. Although there is evidence that these common mental health problems are preventable and treatable in the workplace, uptake of psychological treatments among the working population is low. One way to address this may be the delivery of occupational digital mental health interventions. While there is convincing evidence for delivering digital psychological interventions within a health and community context, there is no systematic review or meta-analysis of these interventions in an occupational setting.

Objective: The aim of this study was to identify the effectiveness of occupational digital mental health interventions in enhancing employee psychological well-being and increasing work effectiveness and to identify intervention features associated with the highest rates of engagement and adherence.

Methods: A systematic review of the literature was conducted using Cochrane guidelines. Papers published from January 2000 to May 2016 were searched in the PsychINFO, MEDLINE, PubMed, Science Direct, and the Cochrane databases, as well as the databases of the researchers and relevant websites. Unpublished data was sought using the Conference Proceedings Citation Index and the Clinical Trials and International Standard Randomized Controlled Trial Number (ISRCTN) research registers. A meta-analysis was conducted by applying a random-effects model to assess the pooled effect size for psychological well-being and the work effectiveness outcomes. A positive deviance approach was used to identify those intervention features associated with the highest rates of engagement and adherence.

Results: In total, 21 randomized controlled trials (RCTs) met the search criteria. Occupational digital mental health interventions had a statistically significant effect post intervention on both psychological well-being (g=0.37, 95% CI 0.23-0.50) and work effectiveness (g=0.25, 95% CI 0.09-0.41) compared with the control condition. No statistically significant differences were found on either outcome between studies using cognitive behavioral therapy (CBT) approaches (as defined by the authors) compared with other psychological approaches, offering guidance compared with self-guidance, or recruiting from a targeted workplace population compared with a universal workplace population. In-depth analysis of the interventions identified by the positive deviance approach suggests that interventions that offer guidance are delivered over a shorter time frame (6 to 7 weeks), utilize secondary modalities for delivering the interventions and engaging users (ie, emails and text messages [short message service, SMS]), and use elements of persuasive technology (ie, self-monitoring and tailoring), which may achieve greater engagement and adherence.

Conclusions: This review provides evidence that occupational digital mental health interventions can improve workers' psychological well-being and increase work effectiveness. It identifies intervention characteristics that may increase engagement. Recommendations are made for future research, practice, and intervention development.

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(J Med Internet Res 2017;19(7):e271) doi:10.2196/jmir.7583

KEYWORDS

adherence; engagement; Internet; meta-analysis; psychological interventions; stress; systematic review; wellbeing; workplace

Introduction

Background

Nearly one in three workers in Europe [1] and the United States [2] report that they are affected by stress at work. Work-related stress, depression, and anxiety can result in reduced work performance and absenteeism [3-7], costing an estimated 3% to 4% of gross national product [1]. There is evidence that these conditions are both preventable and treatable in the workplace [8-9] and that workers who receive treatment are more likely to be highly productive [10,11].

The workplace has been identified as a potentially ideal site for delivering mental health prevention programs [12] and increasing access to appropriate treatment [7], resulting in a benefit to both employees and employers [11]. However, uptake of psychological treatments among the working population is low [10], with one study reporting that only 15% of workers with a mental health problem had sought help in the preceding month [13], resulting in many depressed workers going untreated or being inadequately treated [11]. Help seeking among the working population has been reported at between 43% [10] and 15% [13]. People are increasingly turning to the Internet for health care information [14], prevention, and treatment [15]. Although there is convincing empirical evidence for the effectiveness of evidence-based digital psychological interventions delivered within a health and community context, the evidence for digital interventions delivered in a workplace setting is less clear [16].

Several meta-analyses and systematic reviews have found evidence for the effectiveness of digital psychological interventions delivered in nonworkplace settings for common mental health problems including depression, anxiety [17-23], and stress in adults [24], but these reviews do not focus on the delivery of these interventions to working adults or in the workplace. We suggest that the delivery of occupational health interventions is different to the delivery of interventions in health or community settings and that the context of the workplace is likely to impact on the way that these interventions are delivered and received, and is therefore, likely to impact on their effectiveness. To our knowledge no previous systematic review has specifically reported on digital interventions for stress and mental health in the workplace.

This systematic review and meta-analysis seeks to address this gap in the literature by identifying studies that deliver digital occupational mental health interventions and evaluating their effectiveness at increasing employee psychological well-being (by targeting a reduction in stress, depression, and psychological distress) and work effectiveness.

Engagement and adherence are two of the major challenges to delivering and evaluating Web-based interventions [25-27]. Boosting engagement and adherence with Web-based interventions increases the extent to which users are exposed to the content and may be an important determinant of effectiveness [28] and a consistent predictor of positive outcomes [29-31].

This review uses a positive deviance approach (eg, [32,33]) to identify the intervention features that are associated with the highest levels of intervention engagement and adherence in the workplace context.

Aims of This Review

The aims of this systematic review and meta-analysis are to evaluate the overall effectiveness of occupational digital mental health interventions for employee psychological well-being and work effectiveness and to identify, through the partial implementation of positive deviance methodology, which intervention features influence engagement and adherence. To this end, the review will address the following three questions:

1. Are occupational digital mental health interventions associated with lower levels of stress and mental health symptoms post intervention than control groups?
2. Are occupational digital mental health interventions associated with increased work effectiveness post intervention?
3. Which intervention features are associated with the highest levels of engagement and adherence?

Methods

Search Strategy

This review was conducted following the Cochrane guidance for systematic reviews [34]. We searched PsychINFO, MEDLINE, PubMed, Science Direct, and the Cochrane database of systematic reviews for relevant studies published from January 2000 to May 2016. The key terms used for these searches are displayed in Table 1. To increase coverage, we searched the databases of the researchers, relevant websites (eg, the Health and Safety Executive, the Faculty of Occupational Medicine, and the National Institute for Heath and Care Excellence), reference lists of included studies, and relevant journals. Unpublished data was sought using the Conference Proceedings Citation Index and the Clinical Trials and ISRCTN research registers. Three potentially relevant trials were identified through the research registers, and the researchers were contacted. However, no additional data from these unpublished studies became available.

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Table 1. Search terms.

(stress OR	AND (intervention OR	AND (online OR	AND (Workplace OR
resilien*	"stress management"	Internet	"work place"
"mental health"	"stress inoculation training"	web-based	"occupational health"
depress*	resilience	app	worker*
anxiety	"problem solving"	computer)	employee*
"mental illness"	self-help		business*
burnout	CBT		staff
"psychological ill health"	"cognitive behav* therapy")		work
"mental disorder"			"work related"
"mood disorder")			job*)

Inclusion and Exclusion Criteria

To meet the aims of this review, a study had to meet the following criteria: (1) use a randomized controlled design; (2) utilize a nontreatment, treatment as usual, or active control; (3) aimed at employed participants aged 18 years or over; (4) comprise a psychological intervention aimed at increasing psychological well-being (eg, by reducing symptoms of stress or depression) or work effectiveness (eg, by increasing engagement or productivity); (5) be delivered via the Internet, mobile technology, or a computer program; (6) written in English; and (7) offer sufficient post intervention data (sample sizes, means, and standard deviations [SDs] for both the control and the treatment condition) in the paper or by contacting the authors to calculate the effect size for either a well-being or a work effectiveness outcome.

Studies were excluded if they exclusively targeted people on extended sick leave or were targeting populations with complex mental health problems including post-traumatic stress disorder (PTSD), schizophrenia, or comorbid substance misuse. Studies were also excluded if technology was used purely as a medium for communication (eg, Skype, videoconference, e-counseling): the active element of the intervention had to be delivered on the Web or via mobile technology. Studies were also excluded if homework was completed on the Web but the intervention was delivered in person.

Data Extraction

The data was coded at four levels: study, intervention, participants, and outcomes. Further information about coding categories is available from the study registration (the protocol for this systematic review and meta-analysis was registered with the International Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42016033935).

Data Analysis

The number of participants and the between group, post intervention means, and SD for the control and the experimental group on selected psychological measures (measures prioritized in the order: stress, depression, and psychological distress) and selected work effectiveness measures (prioritized in the order: work engagement, productivity or job specific effectiveness, work related self-efficacy, and work related rumination) were entered into Review Manager (RevMan) version 5.3 and SPSS version 22 (IBM Corp). Where more than one measure was available, the measures were prioritized in the order given above. Forest plots of the between group, post intervention effect size (Hedges *g*) for both outcome variables (psychological well-being and work effectiveness) were produced using RevMan. The magnitude of effect size was interpreted using the classification given by Cohen (small=0.2, medium=0.5, and large=0.8) [35].

To test for the presence of heterogeneity of effect size, we used the chi-square (χ^2) and the heterogeneity (I^2) statistics. A large χ^2 relative to its degree of freedom and a low *P* value provides evidence of heterogeneity [34]. An I^2 value of 25% suggests that heterogeneity is low, 50% suggests medium, and 75% suggests high [36]. Since we expected considerable heterogeneity, a random effects model was performed [37]. Heterogeneity was explored using subgroup analyses. Possible moderating factors included (1) therapeutic approach (cognitive behavioral therapy [CBT] vs other), (2) guidance (guided vs nonguided), and (3) population (targeted vs universal). Interventions were coded as using CBT if the authors of the studies described the therapeutic approach as cognitive or cognitive behavior and as guided if guidance from a person was described. We coded the population as targeted if the inclusion criteria included elevated levels of stress, depression, or insomnia. Publication bias was tested using funnel plots for both outcome measures.

Risk of Bias Assessment

An assessment of the methodological quality of the studies included in this review was conducted using the Cochrane Collaboration's risk of bias tool [34]. The tool assesses possible sources of bias using seven main categories: (1) random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias. Twenty-five percent of studies were assessed by the first and second author independently, with a high rate of agreement; differences were discussed and resolved. The first author completed all subsequent bias assessments. Publication bias was assessed by appraising funnel plots for asymmetry.

Positive Deviance

A partial implementation of the positive deviance approach was used to identify intervention features associated with the highest levels of engagement and adherence. Positive deviance is as an

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assets-based approach used to identify sustainable solutions to difficult problems by identifying "uncommon, beneficial practices" [33]. Bradley et al [32] describe four steps to using the positive deviance approach: (1) identify "positive deviants," that is, organizations that consistently demonstrate exceptionally high performance in the area of interest, (2) study the organizations in depth to generate hypotheses about practices that enable organizations to achieve high performance, (3) test hypotheses with other organizations, and (4) work with other organizations to disseminate the evidence about high performance. In this study, the first two steps were adapted and applied to study interventions showing the highest levels of engagement (cf. [38]). To assess engagement, we ranked the 21 studies in this review in percentile order in terms of intervention completion and intervention group study attrition. Completion of the intervention and intervention group study attrition were seen as the most relevant and widely report measures of intervention engagement and adherence. Studies at the 70th percentile and above were selected and their interventions were reviewed in depth to generate hypotheses about intervention features that may enable high levels of engagement (hypotheses generation). This is a modification from our protocol.

Results

Search Results

The initial search resulted in 1129 citations after duplicates had been removed. These citations were screened using the exclusion and inclusion criteria and 1076 excluded. Full papers were retrieved and examined for eligibility for the remaining 53 studies. We included 21 studies in the review: 21 in the qualitative synthesis, 21 in the psychological well-being meta-analysis, and 13 of the 21 in the work effectiveness meta-analysis. See Figure 1 for the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart of study selection. One study [39] did not exclude unemployed participants, but the aim of the study was to assess effectiveness of cognitive behavioral treatment for work related stress; 80% of the participants were in full time work and a number were unemployed because of work-related stress or were experiencing stress in unpaid jobs. For these reasons we included the study in the review. A sensitivity analysis indicated no difference in our overall results if this study was excluded. A second study [40] examined the effects on job stress of Web-based career identity training on Japanese hospital nurses. This study was excluded from the review as it was felt that the intervention was closer to a career counseling intervention than a psychological intervention.

Designs of the Included Studies

The 21 RCTs included in this review compared a Web-based psychological intervention delivered in the workplace with a wait list control (WLC) (71%, 15/21), an active control (19%, 4/21), or care as usual (9%, 2/21). Additionally, 17 (81%, 17/21) of the studies completed an intention-to-treat analysis, and 4 (19%, 4/21) completed a per-protocol analysis. Multimedia Appendix 1 describes the selected characteristics for the 21 identified studies.

Risk of Bias

Figure 2 shows an estimation of the risk of bias across all studies. Of the 21 studies included in this review, only 8 (38%) were able to fulfill 5 or more low risk of bias ratings across the seven categories used. Only 2 of the studies (9%, 2/21) were able to blind both participants and personnel to the condition allocation (performance bias), and only 6 (29%, 6/21) demonstrated low reporting bias by preregistering or making their study protocol available and by reporting all the primary outcomes. Less than half of all ratings (45.6%, 67/147) were unclear or high risk.

Publication Bias

Funnel plots for the effect sizes for the psychological wellbeing outcome and the work effectiveness outcome are shown in Figures 3 and 4, respectively. There is no indication of problematic clustering in these plots, which are fairly evenly distributed around the mean effect size, suggesting little evidence of publication bias.

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Figure 1. Flow diagram of study selection.

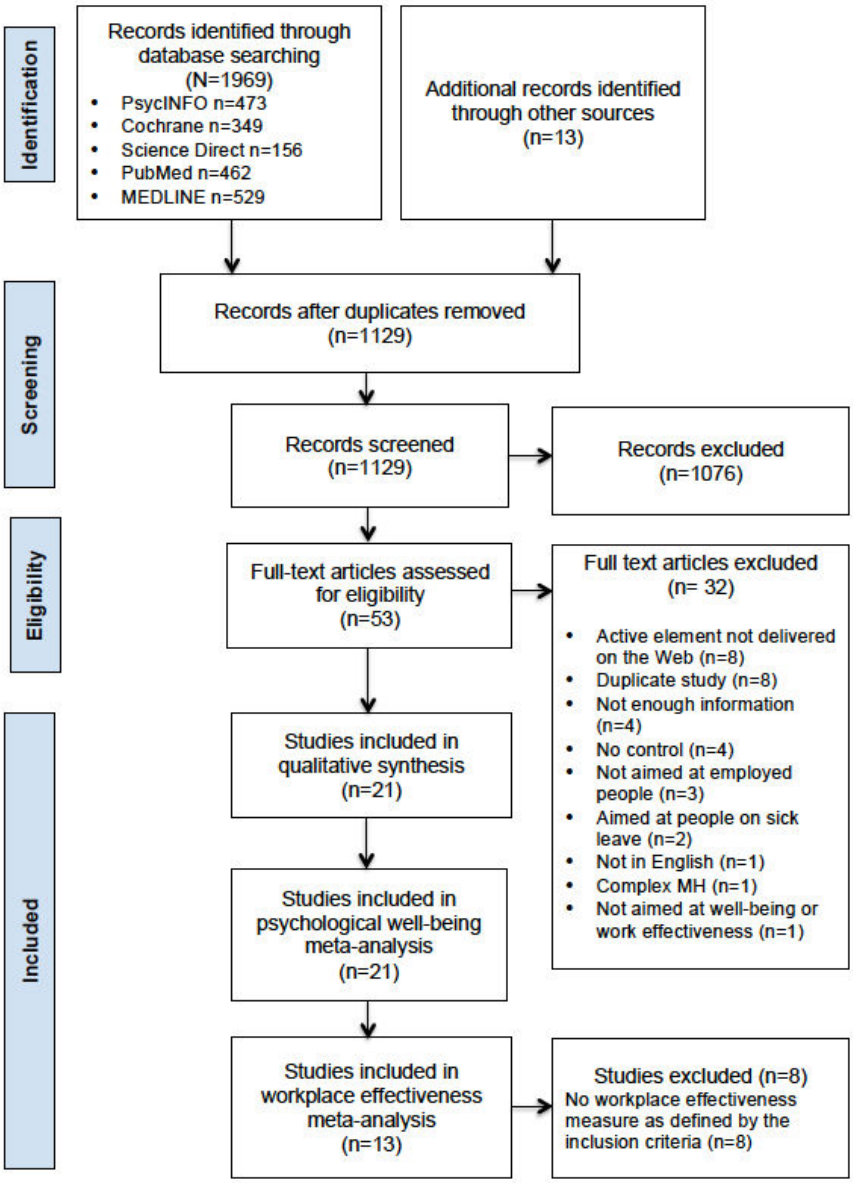
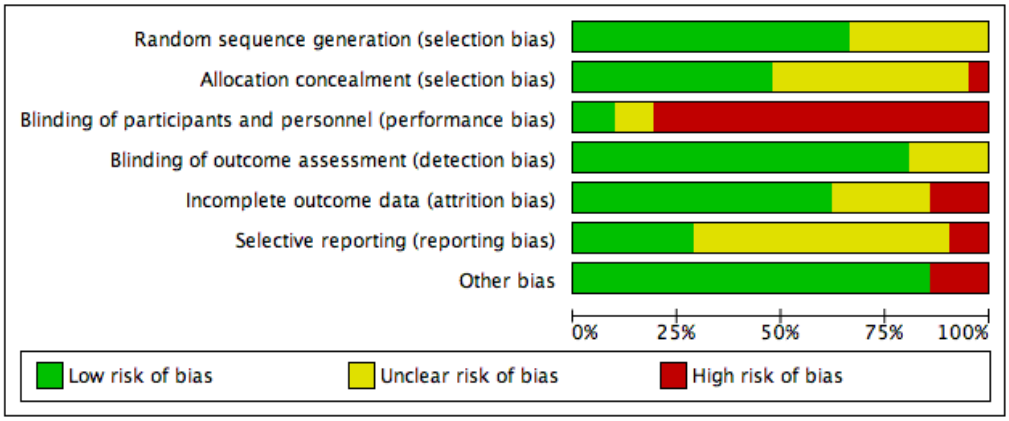


Figure 2. Estimated risk of bias across all studies.



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Figure 3. Funnel plot of post intervention effect sizes by standard error for the psychological wellbeing outcome.

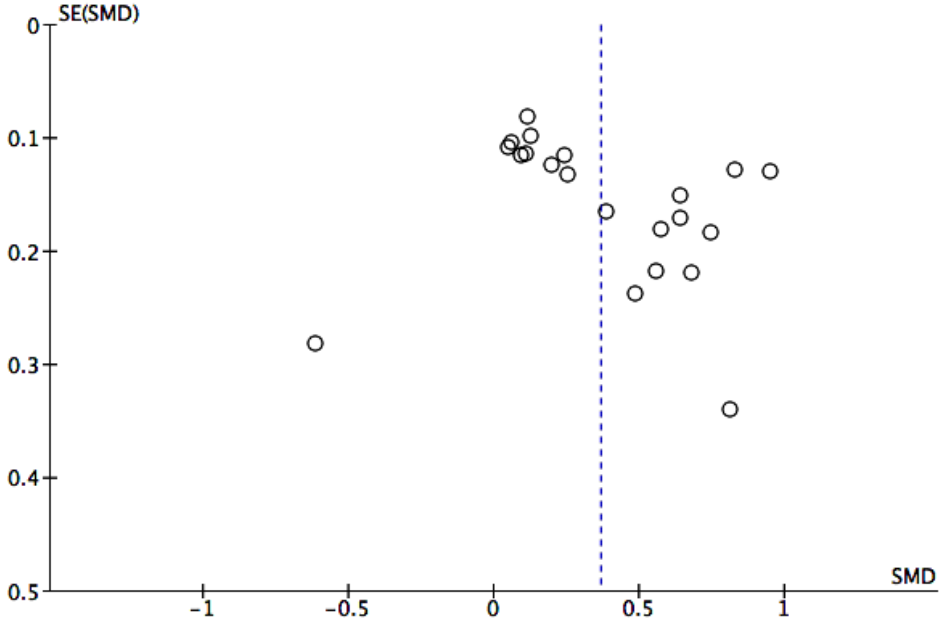
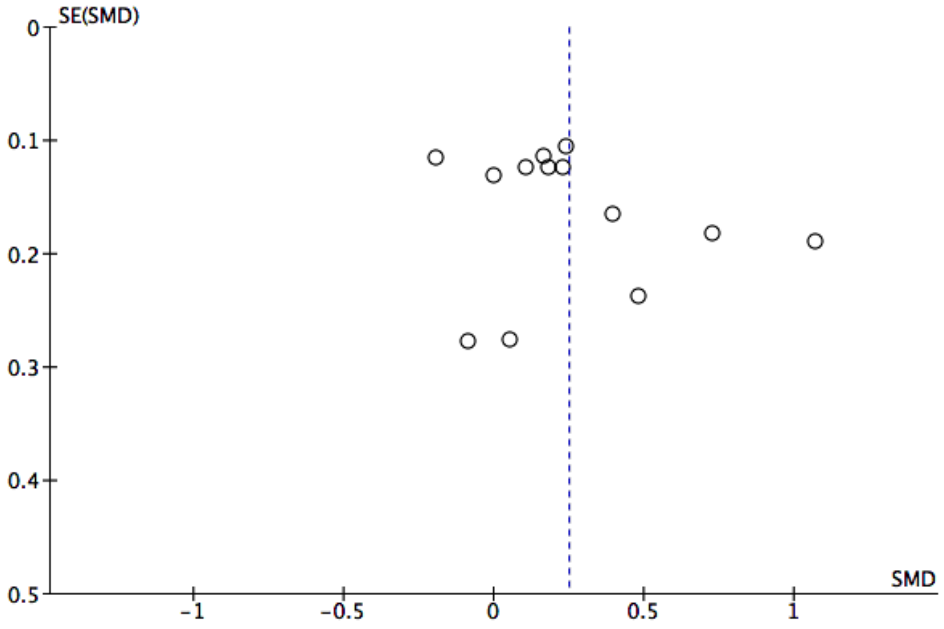


Figure 4. Funnel plot of post intervention effect sizes by standard error for the work effectiveness outcome.



Sample and Study Characteristics

The 21 studies included in this review originated from 7 countries: 6 from the United States [41-46], 6 from Germany [47-52], 3 from the Netherlands [39,53,54], two each from the United Kingdom [55,56] and Japan [57,58], and one each from Australia [59] and Sweden [60]. Four of the studies recruited from the general working population [39,41,47,48], whereas the other studies recruited from organizations working in education [49-51], health, or local authorities [53,55,56]; a call center [42]; manufacturing [57]; technology [43,58]; sales [59]; chemicals [44]; human resource (HR) [45]; insurance [52]; and transport and communication [56]. One study recruited from organizations working in banking, research, education, and

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security [54]; 1 study recruited middle managers from medium and large companies [60], and another recruited employed care-givers of people with dementia [46].

The sample size in the studies ranged from 48 to 762. Overall, the studies recruited and randomized 5260 participants: 2711 to a psychological intervention delivered predominantly on the Web and 2549 to a control condition. The data for 2438 participants was analyzed in the experimental group and 2360 in the control group. The discrepancy in numbers between randomized and analyzed is accounted for by study attrition [55,56,58].

Women made up 58% (3051/5260) of all randomized participants. All the studies were aimed at a working age population. The range of mean ages reported across the studies was 36.4 to 48.4 years in the intervention groups and 34.3 to 47.8 years in the control groups. Nine of the studies (43%) recruited from a targeted population, including individuals with elevated levels of depression [41,54,56], stress [47-49], and insomnia [50,51]; one study recruited participants who had taken 10 or more consecutive days off work for stress, anxiety, or depression [55]. The remaining 12 studies (57%, 12/21) targeted a universal population with no set psychological inclusion criteria.

Intervention Characteristics

Multimedia Appendix 2 describes the selected characteristics of the interventions used in the studies included in this review. Over half of the interventions were based on cognitive or cognitive behaviour therapy (12/21, 57%) [39,41,43,50,51,53-59], with 3 based on stress and coping (14%) [46-48], 2 on mindfulness (10%) [42,44], and one each (5%) on social cognitive theory [45], problem solving training [49], positive psychology [52], and acceptance and commitment therapy [60]. The mean duration of the interventions was 7.6 weeks (SD=2.5; range 4.3 to 13.0). Seventeen (81%) of the interventions included in the studies used a website as their primary means of delivering the intervention [42-54,56-59], 2 (10%) delivered the intervention via a computer application [41,60], 1 (5%) via email [39], and one (5%) through a standalone computer [55]. Secondary modalities used by the studies to deliver the intervention and to engage users were email (12/21, 57%) [41,42,44,46,48,51-54,57-59], texting (4/21, 19%) [44,47,48,60], conference calls (2/21, 10%) [44,59], telephone calls (1/21, 5%) [59], face-to-face delivery (1/21, 5%) [44], a workbook (1/21, 5%) [44], and a compact disc (CD; 1/21, 5%) [42]. Just over half of the interventions (11/21, 52%) were self-guided [41-43,45-47,50,52,53,55,56], and 10 (48%, 10/21) offered users of the intervention some form of guidance: seven of those 10 studies (70%) described the guidance as coming from a therapist or coach [39,44,48,49,51,54,60], 2 (20%) were described as a coordinator or member of staff [57,59], and one (10%) as a clinical psychologist [58].

Study Attrition and Intervention Completion

Study attrition for the control and the intervention groups separately was available for 20 of the studies (one study reported combined study attrition [46]). The mean attrition for the intervention groups was 23% (SD=16.1, range 3% to 54%) and for the control groups 13% (SD=11.6, range 0% to 41%).

Intervention completion (adherence) data was available for 19 of the studies (data not available for 2 of the studies [41,52]). Most studies reported the percentage of participants that completed all or part of the intervention. The mean adherence (taken as the highest level of completion reported by the authors) was 45% (SD=29.3, range 3% to 95%).

Persuasive Technology

Studies were coded to see what if any elements of persuasive technology the interventions used to help support users to benefit from the intervention. They were coded using the classifications given by Fogg [61]. These are (1) reduction (reducing complex behavior to simple tasks), (2) tunneling (leading users through a predetermined sequence of actions or events), (3) tailoring (providing information relevant to specific individuals), (4) suggestion (making a suggestion at the most appropriate time), (5) self-monitoring (enabling people to monitor themselves), (6) surveillance (the use of computer technology to allow one party to monitor the behavior of another), and (7) conditioning (using technology to reinforce target behaviors). Seventeen of the 21 studies (81%) reported using a form of persuasive technology [39,41,43,44,46-51,53-55,57-60]. Tailoring was used by 57% (12/21) of interventions [39,43,44,46-51,53,54,58], self-monitoring by 43% (9/21) [41,44,47,50,51,55,57,59,60], and tunneling by 14% (3/21) [41,54,55]. We were unable to identify any forms of persuasive technology in the descriptions of 19% (4/21) of studies [42,45,52,56].

Meta-Analyses Findings

Post intervention means, SDs, and group numbers were extracted from the 21 studies included in this review. Two separate meta-analyses were completed for (1) psychological well-being, and (2) work effectiveness. Of the 21 studies included in the psychological well-being meta-analysis, 13 were also included in the work effectiveness meta-analysis. Both analyses were conducted using a random-effects model.

Figure 5 is a forest plot for the 21 studies that included a measure of psychological well-being. The Web-based psychological intervention delivered in the workplace resulted in significantly reduced levels of stress, depression, and psychological distress scores post intervention for the intervention condition compared with the control condition (z_{20}=5.24, P<.001) with a small effect size (g=0.37, 95% CI 0.23-0.50). The resulting effect sizes were significantly and highly heterogeneous (χ^2_{20}=103.1 P<.001; I^2=81%).

Figure 6 shows a forest plot for the 13 studies that included a work effectiveness measure. Participants in the intervention group showed significantly greater workplace effectiveness scores compared with those in the control conditions (z_{12}=3.00, P=.003) with a small effect size (g=0.25, 95% CI 0.09-0.41). The resulting effect sizes were significantly and highly heterogeneous (χ^2_{12}=48.2, P<.001, I^2= 75%).

The results of both meta-analyses suggested that further subgroup analyses were warranted.

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Figure 5. Forest plot of post intervention effect size for the psychological wellbeing outcome.

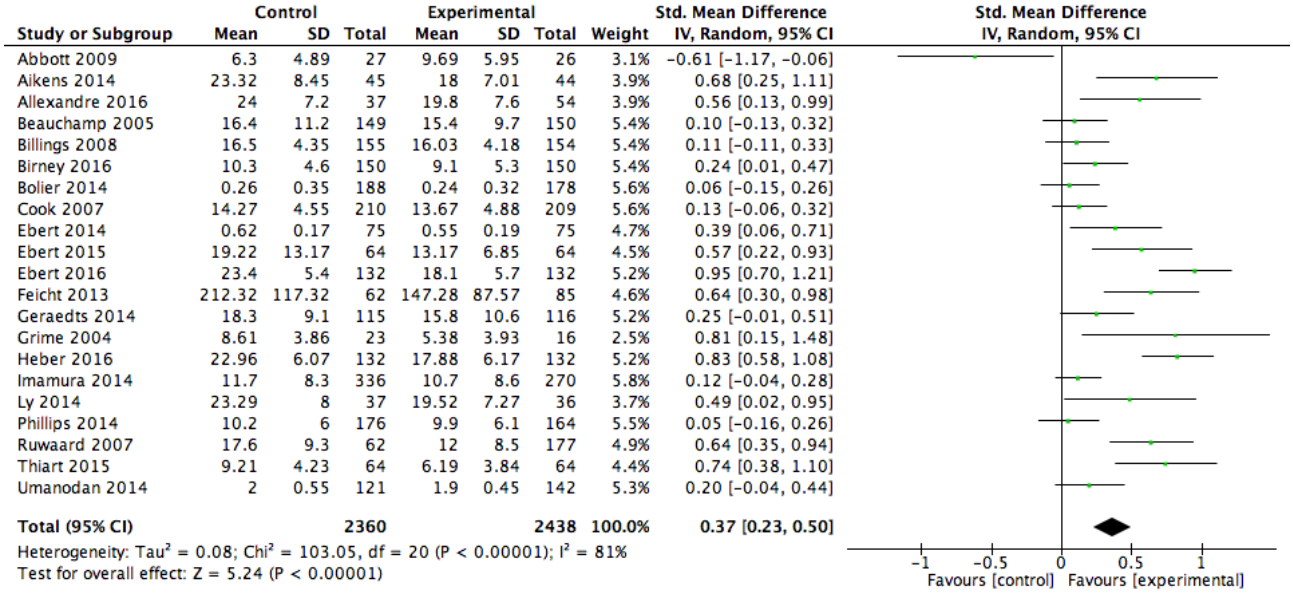
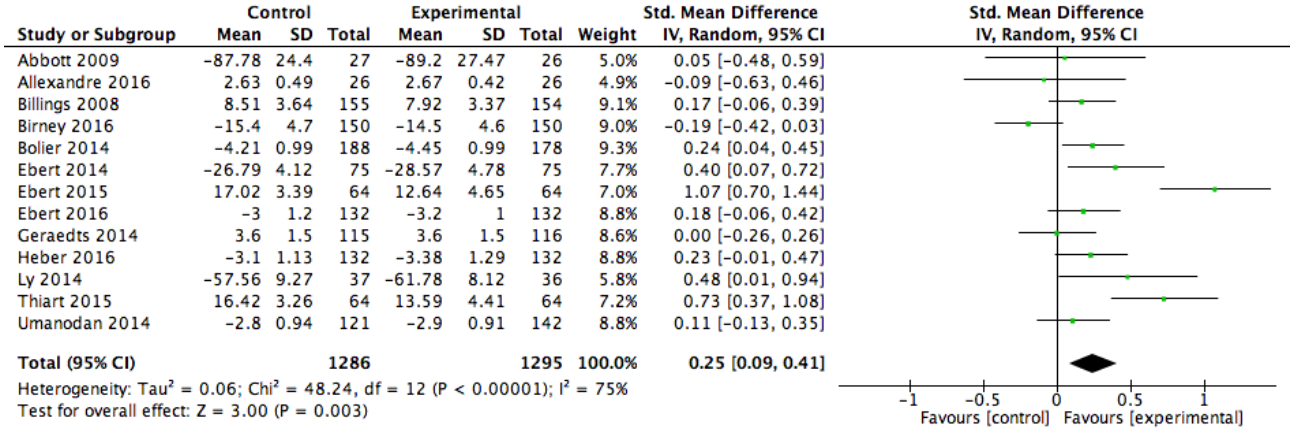


Figure 6. Forest plot of post intervention effect size for the work effectiveness outcome.



Sensitivity Analysis

We conducted outlier analysis by examining the forest plots of standard mean difference effect sizes and CIs for both the psychological well-being measure and the work effectiveness measure. One study was identified as a possible outlier on the psychological well-being outcome [59] because of its negative effect size (contrary to the other studies) and because its CIs did not fall into the range of the other studies. A sensitivity analysis excluding the study from analysis shows that the result of the main effect remains robust. A sensitivity analysis was also conducted comparing studies with lower and higher risk of bias. Studies with a low risk of bias produced larger effect sizes on the psychological well-being outcome (d=0.57, 95% CI 0.35-0.78) than studies with a high risk of bias (d=0.23, 95% CI 0.10-0.36). The groups were significantly different from each other (χ^2_1=6.9, *P*=.009). No significant difference was found between the two groups on the work effectiveness outcome.

Subgroup Analyses

Subgroup analyses for both the psychological well-being and work effectiveness outcomes were conducted looking at (1) therapeutic approach (CBT vs other), (2) guidance (guided vs nonguided), and (3) population (targeted vs universal). Table 2 shows the results of the subgroup analyses.

Therapeutic Approach

Subgroup analysis of the psychological well-being outcome comparing studies using CBT (k=12; as described by the authors) with studies using other psychological approaches (k=9) showed that the groups were not significantly different from each other (χ^2_1=3.63, *P*=.06), suggesting that for the psychological well-being outcome, the psychological approach used was not a source of heterogeneity. The pooled effect size for studies using the psychological approach of CBT was small (*g*=0.25, 95% CI 0.10-0.40), and for studies using other psychological approaches it was medium (*g*=0.52, 95% CI 0.28-0.76). Both are significant effect sizes (z_{11}=3.35, *P* ≤.001; and z_8=4.28, *P* ≤.001, respectively).

Subgroup analysis of the work effectiveness outcome comparing studies using predominantly CBT (k=8) with studies using other psychological approaches (k=5) showed that the groups were not significantly different from each other (χ^2_1=0.01, *P*=.94),

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suggesting that for the work effectiveness outcome, the therapeutic approach was not a source of heterogeneity. The small pooled effect size for studies using CBT (g=0.26, 95% CI 0.01-0.50) and other psychological approaches (g=0.25, 95% CI 0.11-0.39) are significant (z_7=2.05, P=.04; and z_4=3.47, P≤.001, respectively).

Guidance

Subgroup analysis of the psychological well-being outcome comparing interventions providing guidance (k=10) with interventions that were self-guided (k=11) showed that the groups were not significantly different from each other (χ^2_1=0.11, P=.74), suggesting that for the psychological well-being outcome, guidance was not a source of heterogeneity. The pooled effect size for both groups was small (guided interventions: g=0.39, 95% CI 0.18-0.61; and self-guided interventions: g=0.34, 95% CI 0.16-0.53) both were significant effect sizes (z_9=3.58, P≤.001; and z_{10}=3.63, P≤.001, respectively).

Subgroup analysis of the work effectiveness outcome comparing interventions providing guidance (k=7) with interventions that were self-guided (k=6) showed that the groups were not significantly different from each other suggesting that for the work effectiveness measure, guidance was not a source of heterogeneity (χ^2_1=0.1, P=.81). The pooled effect size for studies using interventions that are guided was a small significant effect size (g=0.27, 95% CI 0.08-0.45; z_6=2.84, P=.005). The pooled effect size for interventions that are self-guided was a small nonsignificant effect size (g=0.23, 95% CI −0.06 to 0.51; z_5=1.55, P=.12).

Table 2. Results of subgroup analyses investigating the effect of therapeutic approach, guidance, and population on outcome.

Outcome	Moderator	k (n)	Intervention effects				Heterogeneity within each subgroup			
			g	95% CI	Z	P	χ^2	df	P	I^2
Therapeutic approach										
Well-being	CBT	12 (3002)	0.25	0.10-0.40	3.35	<.001	38.9	11	<.001	72%
	Other	9 (1796)	0.52	0.28-0.76	4.28	<.001	46.6	8	<.001	83%
	Test for subgroup difference						3.6	1	.06	72%
Work effectiveness	CBT	8 (1778)	0.26	0.01-0.50	2.05	.04	44.1	7	<.001	84%
	Other	5 (803)	0.25	0.11-0.39	3.47	<.001	3.5	4	.47	0%
	Test for subgroup difference						0.01	1	.94	0%
Guidance										
Well-being	Guided	10 (2096)	0.39	0.18-0.61	3.58	<.001	46.6	9	<.001	81%
	Self-guided	11 (2702)	0.34	0.16-0.53	3.63	<.001	53.9	10	<.001	81%
	Test for subgroup difference						0.1	1	.74	0%
Work effectiveness	Guided	7 (1162)	0.27	0.08-0.45	2.84	.005	13.9	6	.03	57%
	Self-guided	6 (1419)	0.23	−0.06 to 0.51	1.55	.12	33.8	5	<.001	85%
	Test for subgroup differences						0.1	1	.81	0%
Population										
Well-being	Targeted	9 (1844)	0.52	0.28-0.75	4.32	<.001	46.9	8	<.001	83%
	Universal	12 (2954)	0.25	0.11-0.40	3.39	<.001	37.3	11	<.001	71%
	Test for subgroup difference						3.6	1	.06	72%
Work effectiveness	Targeted	7 (1465)	0.32	0.04-0.61	2.21	.03	44.6	6	<.001	87%
	Universal	6 (1116)	0.18	0.06-0.30	3.00	.003	3.4	5	.64	0%
	Test for subgroup difference						0.8	1	.37	0%

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Population

Subgroup analysis of the psychological well-being outcome comparing a targeted working population (k=9) with a universal working population (k=12) showed that the groups were not significantly different from each other (χ^2_1= 3.59, *P*=.06), suggesting that for the psychological well-being outcome, population was not a source of heterogeneity. The pooled effect size for the targeted working population was medium (*g*=0.52, 95% CI 0.28-0.75) and for the universal working population it was small (*g*=0.25, 95% CI 0.11-0.40). Both were significant effect sizes (z_8=4.32, *P* ≤.001 and z_{11}=3.39, *P* ≤.001, respectively).

Subgroup analysis of the work effectiveness outcome comparing a targeted working population (k=7) with a universal working population (k=6) showed that the groups were not significantly different from each other (χ^2_1=0.81, *P*=.37), suggesting that for the work effectiveness measure, population was not a source of heterogeneity. The pooled effect size for both groups was small (targeted working population: *g*=0.32, 95% CI 0.04-0.61, and universal working population: *g*=0.18, 95% CI 0.06-0.30); both effect sizes were significant (z_6=2.21, *P*=.03, and z_5=3.00, *P*=.003, respectively).

Positive Deviance Analysis

Of the 21 studies included in this review, 6 studies were in the 70th percentile and above for the lowest attrition in the intervention group [41,47,48,51,57,60], and 4 studies were in the 70th percentile and above for the highest intervention completion [48,49,51,57]. Three studies appeared in both groups [48,51,57], leaving 7 unique studies [41,47-49,51,57,60] that we reviewed in depth to generate hypotheses about intervention features associated with the highest levels of engagement.

The mean percentage of intervention group attrition in the high engagement group was 8% (SD 4.4), and for the other studies it was 31% (SD 14.5). The mean of the highest intervention completion reported by the authors for the high engagement group was 68% (SD 22.0) and for the other studies it was 33% (SD 26.0).

Interventions presented in the 7 studies in the high engagement group were reviewed. The interventions for 5 out of the 7 studies offered guidance (71%), compared with only 5/14 of the remaining studies (36%). The mean number of weeks that the intervention was delivered in the high engagement group was 6.6 (SD=0.54, range 6-7 weeks), compared with a mean of 8.1 (SD=3.0, range 4.3-13.0 weeks) in the other studies. All 7 of the studies in the high engagement group described the use of persuasive technology (5/7, 71% self-monitoring, 4/7, 57% tailoring, 1/7, 14% tunneling), compared with 10/14 (71%) in the remaining studies (8/14, 57% tailoring, 5/14, 29% self-monitoring, and 2/14, 14% tunneling).

Six of the 7 studies (86%) in the high engagement group utilized a secondary modality for delivering the intervention and engaging users (4 studies used emailing and 3 studies used texting), compared with only 8 of the remaining 14 studies (57%). Only 2 of the 21 studies included in this review used a mobile phone app as their primary modality for delivering the intervention; both studies were included in the high engagement group.

Hypotheses Generation

These findings suggest that interventions that achieve the greatest engagement and adherence offer guidance, are delivered over a shorter time frame (6 to 7 weeks), utilize secondary modalities for delivering the intervention and engaging users (ie, email and text messages), and use persuasive technology (ie, self-monitoring and tailoring). There is also a suggestion that a mobile phone app is a promising modality for engaging users of occupational digital mental health interventions.

Discussion

This review is the first meta-analysis that brings together RCTs of occupational digital mental health interventions and allows us to draw conclusions about both psychological well-being and work effectiveness outcomes. The adaptation of the positive deviance approach was helpful in enabling us to identify and explore in depth the features of high performing interventions in order to generate hypotheses about the intervention features that may promote engagement.

Study Characteristics

The 21 studies included in this review recruited and randomized 5260 participants. They were predominantly recruited from the knowledge sector (ie, communication, finance, business, information, research, and education services). The mean reported completion of interventions was 45%. These rates are similar to adherence rates reported for digital health (50%) [62] and digital CBT (median 56%) [63] interventions and are slightly less than those reported for guided digital CBT interventions (67.5%) [64]. Mean study attrition was higher for the intervention groups (23%) than for the control groups (13%). This is in line with a review of computerized CBT [63], which reported that participants in the intervention arm were twice as likely to drop out.

Intervention Characteristics

Over half of the studies included in this review used interventions that were predominantly based on CBT (57%). The mean duration of the interventions was 7.6 weeks, with just under half (48%) of the interventions offering some form of guidance. The mean adherence to the interventions was 45%. In a review of digital health interventions, Kelders et al [62] reported a mean duration of 10 weeks, adherence of 50%, and 76% of interventions offering some form of guidance, suggesting that occupational digital mental health interventions may differ somewhat from broader digital health interventions.

In this review, 81% of the interventions described in the studies used some form of persuasive technology: tailoring was used by 57%, self-monitoring by 43%, and tunneling by 14%. Kelders et al [62] report that for the 48 mental health studies that were included in their review of digital health interventions, tailoring was used by 90%, self-monitoring by 12%, and tunneling by 100%. The discrepancy between the number and type of persuasive technologies identified in our review and the Kelders et al [62] review is explained by differences in coding. For

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example, Kelders et al [62] did not code computer-mediated communication as persuasive technology, whereas we did. If a coach provided personalized feedback on assignments, we coded this as tailoring, whereas Kelders et al [62] only coded technology initiated communication (ie, when an automated message was sent). This and other differences in the coding make a comparison between the two reviews difficult.

Meta-Analyses Findings

Our results indicate that digital mental health interventions delivered in the workplace produced a small positive effect on psychological well-being (g=0.37, 95% CI 0.23-0.50, k=21), and a small positive effect on work effectiveness (g=0.25, 95% CI 0.09-0.41, k=13).

Our findings situate occupational digital mental health interventions as comparable with other (nondigital specific) occupational interventions in terms of impact on mental health and work effectiveness. The psychological well-being effect size is smaller but not significantly different from the medium effect size reported for a meta-analysis of occupational stress management interventions (d=0.53 95% CI 0.36-0.69) [65] and is larger but not significantly different from the small effect sizes reported in meta-analyses of occupational resilience building programs (d=0.21, 95% CI 0.13-0.29) [66] and health promotion in the workplace programs (depression: g=0.28, 95% CI 0.12-0.44; anxiety g=0.29, 95% CI 0.06-0.53) [67], suggesting that on the psychological outcome, digital mental health interventions have a comparable effect with other occupational interventions. The work effectiveness effect size is comparable with the small effect size reported in a meta-analysis of work engagement interventions (g=0.29, 95% CI 0.12-0.46) [68], suggesting that digital mental health interventions have comparable effects with alternative approaches to enhancing engagement in the workplace.

The psychological well-being effect size for occupational digital mental health interventions in our review is also comparable with digital mental health interventions delivered in health and community settings for adults with depression [17,22] and similar to digital stress management interventions delivered in community, occupational, and health contexts [24]. Eight studies in the Heber et al [24] review also met the criteria for inclusion in the present review, but less than half of the 23 studies were set within an occupational context.

Our findings suggest that occupational digital mental health interventions are as effective at improving mental health outcomes as are other more traditional, nondigital occupational programs and other digital interventions delivered in nonoccupational settings. This is impressive given that the workplace context may impact on the way that digital mental health interventions are delivered and received. For example, it has been suggested that two of the advantages of digital health interventions compared with face-to-face or group interventions are increased accessibility, with participants being able to access at a time and a pace convenient for them [23,25,27,30,69], and increased anonymity [23,27,30]. It is these perceived advantages that researchers suggest make digital interventions particularly suited to the workplace [70]. But it is possible that these attributes don't manifest as advantages in occupational settings; the lack of structure around "attending" digital health interventions may impact on uptake and attendance. Face-to-face or group interventions have a predetermined time for attendance during the working day, possibly with monitoring or reporting of participation to line managers. Digital mental health interventions tend to have less formal attendance with participants expected to attend at a time convenient to them. This flexibility and lack of monitoring, especially among a stressed population who may perceive themselves as time poor, may have a negative impact on intervention engagement; participants may not prioritize the time they need to engage with the intervention during their working day and may resent the intrusion of what they could perceive as work into their evening or weekends.

Furthermore, within an occupational setting, accessing digital mental health interventions may not be anonymous or even confidential. Access to the intervention may be managed through line management or occupational health; employees that do not have job autonomy may need to get permission to access the intervention during the working day, and employees working in an open plan office or sharing computer equipment may feel exposed when accessing the intervention at work. It is also possible that during the working day employees are so invested in appearing competent and strong that they are not willing or able to engage with a digital mental health intervention. The workplace may not be the appropriate setting to embrace the vulnerability that comes with acknowledging and addressing mental health challenges.

Further research is needed to gain a clearer understanding of the challenges and benefits of delivering digital mental health interventions within occupational settings. Nevertheless, despite the possibility that the workplace may provide additional challenges to the way that these interventions are delivered and received, our study has shown that occupational digital mental health interventions are effective at improving psychological well-being and work effectiveness.

Subgroup Analyses

Therapeutic Approach

The results of our review would suggest that as it is currently being delivered; CBT-based occupational digital mental health interventions are not producing superior results compared with digital interventions using other psychological approaches. Subgroup analysis comparing studies in our review using approaches described by the study authors as cognitive or cognitive behavioral therapy with studies using other psychological approaches revealed that the groups are not significantly different from each other on either the psychological well-being or work effectiveness measures. These findings are contrary to the established literature.

A meta-analysis of digital psychological treatments for adult depression also found no difference between CBT and other approaches [17], but a meta-analysis of digital psychological interventions for a range of problems did report a larger effect size for interventions using CBT compared with other therapeutic approaches [71]. Furthermore, meta-analyses on

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digital CBT consistently report higher effect sizes than were found in this review [20,23].

One explanation for this may be that as they are currently being delivered, CBT-based digital mental health interventions are not optimized for delivery in occupational settings. In a recent review of occupational digital health, Lehr et al [16] observed that the theoretical background for many of these predominantly CBT-based interventions fails to incorporate theoretical frameworks of occupational stress. Relevant theoretical models include the effort reward imbalance model [72], the person-environment fit model (for an overview see [73]), and the job demands-control model [74]. Incorporating these frameworks into the content of occupational digital mental health interventions may make the interventions more relevant and sensitive to the workplace [16] and may increase the capacity of all psychological approaches to meet the needs of occupational groups.

Guidance

No significant difference was found in our review between interventions that provide guidance with those that are self-guided. This is different to the established literature, which has consistently found that guided Internet interventions are significantly superior to unguided interventions [17,22-24,28,75-78]. A review by Grist and Cavanagh [20] on computerized CBT for common mental health problems also found no significant difference in effect size between guided and unguided programs. The authors suggested caution in interpreting their findings as only 5 studies using unguided programs had been identified. Low power from a small number of studies may also be an issue for this study; consequently, we too suggest caution in interpreting these findings. Another explanation for these findings may be the failure of this review to adequately code and differentiate the extent and form of guidance that is offered to participants and the extent to which that guidance is utilized. A recent review of digital interventions for stress differentiated between (1) guided interventions, (2) adherence-focused guidance (feedback on request), and (3) unguided interventions that provided email or telephone reminders [24]. This review did not make such a distinction, differentiating solely between interventions that did not describe guidance in any form and interventions that did describe some form of guidance. Furthermore, some studies' failure to adequately describe the in-program-support offered to participants may have resulted in some studies being wrongly categorized as unguided or guided. It is also unclear from some of the study descriptions whether support was being offered to participants outside the digital intervention, such as from an employee assistance program (EAP) or an occupational health team.

It is worth noting that the positive deviance analysis found 71% of studies in the high engagement group offered guidance compared with only 36% in the remaining studies, suggesting that there may be a link between the provision of guidance and increased engagement with occupational digital mental health interventions.

Targeted and Universal Populations

No significant differences were found in the review between studies that recruited a targeted population (elevated levels of depression, stress, and insomnia) and studies that targeted a universal population for either well-being or work effectiveness outcomes. However, there was a trend in both cases for studies with a targeted population to have a larger effect size, suggesting that individuals with raised levels of stress, depression, and insomnia benefit more from occupational digital mental health. One explanation for this might be that the measures used may not be sensitive to change at the lower end of the scale. Another explanation might be that participants with raised levels of psychological distress may be more motivated to implement the learning in the program and therefore produce more immediate post intervention results.

These findings are contrary to a meta-analysis on workplace resilience interventions, which found weaker effects among targeted populations compared with universal populations at post intervention [66]. That study reported that the effects of occupational resilience-building diminished sharply over time among the universal population but increased in the targeted population, suggesting that for a resilience-building program the benefits amongst a targeted population may increase with time [66].

Positive Deviance

Maximizing engagement with, and adherence to, digital heath interventions remains a pressing concern. The partial implementation of the positive deviance approach used in this review suggests that, within an occupational setting, These findings suggest that interventions that achieve the greatest engagement and adherence offer guidance, are delivered over a shorter time frame (6 to 7 weeks), utilize secondary modalities for delivering the intervention and engaging users (ie, email and text messages), and use persuasive technology (ie, self-monitoring and tailoring). These findings echo the literature on digital health interventions. In reviews of the design features that promote adherence to digital health interventions, evidence has also been found for increased guidance [62], the shorter duration of the intervention [78], contact through email or phone [30], and incorporating tailoring and self-monitoring [79]. Meta-analyses of occupational stress management interventions [65], digital stress management in the general adult population [24], and digital psychological treatment for depression [22] also found evidence for the increased effectiveness of interventions delivered over a similar period. We would recommend the development and testing of optimized occupational digital mental health interventions based on these principles.

Only 2 of the 21 studies included in this review used a mobile phone app as their primary modality of intervention delivery. Both studies were included in the high engagement group, suggesting that app technology is a promising modality for engaging users of occupational digital mental health interventions.

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Limitations

This study highlights limitations in the broader digital mental well-being literature. One limitation is the small number of studies that measured occupational outcomes. Although the studies included in the review were aimed at employed participants and delivered within workplace contexts, most of them reported the reduction of psychological symptoms and failed to report occupational outcomes. We would recommend that future trials of psychological interventions delivered in the workplace incorporate occupational outcome measures, including work effectiveness.

Another limitation was the considerable heterogeneity that was found across the studies. This included variation in the measures used (particularly in the work effectiveness measures), variations in the guidance given and the adherence, therapeutic approach and delivery of interventions, variation in the participants including country, type of organization, role and symptom severity, and variation in the quality of the study. The large number of unclear and high-risk of bias ratings limit the quality of the studies included in the review. The variation across the studies suggests that the results of our study should be interpreted with caution. We recommend that future research uses more robust study designs.

The coding used in the review was limited by the description given about the interventions in the published literature. Many of the descriptions were short and appeared incomplete. This is a limitation described by other researchers [30,62,80]. Naturally, incomplete descriptions, especially descriptions of the persuasive technology and guidance, limit the strength of the conclusions that can be drawn here.

Other limitations specific to this review include the use in the positive deviance analysis of intervention completion and intervention group attrition as proxy measures of intervention engagement and adherence; the number of times that a participant logs in to an intervention or the number of modules that they complete cannot necessarily be taken as a measure of the extent to which they engage psychologically with the intervention [80,81]; Likewise, the extent to which participants comply with the study protocol is not a perfect measure of psychological engagement. It is reassuring to note, however, that a review of adherence and its impact on digital therapies [82] reported that module completion was found to be the adherence measure most related to outcomes in psychological health interventions. Other limitations to the review include our use of the term “psychological well-being.” We recognize that psychological well-being is more than the absence of stress or depression and that our use of the term in this review does not capture aspects of well-being such as autonomy, personal growth, functioning, and relationships with others. Finally, this review did not analyze follow-up data, so we are unable to draw conclusions on the long-term effect of digital occupational mental health programs.

Implications

This review has demonstrated that delivering digital mental health interventions in the workplace can result in improved psychological well-being and work effectiveness. Our findings suggest that interventions that achieve the greatest engagement and adherence offer guidance, are delivered over a shorter time frame (6 to 7 weeks), utilize secondary modalities for delivering the intervention and engaging users (ie, email and text messages), and use persuasive technology (ie, self-monitoring and tailoring). Further research is needed to test these hypotheses.

We recommend that researchers and developers of occupational digital mental health interventions acknowledge the importance of the workplace setting in the content, delivery, and analysis of their interventions. We strongly recommend that therapeutic approaches incorporate relevant theoretical frameworks of occupational stress and that further research is conducted to better understand the challenges and benefits to delivering digital mental health interventions in the workplace. We also recommend that researchers incorporate in future research nonclinical measures of psychological distress and measures of occupational outcomes so that we can learn more about the psychological and occupational impact of digital mental health. A future area of research would be the long-term effect of these interventions.

Conclusions

This review provides evidence that occupational digital mental health interventions can improve workers’ psychological well-being and increase work effectiveness and identifies intervention characteristics that may increase engagement. We recommend that researchers and intervention developers recognize that the workplace is a dynamic and complex environment that may affect the way that individuals receive and engage with digital mental health interventions.

Acknowledgments

The authors would like to thank Kim Aikens, Douglas W Billings, Amelia Birney, Royer F Cook, Dan Hasson, Elena Heber, and Rino Umanodan for providing further information on their studies.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Selected characteristics of included studies.

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[PDF File (Adobe PDF File), 142KB - jmir_v19i7e271_app1.pdf]

Multimedia Appendix 2

Selected characteristics of included interventions.

[PDF File (Adobe PDF File), 147KB - jmir_v19i7e271_app2.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
EAP: employee assistance program
RCT: randomized controlled trial
SD: standard deviation
WLC: wait list control

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Edited by G Eysenbach; submitted 24.02.17; peer-reviewed by S Kraft, L Tetrick; comments to author 09.05.17; revised version received 22.05.17; accepted 23.05.17; published 26.07.17.

Please cite as:
Carolan S, Harris PR, Cavanagh K
Improving Employee Well-Being and Effectiveness: Systematic Review and Meta-Analysis of Web-Based Psychological Interventions Delivered in the Workplace
J Med Internet Res 2017;19(7):e271
URL: http://www.jmir.org/2017/7/e271/
doi:10.2196/jmir.7583
PMID:28747293

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Original Paper

Twelve-Month Follow-Up of a Randomized Controlled Trial of Internet-Based Guided Self-Help for Parents of Children on Cancer Treatment

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Abstract

Background: A substantial proportion of parents of children on cancer treatment report psychological distress such as symptoms of post-traumatic stress (PTSS), depression, and anxiety. During their child's treatment many parents also experience an economic burden.

Objective: The aim of this study was to evaluate the long-term efficacy of Internet-based guided self-help for parents of children on cancer treatment.

Methods: This study was a parallel randomized controlled trial comparing a 10-week Internet-based guided self-help program, including weekly support from a therapist via encrypted email, with a wait-list control condition. The intervention was based on cognitive behavior therapy (CBT) and focused on psychoeducation and skills to cope with difficult thoughts and feelings. Primary outcome was self-reported PTSS. Secondary outcomes were self-reported symptoms of depression, anxiety, health care consumption, and sick leave during the past month. Outcomes were assessed pre- and postintervention and at 12-month follow-up. Parents of children on cancer treatment were invited by health care personnel at pediatric oncology centers, and parents meeting the modified symptom criteria on the PCL-C were included in the study. Self-report assessments were provided on the Web.

Results: A total of 58 parents of children on cancer treatment (median months since diagnosis=3) were included in the study (intervention n=31 and control n=27). A total of 18 participants completed the intervention, and 16 participants in each group participated in the 12-month follow-up. Intention-to-treat analyses revealed significant effects in favor of the intervention on the primary outcome PTSS, with large between-group effect sizes at postassessment (d=0.89; 95% CI 0.35-1.43) and at 12-month follow-up (d=0.78; 95% CI 0.25-1.32). Significant effects in favor of the intervention on the secondary outcomes depression and anxiety were also observed. However, there was no evidence for intervention efficacy on health care consumption or sick leave.

Conclusions: Using the Internet to provide psychological interventions shows promise as an effective mode of delivery for parents reporting an increased level of PTSS and who consider Internet-based interventions as a viable option. Future research should corroborate these findings and also develop and evaluate interventions and policies that may help ameliorate the economic burden that parents may face during their child's treatment for cancer.

(J Med Internet Res 2017;19(7):e273) doi:10.2196/jmir.6852

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KEYWORDS

cancer; parents; Internet; PTSS; depression; anxiety; clinical trial

Introduction

Being a parent of a child diagnosed with cancer is burdensome. During the child's treatment, parents have to cope with the disease itself, invasive treatments, and uncertainty about the child's health and outcome. Indeed, parents of children on cancer treatment report psychological distress such as symptoms of post-traumatic stress disorder (PTSS) [1-3] and depression [4]. In addition, many parents of children on cancer treatment are affected economically. Cross-sectional studies indicate that the strain on household economy is highest during the first 6 months of treatment [5,6]. A recent longitudinal study found that the reduction in parents' working hours is highest 2 months after the child's diagnosis and then almost restored 1 year after end of treatment. However, 1 year after end of treatment, more mothers are still on sick leave than at the time of diagnosis [7]. Recent evidence from the same cohort suggests that reductions in working hours are restored 5 years after end of treatment [8].

There is evidence that psychological interventions can be of benefit to parents of children with chronic illnesses [9]. To the best of our knowledge, the intervention with best empirical support for reducing psychological distress among parents of children on cancer treatment is problem-solving training administered face to face [10,11]. This intervention is effective in reducing PTSS and depression among mothers of children on cancer treatment when compared with an inactive condition [11] and when compared with an active [12] condition consisting of nondirective support including active listening and reflective support. The intervention is 8 weeks in duration and has been evaluated up to 3 months after end of the intervention. A limitation of these studies is the lack of long term follow-up assessments. Importantly, there are no published findings regarding the effects of psychosocial interventions on health-related costs among parents of children on cancer treatment.

As the medical treatment for pediatric cancer is highly specialized, families where a child is treated for cancer often live far from the center where the child receives its care. This distance can make it difficult to maintain proper psychosocial and psychological support. Research has reported that less than half of parents who report a need to see a psychologist have had the opportunity to do so [13]. Cognitive behavior therapy (CBT) provided via the Internet is a promising treatment modality for a range of conditions [14], including parents of children with traumatic brain injury [15]. Providing interventions via the Internet could potentially increase access of support for parents of children who are receiving treatment for cancer. Recent developments and ongoing work in the wider field of interventions for parents of children with cancer also include Web-based CBT to improve quality of life in families of young cancer survivors [16].

We have developed a 10-week guided self-help intervention for parents of children on cancer treatment to be administrated via the Internet [17]. The intervention is based on principles from cognitive and behavioral therapies and aims to teach parents skills to cope with distress related to their child's disease and treatment. We have previously reported that the intervention seems effective in the short term with significant reductions in the primary outcome PTSS and the secondary outcomes depression and anxiety, with large effect sizes at postassessment compared with a wait-list control condition [18]. The purpose of this study is to investigate the efficacy of the intervention including data from the controlled follow-up 12 months after randomization. PTSS was the primary outcome, and secondary outcomes included symptoms of depression, anxiety, and health-economic outcomes such as health care consumption and sick leave.

Methods

Design

This is a parallel randomized controlled trial including pre- and postassessments and a controlled follow-up 12 months after randomization, comparing an Internet-based guided self-help program with a wait-list control condition. Participants were recruited consecutively from five of the six Swedish pediatric oncology centers. Participants allocated to the intervention condition received the intervention immediately after randomization, whereas participants allocated to the wait-list condition received the intervention 12 months after randomization. Neither participants nor therapists in the study were blind to condition allocation. This study relied on self-reported outcomes.

Participants and Procedure

Participants and procedure have been described in detail previously [18]. In brief, eligible participants were parents of children on treatment for a cancer disease who were fluent in Swedish, had access to a computer with an Internet connection, fulfilled the modified symptom criteria on the PTSD-Checklist-Civilian version (PCL-C) [19], a self-report instrument corresponding to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria for PTSD [20], and did not suffer from any other psychiatric disorder in immediate need of treatment. The modified symptom criteria comprise scoring ≥3 on at least one of five symptoms of reexperiencing, one of seven symptoms of avoidance and numbing, and one of five symptoms of hyperarousal, corresponding to partial PTSD [21]. A power analysis indicated that a total of 72 participants needed to be included to, with a power of .80, detect a large effect size (d=0.80) on the PCL-C assuming P<.05. Given that data on health care visits and sick leave were collected and that such variables generally vary more than clinical efficacy, a sample of 120 participants was estimated appropriate. However, the participation rate during the 4 years of inclusion was considerably lower than expected, and due to administrative reasons inclusion had to be terminated before this sample size was reached.

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Potential participants were approached in person by a nurse or physician on the wards at the pediatric oncology centers 4-12 weeks after the child's diagnosis. In the initial protocol, potential participants were to be approached 1-2 weeks after diagnosis. However, during the first months of inclusion it was evident that this was not feasible, and parents often were approached later, and the protocol was changed to the time frame reported. Potential participants were provided written and oral information about the study and were asked for written consent to participate. Nurses responsible for the recruitment at each center were not affiliated with the research group responsible for the study but were reimbursed for their work. Parents were informed that the intervention would be 10 weeks in duration and require approximately 4 hours of work per week to complete. A psychologist from the research group contacted consenting parents via telephone, and parents were instructed to complete the screening and preassessment on the Web. Thereafter, a clinical interview with a psychologist was conducted via telephone. Three master's level psychologists conducted the interviews. Participants in the intervention condition completed the postassessment on the Web immediately after the intervention. Participants in the wait-list control condition completed the postassessment on the Web after the corresponding time (ie, 10-weeks post randomization). Participants in both conditions completed the follow-up on the Web 12 months after randomization. Thereafter, participants in the wait-list condition were offered access to the intervention. The procedure was approved by the regional ethics review board in Uppsala (Dnr 2008/238), and all participants provided written informed consent. Inclusion to the study started in April 2010. During the planning of this study, trial registration was less common in the field of psychology than it is currently. Therefore, this trial was not registered in a World Health Organization (WHO) accredited trial registry.

Intervention

The intervention consists of Internet-based guided self-help provided during 10 weeks. The material has been described in detail [17] as well as its use in the current trial [18]. It consists of approximately 100 pages (A4 format) of text and visual material presented in nine modules. The intervention is based on CBT-principles [22-24] and focuses on psycho-education and teaching strategies to manage the current situation of being a parent of a child on cancer treatment and the stressors it entails. Components include relaxation training, coping with distressing thoughts and feelings, behavioral experiments, problem-solving, structured emotional writing, values and goal setting, general self-care, and maintenance of behavior change.

Participants accessed the intervention material via a Web-based portal and were instructed to work with each module for 1 week. Each participant was assigned a therapist and was instructed to send completed homework assignments via the portal to the therapist once each week. The therapist provided written feedback on each assignment and general progress through the intervention via the portal. The sequence of modules was fixed, which enhanced treatment integrity. If participants had not submitted their homework they were sent an email reminder to log in to the system. During the recruitment phase and in the informed consent, participants had been informed that the intervention would imply about 4 hours of work per week.

There were three therapists in the study. One licensed psychologist and two psychologists with a master's degree in psychology. The two nonlicensed psychologists received supervision from the licensed psychologist. The therapists were affiliated with the research group responsible for the study and independent from centers from which participants were recruited. Logging of therapist time and activities was not supported by the portal, but therapists were instructed to spend 15-20 min per week when providing feedback to each participant. Individuals randomized to the intervention who had their partner included in the study received individual feedback but were encouraged to work together with their partner during the intervention if that suited them.

All participants were free to receive psychosocial services from the regular health care. These may have differed between centers as there are no standardized psychosocial services for parents within the Swedish pediatric oncology care setting.

Outcomes

Primary Outcome

Post-traumatic stress symptoms related to the child's cancer disease were assessed with the PCL-C [19]. The PCL-C consists of 17 items rated on a 5-point scale (1=not at all and 5=extremely), corresponding to the items assessing the B (reexperiencing), C (avoidance and numbing), and D (hyper-arousal) criteria in the DSM-IV. The instrument has adequate internal consistency, test-retest reliability, and evidence for convergent and discriminant validity when compared with other well-established measures of PTSS, depression, and general anxiety [25]. A score of 44 or above on the full scale suggests a diagnosis of PTSD [26]. Cronbach alpha in the current sample was .84 at preassessment.

Secondary Outcomes

Depression was assessed with the Beck Depression Inventory-II (BDI-II) [27] consisting of 21 items rated on a 4-point scale (0-3). The BDI-II has good concurrent validity with the BDI and the Hamilton Psychiatric Rating Scale; the suggested cut-offs are 0-13 indicating minimal, 14-19 mild, 20-28 moderate, and 29-63 severe depression. Cronbach alpha in the current sample was .82 at preassessment. Anxiety was assessed with the Beck Anxiety Inventory (BAI) [28] consisting of 21 items rated on a 4-point scale (0-3). The BAI has good test-retest reliability and convergent validity; suggested cut-offs are 0-7 indicating minimal,

8-15 mild, 16-23 moderate, and 24-63 severe anxiety. Cronbach alpha in the current sample was .87 at preassessment. Economic outcomes were assessed with questions from the Trimbos iMTA questionnaire for costs associated with psychiatric illness (TiC-P) [29]. Questions used in this report assessed frequency of health care use and sick leave during the last month. For health care use, one or more visits to different health care providers were coded as a "yes." Similarly, for sick leave, 1 day or more of absence due to sickness during the last month was coded as a "yes."

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Randomization

Randomization was performed by a consultant independent from the research group. Proc Plan SAS version 9.1 (SAS Institute, Cary, North Carolina, USA) was used to generate the randomization schedule, and sealed envelopes were prepared by the consultant and handed to the research group. Parents were randomized in 1:1 ratio to intervention or wait-list, and the randomization was stratified according to center, parental gender, and whether a participant had a partner in the study or not. Partners were randomized to the same condition.

Statistical Analyses

Independent samples *t* test, Mann Whitney *U* test, chi-square test, and Fisher exact test were used to test for between-group differences on demographic characteristics and outcomes at preassessment. For the continuous outcomes (PCL-C, BDI-II, and BAI), mixed effects modeling with full maximum likelihood estimation was used to examine potential change across assessments and effects of the intervention [30], including random intercepts and slopes. Analyses were conducted on the intention-to-treat (ITT) principle where all randomized participants are included in the analyses, assuming missing data to be missing at random [31]. The data missing mechanism was assessed before the main analyses by exploring the relationships between characteristics at preassessment and missing data. Condition was dummy coded with intervention=1 and control=0. Assessment (pre, post, and 12-month follow-up) was included as a continuous time-variable coded as pre=0, post=1, and follow-up=2. Models were tested stepwise with increasing complexity and selected based on model fit indices, that is, -2loglikelihood difference test, Akaike Information Criteria (AIC), and Bayesian Information Criteria (BIC). All models tested included variance component as covariance structure. The complete model development is presented in Multimedia Appendices 1-3. For each outcome, we started with an unconditional model including a random intercept and slope (model A), as a second step we added linear growth as a fixed effect (model B), as a third step we added group as a fixed effect (model C), and as a fourth step we added quadratic growth as a fixed effect (model D). Standardized effect sizes (Cohen *d*) between groups at postassessment and 12-month follow-up were calculated using the model estimated mean differences (by recoding the continuous time-variable to −1 0 1 to set the intercept at the postassessment and −2 −1 0 to set the intercept at the 12-month follow-up assessment) and standard deviations from preassessment [32]. The magnitude of the effect expressed in *d* was interpreted according to Cohen [33], that is, 0.2=small, 0.5=medium, and 0.8=large. Variables pertaining to economic data consisted of frequencies of health care visits and days on sick leave. Due to the distribution of these frequencies, these variables were recoded to binary categorical variables representing no visits or days on sick leave (coded as 0) and any one or more visits or days on sick leave (coded as 1). However, ITT analyses with these data using, for example, generalized estimating equations, were not feasible due to the small sample size, and results for this secondary outcome are based on the available data excluding participants with missing data. Between-group differences at pre-, post- and follow-up assessments were analyzed with chi-square tests or Fisher exact test. Due to the small sample size, clustering by center and child was not addressed in any of the analyses. Analyses were performed in IBM SPSS Statistics 22 (IBM Corporation, Armonk, New York, USA).

Results

Recruitment and Baseline Characteristics

Participant flow through the study is outlined in Figure 1. From April 2010 to May 2014, 747 potential participants were informed about the study and asked for consent to be contacted again of which 553 declined. A total of 174 were reached by telephone, and 92 of these completed the screening, preassessment and clinical interview, and were assessed for eligibility. Fifty-eight parents of 46 children were included and randomized. Baseline characteristics have been described previously [18], and observed characteristics are presented in Tables 1 and 2. There were no differences in baseline characteristics between groups except for the BAI with a higher score in the intervention group. The last follow-up assessment took place in August 2015.

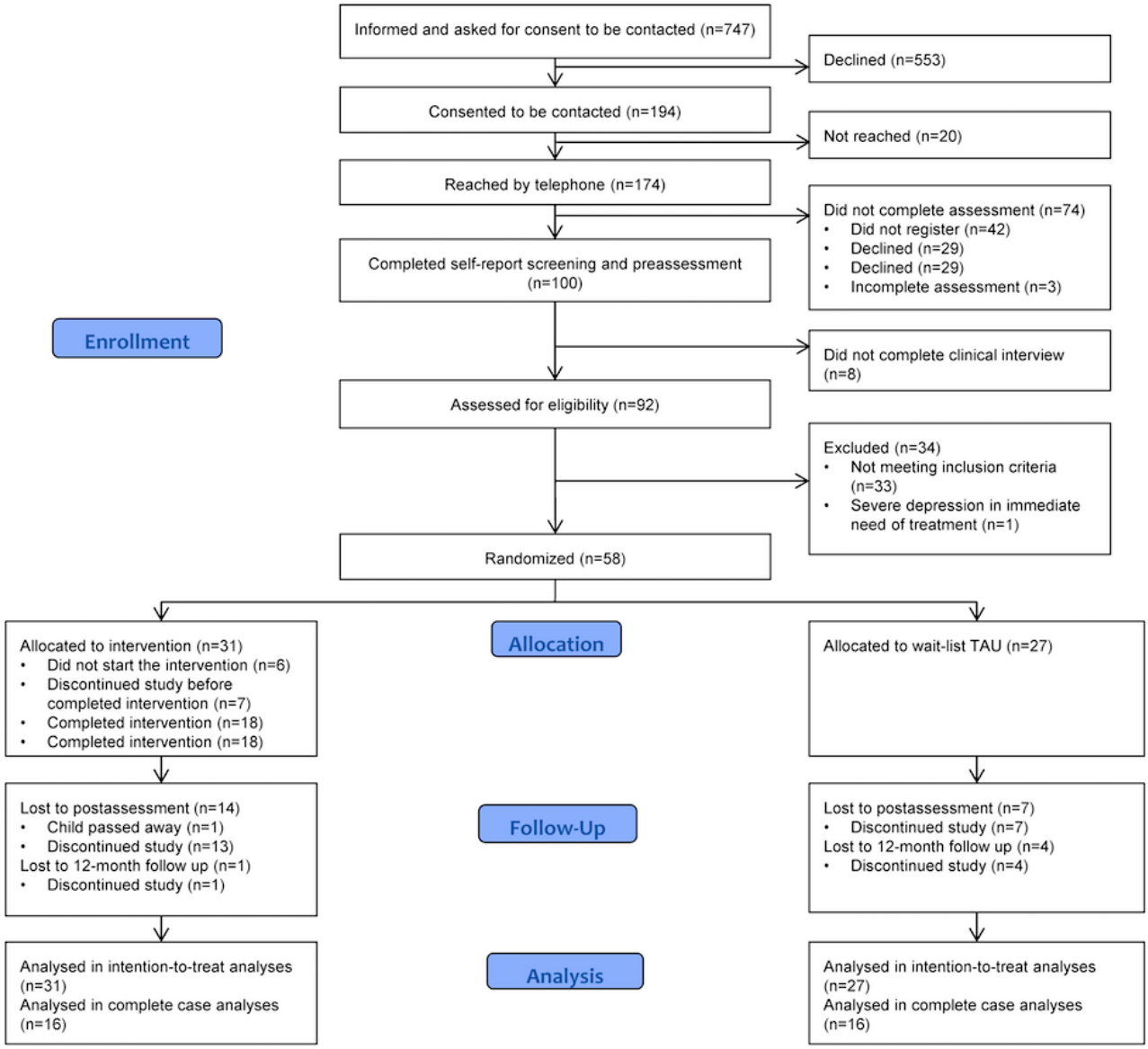
Attrition and Adherence

Fourteen participants in the intervention group (45%, 14/31) and 7 in the wait-list group (26%, 7/27) did not provide postassessments. Furthermore, 1 participant in the intervention group and 4 in the wait-list group did not provide follow-up assessments, resulting in 16 participants in each group at 12-month follow-up. At preassessment, there were no differences in terms of demographic characteristics or outcome measures between those who provided post- and follow-up assessments and those who did not (*P* value ranging .14-.98) except for gender where fathers were less likely to provide data at 12-month follow-up compared with mothers (χ^2_1=6.4, *P*=.01).

As reported previously [18], adherence to the intervention was operationalized as the numbers of treatment modules accessed and log-ins to the Web-based portal. In the intervention group, 6 participants did not start the intervention, and 7 discontinued before completion. A total of 18 out of 31 participants were considered as completers, representing 58% of those allocated to the intervention. For the ITT-sample, the median number (interquartile range [IQR]) of accessed modules was 4 (4), and the median number (IQR) of log-ins was 13 (22). For the completer-sample, the median number (IQR) of accessed modules was 5 (3.5), and the median number (IQR) of log-ins was 20 (20).

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Figure 1. Consort diagram of participant flow through the study.



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Table 1. Baseline characteristics of parents.

Characteristics	Total sample n=58	Intervention n=31	Wait-list n=27	*P* value
Mothers, n (%)	39 (67)	21 (68)	18 (67)	.76
Partner also included in study, n (%)	22 (38)	12 (39)	10 (37)	.90
Age, mean (SD[a])	38 (7.2)[b]	40 (7.4)[c]	36 (6.6)[d]	.06
Living with child's biological parent, n (%)	51 (88)	26 (84)	25 (93)	.31
Completed university studies, n (%)	30 (52)	17 (55)	13 (48)	.61
In active employment, n (%)	47 (81)	26 (84)	21 (78)	.56
Median distance in km to POC[e] (IQR[f])	35 (61)	39 (62)	20 (50)	.39
Experience of previous traumatic event(s), n (%)	26 (45)	14 (45)	12 (44)	.96
Median months since child´s dx[g] (IQR)	3.0 (3.0)[h]	3.0 (2.25)[i]	3.0 (3.0)	.39
Outcomes, mean (SD)				
PCL-C[j]	49.1 (10.3)	51.5 (9.4)	46.6 (10.7)	.06
BDI-II[k]	20.6 (7.5)	21.6 (8.1)	19.3 (6.7)	.24
BAI[l]	14.7 (7.6)	17.2 (7.8)	11.9 (6.3)	<.01

[a]SD: standard deviation.
[b]n=55.
[c]n=29.
[d]n=26.
[e]POC: pediatric oncology center.
[f]IQR: interquartile range.
[g]dx: diagnosis.
[h]n=57.
[i]n=30.
[j]PCL-C: PTSD-Checklist-Civilian version.
[k]BDI-II: Beck Depression Inventory-II.
[l]BAI: Beck Anxiety Inventory.

Table 2. Baseline characteristics of children.

Characteristics	Total sample n=46	Intervention n=25	Wait-list n=21	*P* value
Female, n (%)	25 (54)	16 (64)	9 (43)	.15
Median age (IQR[a])	5 (9.0)	6 (10.5)	4 (8.0)	.26
Diagnosis, n (%)				.33
Leukemia	24 (52)	13 (52)	11 (52)	
Sarcoma	8 (17)	5 (20)	3 (14)	
Lymphoma	3 (7)	3 (12)	0 (0)	
CNS[b]-tumor	7 (15)	2 (8)	5 (24)	
Other malignant disease	4 (9)	2 (8)	2 (10)	

[a]IQR: interquartile range.
[b]CNS: central nervous system.

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Table 3. Estimated outcomes of mixed effects models and effect sizes (n=58 in intention-to-treat analyses). Cohen *d* is the standardized mean difference and was calculated using the estimated mean difference and the standard deviation of the complete sample at the preassessment.

Outcome	Degrees of freedom	Estimate (SE[a])	95% CI	*F* test value	*t* test value	*P* value
PCL-C[b]						
Intercept	1, 66.6	46.26 (2.09)	42.08-50.44	488.11	22.10	<.001
Group	1, 66.6	5.22 (2.86)	−0.49 to 10.94	3.33	1.82	.07
Linear	1, 58.0	−2.29 (4.06)	−10.42 to 5.84	0.32	−0.56	.57
Quadratic	1, 52.1	1.11 (2.00)	−2.90 to 5.14	0.31	0.56	.58
Linear × Group	1, 59.2	−21.87 (5.92)	−33.73 to −10.02	13.63	−3.70	<.001
Quadratic × Group	1, 50.8	7.47 (2.90)	1.63-13.30	6.61	2.57	.01
Difference POST		−9.16 (3.50)	−16.09 to −2.23	6.86		.01
d POST		0.89	0.35-1.43			
Difference 12mFU		−8.07 (3.67)	−15.33 to −0.8	4.84		.03
d 12mFU		0.78	0.25-1.32			
BDI-II[c]						
Intercept	1, 63.9	19.33 (1.45)	16.43-22.22	177.50	13.32	<.001
Group	1, 64.2	1.62 (1.99]	−2.36 to 5.59	0.66	0.81	.42
Linear	1, 37.5	0.41 (0.92)	−1.47 to 2.28	0.19	0.44	.66
Quadratic		-	-			-
Linear × Group	1, 36.1	−5.58 (1.31)	−8.23 to −2.92	18.12	−4.26	<.001
Quadratic × Group		-	-			-
Difference POST		−3.91 (1.89)	−7.68 to −0.13	4.29		.04
d POST		0.52	−0.003 to 1.04			
Difference 12mFU		−9.41 (2.49)	−14.34 to −4.48	14.31		<.001
d 12mFU		1.25	0.69-1.82			
BAI[d]						
Intercept	1, 57.8	11.48 (1.52)	8.44-14.51	57.36	7.57	<.001
Group	1, 57.9	5.11 (2.08)	0.95-9.26	6.06	2.5	.02
Linear	1, 33.0	1.84 (0.83)	0.15-3.52	4.93	2.2	.03
Quadratic		-	-			-
Linear × Group	1, 32.2	−6.06 (1.17)	−8.44 to −3.67	26.80	−5.2	<.001
Quadratic × Group		-	-			-
Difference POST		0.94 (1.98)	−4.91 to 3.03	0.23		.23
d POST		0.12	−0.39 to 0.64			
Difference 12mFU		−6.99(2.50)	−11.94 to −2.04	7.85		.006
d 12mFU		0.92	0.38-1.46			

[a]SE: standard error.

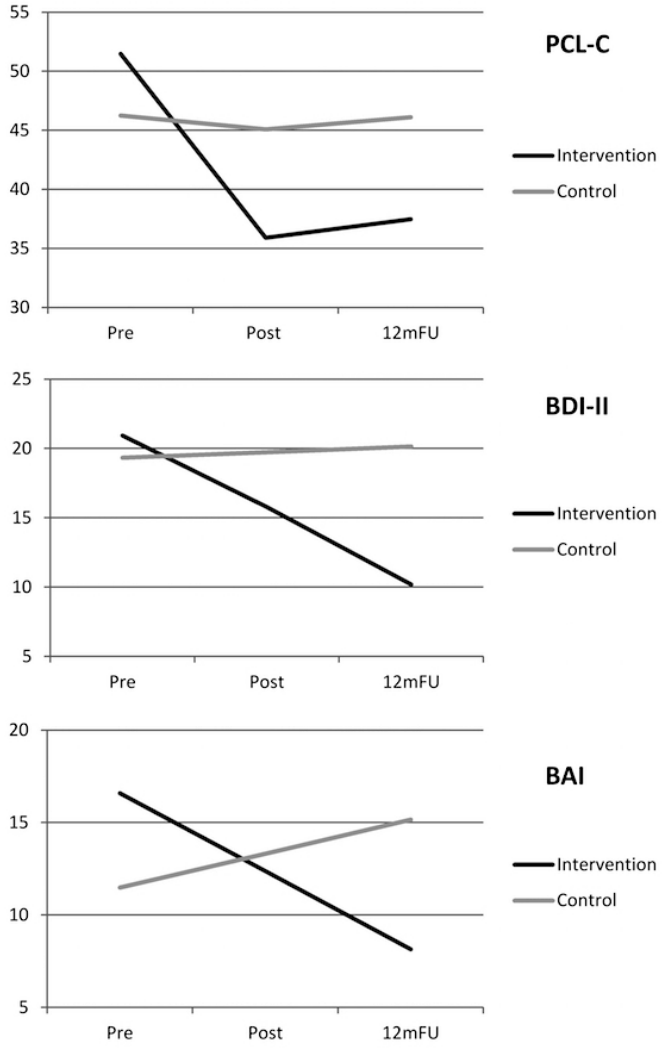
[b]PCL-C: PTSD-Checklist-Civilian version.

[c]BDI-II: Beck Depression Inventory-II.

[d]BAI: Beck Anxiety Inventory.

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Figure 2. Estimated outcomes from mixed models with continuous variables.



Outcomes

Table 3 and Figure 2 present the results from the mixed effects models and effect sizes for the continuous outcomes.

Primary Outcome

For PCL-C, a model with a quadratic term, indicating a nonlinear development over time, provided best fit to the data (see Multimedia Appendix 1). The intervention group exhibited a significant decline that abated over time. The control group showed no change. The model difference at postassessment was 9.16 points on the PCL-C in favor of the intervention group, representing a large effects size. At follow-up, the model difference was 8.07 points on the PCL-C in favor of the intervention group, representing a medium to large effect size.

Secondary Outcomes

For BDI-II, a linear model provided best fit to the data (see Multimedia Appendix 2). The intervention group exhibited a significant decline over time. The control group showed no change. The model difference at postassessment was 3.91 points on the BDI-II in favor of the intervention group, representing a medium effect size. The model difference at follow-up was 9.41 points on the BDI-II, representing a large effect size. For BAI, a linear model provided best fit to the data (see Multimedia Appendix 3). At preassessment, the intervention group reported a significantly higher level of symptoms; the model difference was 5.11 points on the BAI. The intervention group exhibited a significant decline over time, whereas the control group exhibited a significant increase in symptoms over time. At postassessment, there was no difference between the groups. However, at follow-up there was a difference of 6.99 points on the BAI in favor of the intervention group, representing a large effect size

Results for the economic variables are presented in Multimedia Appendix 4. Significantly more parents in the intervention group had seen a social worker at preassessment. No other differences between the groups were evident.

Discussion

To the best of our knowledge, this is the first study to report on the long-term outcomes of guided self-help via the Internet for parents of children on cancer treatment. The results indicate that the intervention was effective in terms of reductions in the primary outcome PTSS and that these improvements were maintained at the 12-month follow-up. Significant reductions for the intervention group compared with the control group were

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also evident for the secondary outcomes of depression and anxiety, and between-group effect sizes were even larger at the 12-month follow-up. However, there was no support for the intervention being effective in reducing health care consumption or sick leave.

The findings that psychological distress can be reduced among parents of children with cancer are in line with previous investigations on problem-solving training administered in face-to-face format for mothers [11,12]. In the trial of problem-solving training compared with an inactive control condition [11], similar standardized mean differences between groups, as outlined in this study as metrics of effect-sizes, were not presented, which makes it hard to compare the treatment effects of these two trials. However, in the problem solving trial, significant intervention effects were observed for PTSS and depression at the end of the intervention (3 months post randomization), and these differences were maintained at the follow-up, 6 months post randomization. The results presented herein extend these findings and suggest that significant intervention effects for PTSS and depression observed post intervention can be maintained (PTSS) and seemingly improved (depression) at 12-month follow-up. In addition to mode of administration, another important difference between the two trials is that the current trial included participants reporting an increased level of PTSS, whereas the problem-solving trial included mothers irrespective of self-reported level of distress. Arguably, this results in different populations, which suggest that comparisons between the trials should be made with caution.

We did not find support for treatment efficacy in terms of reduced health care consumption or sick leave. Importantly, the small sample size and substantial attrition made it difficult to use estimation techniques that are in line with the ITT principle (eg, general estimating equations), and we were forced to base the analysis on completers. Furthermore, the frequencies of some of the indicators for health care consumption and sick leave were small and with little variation. It is also important to note that previous research regarding economic strains on families caring for a child with cancer has mainly concerned working hours and expenses [5,6]. Such factors may well impact on parents level of distress as economic burden may be an additional stressor for the parents. However, psychological distress may not impact on working hours and expenses. In this study, we strived to assess economic factors that may be influenced by the parents' level of distress, such as health care consumption and sick leave and to investigate whether reductions in psychological distress would be associated with reductions in health-related expenses or sick leave. Future research should aim to disentangle whether psychological distress contributes to strains on household economy among parents of children on cancer treatment. Such efforts should be able to better prepare research that aims to alleviate the economic burden imposed on parents on children with cancer, be it via psychosocial interventions or targeted policies. It may also be the case that we used a less than optimal instrument for assessing health-related consumption and sick leave. Future research is needed to develop reliable and valid instruments for assessing these factors in the current population, and such research could preferably start with qualitative methods in order to explore the phenomena of health-related costs in this population.

For the clinical outcomes, including the primary outcome PTSS, we used ITT-analyses with maximum likelihood estimation under the assumption of data missing at random, and under such assumption, this procedure produces less biased estimates compared with, for example, last-observation carried forward [31]. The results from these analyses indicate that the intervention produces substantial long-term improvements in PTSS, depression, and anxiety. However, using an inactive control group makes it impossible to draw conclusions regarding the specificity of the intervention. Future trials should include active control conditions that allow for the control of the nonspecific factors (eg, attention, information, and social support) that psychological interventions may be associated with. Furthermore, the sample was small, and attrition was substantial, which may limit the validity of the ITT-analyses and may hamper both the reliability and generalizability of the findings. In addition, the study is limited by the fact that reasons for not participating in the trial were not documented due to ethical reasons, which further limits the generalizability. As the study was small and underpowered, the risk for inflated effect sizes and type-I errors is also increased [34], which should be kept in mind when interpreting the findings. It is our impression that the intervention might have been too reliant on text and perhaps too time-consuming for parents in this difficult situation and might have deterred many from participating and also affected attrition. Potential adjustments include shortening the intervention and relying less on text in favor of other ways of communicating on the Web. In addition, fathers were less likely to participate at the 12-month follow-up than mothers, which may further limit the generalizability. Unfortunately, the small sample size made it difficult to further explore the underlying mechanism of this difference in attrition. Historically, fathers have been less involved in pediatric psychology research [35], and future research with parents of children with cancer should take steps to ensure involvement from parents of both sexes [36]. Finally, this study relied on self-reported outcomes, and participants were not blind to their study condition, which should be kept in mind when interpreting findings. This is a problem for all research on psychological interventions using inactive control conditions, and the fact that participants were aware of their study condition might have affected their expectancies for improvement differently. In this study, no such expectancies were assessed so we cannot estimate or control for this factor in the analyses. Nonspecific factors such as expectancy for improvement might contribute to improvements in all kinds of psychological interventions. An alternative design with an active comparison condition receiving some kind of support, and also assessing treatment credibility and expectancies for improvement in both conditions, would had enabled us to better control for these factors.

To the best of our knowledge, this paper presents the first trial of an intervention administered via the Internet aiming to reduce psychological distress among parents of children on cancer treatment. ITT-analyses indicate substantial improvements in PTSS, depression, and anxiety that are maintained or strengthened at 12-month follow-up. However, we found no

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evidence for effects on health care consumption or sick leave. As such, using the Internet to provide psychological interventions may be an effective mode of delivery for parents reporting an increased level of PTSS and who consider Internet-based interventions as a viable option. Future research should corroborate these findings and also develop and evaluate interventions and policies that may help ameliorate the economic burden that parents may face during their child´s treatment for cancer.

Acknowledgments

This research was supported by grants from the Swedish Research Council (grant numbers K2008-70X-20836-01-3 and K2011-70X-20836-04-4), the Swedish Cancer Society (grant numbers 2010/276 and 2014/613), and the Swedish Childhood Cancer Foundation (grant numbers PROJ08/010 and PRO12/028).

Conflicts of Interest

None declared.

Multimedia Appendix 1

This table describes model development with increasing complexity for the outcome PCL-C. Model D was chosen as the best fitting model as indicated by the significant difference test of the −2loglikelhood statistic and the lowest BIC.

[PDF File (Adobe PDF File), 23KB - jmir_v19i7e273_app1.pdf]

Multimedia Appendix 2

This table describes model development with increasing complexity for the outcome BDI-II. Model C was chosen as the best fitting model as indicated by the nonsignificant difference test of the -2loglikelhood statistic when comparing with model D and the lowest BIC.

[PDF File (Adobe PDF File), 23KB - jmir_v19i7e273_app2.pdf]

Multimedia Appendix 3

This table describes model development with increasing complexity for the outcome BAI. Model C was chosen as the best fitting model because of the lowest BIC. When comparing model C with model D, the -2loglikelhood test was significant indicating a better model fit for model D; however, we chose to present results from the more parsimonious model C because of the lower BIC and because the quadratic*group growth factor was nonsignificant in model D.

[PDF File (Adobe PDF File), 23KB - jmir_v19i7e273_app3.pdf]

Multimedia Appendix 4

Observed frequencies of health care consumption and sick leave.

[PDF File (Adobe PDF File), 30KB - jmir_v19i7e273_app4.pdf]

Multimedia Appendix 5

CONSORT-EHEALTH checklist (V1.6.1).

[PDF File (Adobe PDF File), 510KB - jmir_v19i7e273_app5.pdf]

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Abbreviations

AIC: Akaike information criteria
BAI: Beck Anxiety Inventory
BIC: Bayesian information criteria
BDI-II: Beck Depression Inventory-II
CBT: Cognitive behavior therapy
ITT: Intention to treat
PCL-C: PTSD-Checklist-Civilian version

Edited by G Eysenbach; submitted 20.10.16; peer-reviewed by M Boffo, W Boendermaker; comments to author 01.12.16; revised version received 12.01.17; accepted 24.05.17; published 27.07.17.

Please cite as:
Cernvall M, Carlbring P, Wikman A, Ljungman L, Ljungman G, von Essen L
Twelve-Month Follow-Up of a Randomized Controlled Trial of Internet-Based Guided Self-Help for Parents of Children on Cancer Treatment
J Med Internet Res 2017;19(7):e273
URL: http://www.jmir.org/2017/7/e273/
doi:10.2196/jmir.6852
PMID:28751300

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Original Paper

Personalized Web-Based Advice in Combination With Well-Child Visits to Prevent Overweight in Young Children: Cluster Randomized Controlled Trial

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Abstract

Background: Overweight is a major health issue, and parent-targeted interventions to promote healthy development in children are needed.

Objective: The study aimed to evaluate E-health4Uth Healthy Toddler, an intervention that educates parents of children aged 18 to 24 months regarding health-related behaviors, as compared with usual care. The effect of this intervention on the following primary outcomes was evaluated when the children were 36 months of age: health-related behaviors (breakfast daily, activity and outside play, sweetened beverage consumption, television (TV) viewing and computer time), body mass index (BMI), and the prevalence of overweight and obesity.

Methods: The BeeBOFT (acronym for breastfeeding, breakfast daily, outside playing, few sweet drinks, less TV viewing) study is a cluster randomized controlled trial involving 51 Youth Health Care (YHC) teams. In total, 1094 parents participated in the control group, and 1008 parents participated in the E-health4Uth Healthy Toddler intervention group. The intervention consisted of Web-based personalized advice given to parents who completed an eHealth module and discussion of the advice during a regular well-child visit. In this study the eHealth module was offered to parents before two regular well-child visits at 18 and 24 months of age. During the well-child visits, the parents' personalized advice was combined with face-to-face counseling provided by the YHC professional. Parents in the control group received usual care, consisting of the regular well-child visits during which general information on child health-related behavior was provided to parents. Parents completed questionnaires regarding family characteristics and health-related behaviors when the child was 1 month (inclusion), 6 months, 14 months, and 36 months (follow-up) of age. The child's height and weight were measured by trained health care professionals from birth through 36 months of age at fixed time points. Multilevel linear and logistic regression models were used to evaluate the primary outcomes at 36 months of age.

Results: At 36 months, we observed no differences between health-related behaviors of children, BMI or the percentage of children having overweight or obesity in the control and intervention group (P>.05). An analysis of the intervention effect revealed that boys benefited from eating breakfast daily, non-Dutch children spent more time being active or playing outdoors, children of low-educated parents and of overweight and obese mothers spent less time watching TV or using the computer, and children of normal weight mothers drank less sweetened beverages (P<.05) compared with the control group.

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Conclusions: The E-health4Uth Healthy Toddler intervention resulted in small improvements in health-related behaviors among subgroups but had no significant effects with respect to the children's BMI. We conclude that the E-health4Uth Healthy Toddler intervention may be useful for pediatric health care professionals in terms of providing parents with personalized information regarding their child's health-related behaviors.

Trial Registration: Netherlands Trial Register: NTR1831; http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1831 (Archived by WebCite at http://www.webcitation.org/6mm5YFOB0)

(J Med Internet Res 2017;19(7):e268) doi:10.2196/jmir.7115

KEYWORDS

healthy lifestyle; child, preschool; parenting; child health; intervention study; eHealth; randomized controlled trial; body mass index

Introduction

Background

In 2009, 1.8% of the Dutch boys and 2.2% of the Dutch girls in the age group of 2 to 21 years were classified as being obese, and 12.8% of the boys and 14.8% of the girls were classified as being overweight [1]. Compared with 1980, this is a 4- to 6-fold increase in obesity prevalence and a 2- to 3- fold increase in overweight prevalence among Dutch youth [1]. However, some studies suggest that the prevalence may have stabilized in some parts of the Netherlands, similar to data obtained from the United States [2,3]. Nevertheless, it remains unclear precisely which interventions are responsible for this stabilization [2]. Therefore, evaluating intervention programs may reveal how the prevalence of overweight and/or obese children can be decreased [2].

In the Netherlands, Youth Health Care (YHC) is a free program that monitors each child's health and development and helps families promote healthy behaviors and prevent disease. These benefits are offered to parents and their children in the form of appointments with YHC at set intervals beginning in the child's first year of life; in total, parents are offered a maximum of 11 well-child visits per child. During a well-child visit, growth and development of the child is assessed and discussed using standardized measures and protocols. Although voluntary, approximately 95% of parents in the Netherlands participate in this program [4]. The YHC uses a consensus-based overweight detection and prevention protocol [5,6], which uses international age- and gender-specific body mass index (BMI) cutoff values to evaluate a child's weight status [7]. The prevention protocol provides the YHC professional (eg, community physician or nurse) with the means to offer primary and secondary prevention strategies to parents; parents of overweight children can also be offered additional counseling [5]. These prevention strategies can be translated into interventions suitable for use by the YHC to help prevent overweight among children. One such intervention is the E-health4Uth Healthy Toddler intervention [8], which gives parents of young children a Web-based eHealth module providing personalized education regarding their child's nutritional habits and physical activity. This eHealth module is combined with face-to-face counseling by the YHC professional to the parents during the regular well-child visits [9-11]. During a pilot study wherein E-health4Uth Healthy Toddler intervention was developed and evaluated, results indicated that parents generally appreciate the advice they received from the eHealth module. Therefore, YHC professionals indicated that an eHealth module in combination with counseling could be integrated into their daily practice [12].

The E-health4Uth Healthy Toddler intervention is based on the following theories of behavior change: social-ecological theories and models, including the theory of planned behavior [13], the social learning model [14], and the McGuire communication model [15]. Personalized tailored advice regarding the child's health-related behaviors is generated based on the answers that parents provide when completing the assessment questionnaire of the eHealth module. The advice is based on most recent guidelines for child health-related behavior. In this study, the eHealth module was offered online to parents before two regular well-child visits at a preventive YHC organization at 18 and 24 months of age. During the well-child visit of approximately 20 minutes, the parents' personalized tailored advice was combined with face-to-face counseling provided by the YHC professional (eg, community physician or nurse). In general, in order to change health behavior, the use of Web-based and tailored eHealth tools may enhance intervention effectiveness [11,16,17]. A review by Hammersley et al [18] suggested that parent-focused overweight and obesity eHealth interventions can result in improvements in dietary or physical activity outcomes.

Objective of This Study

The aim of this study was to compare the effects of applying the E-health4Uth Healthy Toddler intervention versus usual care (control) by assessing the following primary outcomes: breakfast daily, activity and outdoor play, sweetened beverages, screen time (ie, television (TV) watching and/or computer use), BMI, and the prevalence of overweight/obesity [8]. Specifically, we tested the following two hypotheses: (1) that children in the E-health4Uth Healthy Toddler intervention group eat breakfast daily, are more active, consume fewer sweetened beverages, and spend less time in front of the TV and/or computer at follow-up (at 36 months of age); and (2) that children in the intervention group would have lower BMI and a lower prevalence of overweight and/or obesity at follow-up. We also examined the effects of the following possible moderating factors: the child's gender, the child's ethnic background, maternal education level, and maternal weight status.

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Methods

Study Design

In 2009, 50 preventive YHC organizations in the Netherlands were invited to participate in a 3-armed cluster randomized controlled trial (RCT) entitled the BeeBOFT (acronym for breastfeeding, breakfast daily, outside playing, few sweet drinks, less TV viewing) study (Netherlands Trial Register: NTR1831) [8]. A total of 10 organizations participated, including a total of 51 YHC teams. Each YHC organization serves a region of the Netherlands, and each team within an organization serves one or more municipalities of the region [4]. A team is comprised of a YHC physician, nurse, and assistant.

Within each of these ten organizations, the teams were randomly assigned to one of the following three groups using a computerized random allocation generator: the control group (n=17 teams), the E-health4Uth Healthy Toddler intervention group (n=17 teams), and the BeeBOFT + intervention group (n=17 teams). The E-health4Uth Healthy Toddler intervention group invited parents, at the child age of 18 and 24 months, to complete a Web-based eHealth module providing tailored health education regarding healthy child nutrition and activity behaviors and to discuss this advice during the regular well-child visit with a YHC professional. Therefore, Internet literacy was an implicit eligibility criterion. The YHC teams allocated to the BeeBOFT + intervention group focused on effective child rearing by parents from birth onwards by enlarging parental skills concerning healthy behavioral lifestyle habits. Parents in the control group received usual care, consisting of the regular well-child visits during which general information is provided with regard to health and development of the child. In this study, we focus only on the effects of the E-health4Uth Healthy Toddler intervention compared with usual care.

It is important to note that the YHC professionals and parents were not blinded with respect to the groups. The research proposal was reviewed by the Medical Ethics Committee of the Erasmus University Medical Center. On the basis of their review, the Committee concluded that the Dutch Medical Research Involving Human Subjects Act (in Dutch: Wet medisch-wetenschappelijk onderzoek met mensen) did not apply to this research proposal. The Medical Ethics Committee therefore had no objection to the execution of this study (proposal number MEC-2008-250). Further details regarding the study design and interventions have been published previously [8].

Procedure and Study Population

From January 2009 through September 2010, the 51 participating YHC teams invited the parents of 7985 children to participate in the BeeBOFT study during their first YHC well-child visit, which was conducted at the parents' home approximately 2-4 weeks after the birth of the child. Parents were requested to provide written informed consent to participate in the 3-year study. In total, 3003 parents agreed to participate in the BeeBOFT study and provided written informed consent (a participation rate of 37.61%; 3003/7985). At inclusion, a questionnaire was completed by the parents; 3 participants did not complete this questionnaire. This questionnaire contained items regarding the pregnancy (eg, duration and complications), childbirth (eg, complications and height and weight at birth), and family demographics (eg, the country of birth of both parents and grandparents, parents' education level, and number of siblings).

When the child was 6, 14, and 36 months of age, all parents participating in the BeeBOFT study were invited to complete a more extensive questionnaire containing items regarding the child's health-related behaviors, determinants of these behaviors, and the child's health-related quality of life (HRQoL). The questionnaires could be completed on paper or online by either the mother or the father. The response rates at the three ages were 77.62% (2331/3003), 77.20% (2318/3003), and 73.46% (2206/3003), respectively.

Here, we present our analysis of the effects comparing children in the E-health4Uth Healthy Toddler intervention group (n=1008 parents) and the control group (n=1094 parents) on the primary outcomes measured when the children were 36 months of age. The results obtained comparing children in the BeeBOFT + intervention group (n=991 parents) and the control group will be reported elsewhere. An overview of the YHC teams and the study participants is presented in Figure 1.

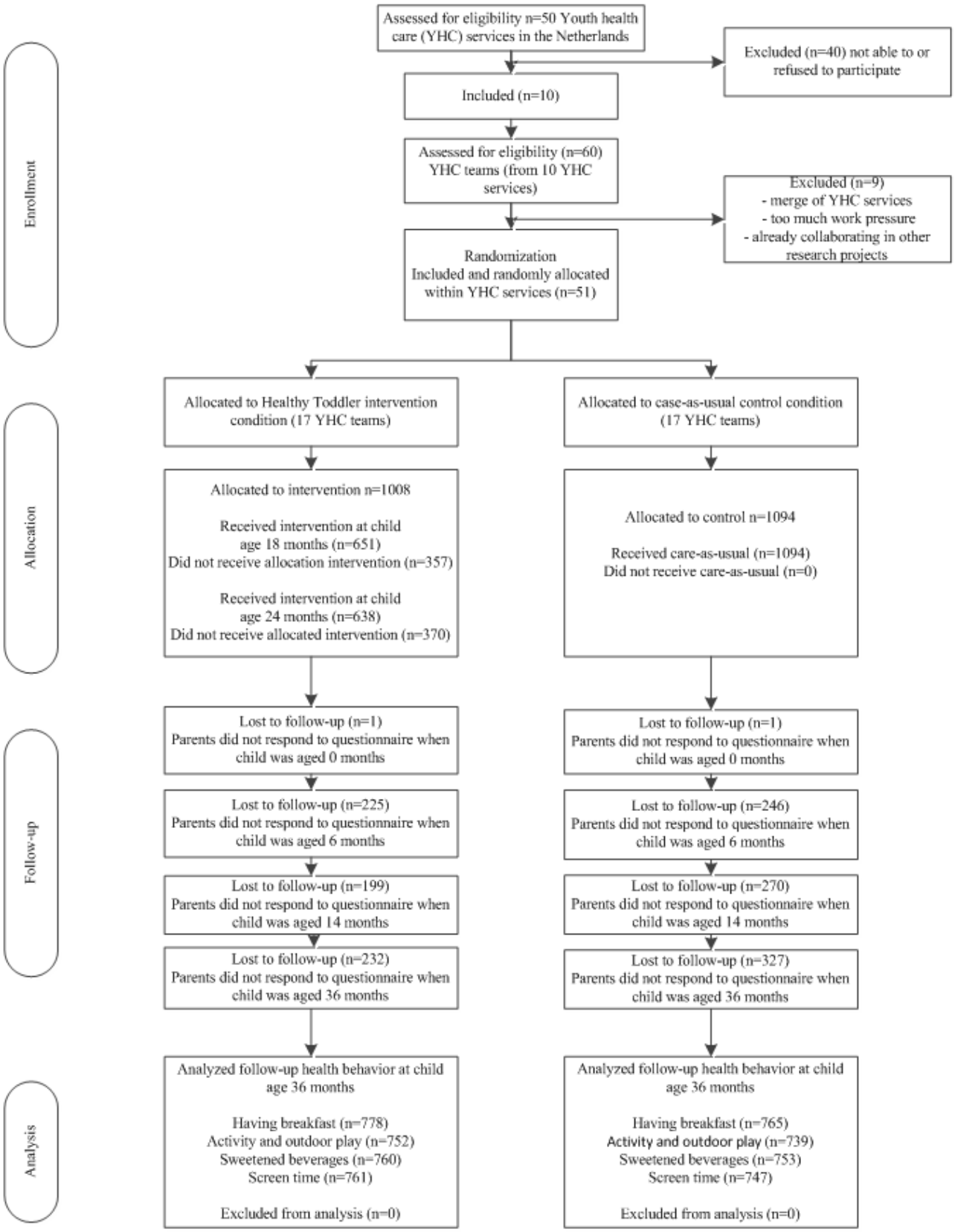
The E-health4Uth Healthy Toddler Intervention

The E-health4Uth Healthy Toddler intervention has been described in detail by Raat et al [8]. Screenshots of the intervention are available in the Multimedia Appendices 1 and 2. In short, the E-health4Uth Healthy Toddler intervention provides parents with customized advice regarding key health behaviors designed to prevent childhood overweight. The following four key behaviors are targeted by the intervention: (1) the promotion of eating breakfast daily, (2) the stimulation of daily exercise and outdoor playing, (3) discouraging the consumption of sweetened beverages, and (4) discouraging TV viewing and computer use. The intervention is based on theories of behavior change (eg, the theory of planned behavior [13] and the social cognitive theory [14]) and information processing theories (eg, the McGuire communication model [15]).

Parents allocated to the intervention group received an invitation to visit the E-health4Uth Healthy Toddler intervention website [19] and complete the eHealth module online one month before the regular well-child visits scheduled for when the child was approximately 18 and 24 months of age. Before the pre-24-month invitation was sent, the eHealth module was evaluated to ensure that it was suitable for the parents of 24-month-old children; no changes were necessary.

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Figure 1. Flow of participants.



As a first step, parents completed the assessment questionnaire; the questions in this questionnaire were based on previous research [20]. The assessment questionnaire started with 4 general questions (ie, gender of the child, age, date of upcoming well-child visit, who completed the questionnaire) used to personalize the advice. Thereafter, the assessment questionnaire assessed child health-related lifestyle behavior. The number of questions parents received depended on the responses provided by the parents (eg, if the parent indicated that the child did not play outside, there would be no follow-up question). There were a maximum of 5 questions on TV viewing and computer gaming, 5 questions on physical activity, 4 questions on breakfast, 11

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questions on sweetened beverages, 9 questions on snacking, and 2 questions on fruit. Seven questions assessed parental attitude towards the behavior (eg, do you think your child drinks too many sweetened beverages). The answers to the assessment questionnaire were used to generate the tailored advice. A total of 96 messages were developed for the tailored advice, which could be combined in various ways, based on the parents' responses. If the health-related behaviors were consistent with established guidelines, the parents received positive feedback [5]. The tailored advice could be read directly online, and parents were able to print the advice.

After reading the tailored advice, parents could make an implementation-intention plan in which they could specify actions (eg, what, when, and where to improve child health-related behavior). The tailored advice and implementation plan was sent by email to the parents. During the subsequent well-child visit, the advice was discussed with the YHC professional. The YHC professional, with permission of the parents, also had access to the advice parents received. During these well-child visits at approximately 18 and 24 months of age, the YHC professionals prescribed intervention conditions based on motivational interviewing techniques to help parents change their child's health-related behaviors [17,21]. At the start of the study, the YHC professionals assigned to perform the intervention received a half-day training session on motivational interviewing techniques (eg, creating awareness, stimulating goal setting). The YHC professionals worked in teams (eg, community physician, nurse), and each team within a preventive YHC organization served one or more municipalities of the region. Each well-child visit was scheduled to last approximately 20 minutes. One month after the well-child visit, the parents received a follow-up email with the advice attached for their convenience and to strengthen the message.

The intervention software (TailorBuiler) was developed by OverNite Software Europe (OSE, Geleen, the Netherlands).

Control Group (Care-As-Usual)

In the control group, the parents received usual care, which included regular YHC well-child visits. The YHC professionals in the control group provided care in accordance with the YHC Overweight Prevention Protocol [5]; they did not receive the information or instructions that were provided to the E-health4Uth Healthy Toddler intervention group [8].

Measures

Primary Outcome Measures

Health-related behaviors were assessed using the BeeBOFT study questionnaires. All questions were adapted from Dutch questionnaires that were used in previous studies [21-23]. The parents reported the following aspects of their child's health-related behavior during the previous 4 weeks: (1) eating breakfast daily, (2) daily exercise and outdoor play, (3) drinking sweetened beverages, and (4) TV viewing and computer use. For details regarding the timing of these assessments and the questions used, see Multimedia Appendix 3.

Daily breakfast was assessed by asking how many days of the week the child ate breakfast. Parents were instructed to report how many days per week and how much time per day their child spent being active and playing outdoors. Activity and outdoor play were added up to calculate an average hours of activity per day. Parents were instructed to indicate the number of glasses of sweetened beverages their child drank per weekday and weekend day. Examples of sweetened beverages were provided. Daily consumption in glasses per day was calculated. Finally, TV viewing and computer use were assessed by asking parents to report the average number of hours their child spent watching TV and/or using the computer per weekday and weekend day. Screen time in hours per day was calculated by adding up TV viewing time and computer time. At each YHC well-child visit, the child's height and weight were measured in accordance with standardized protocols [6]. In addition, any missing birth weight data were obtained from the parent-reported questionnaire. BMI was calculated by dividing the child's weight (in kilograms) by the child's height (in meters squared). Each child was classified as being "normal" weight, overweight, or obese in accordance with international age- and gender-specific cutoff values [7]. A dichotomous variable was created of "normal weight" versus "overweight and obese." In addition, Dutch reference values for children's height and weight measured in 1980 were used to calculate the BMI standard deviation score (BMI-SDS) [1].

Other Measures

The following measures were included to describe the study population, evaluate potential confounding factors [8], and to evaluate potential moderating factors [8]. Data regarding the child and parents' sociodemographic characteristics were obtained from the inclusion questionnaire. Any missing data were obtained using data collected from the questionnaire when the child was 6 months of age. In the questionnaire, the respondents reported their country of birth, the other parent's country of birth, and the country of birth of the child's grandparents. The child's ethnic background was defined as follows in accordance with the definition established by Statistics Netherlands: a parent was classified as non-Dutch if one of his/her own parents was born outside the Netherlands. If one or both of the child's parents were classified as non-Dutch, that child's ethnic background was non-Dutch [24]. The respondents also reported the education level of both parents; education level was classified as one of the following three categories: low (no education or primary school), middle (high school or secondary education level), or high (junior college or university education) [25]. The parents' employment status (unemployed or employed) and height and weight were also assessed. The parents' BMI was calculated by dividing the parent-reported weight (in kilograms) by the height (in meters squared). Each parent was classified as either "normal" weight (BMI <25.0) or overweight and obese (BMI ≥25.0). Respondent self-rated health was assessed with a single item (ie, In general, would you say your health is excellent, very good, good, fair, or poor? Response options: (1) Excellent, (2) Very good, (3) Good, (4) Fair, (5) Poor) [26]. The respondents also reported the expected delivery date and whether breastfeeding had been started after giving birth to the child. Pregnancy duration in days was calculated using parent-reported due date based on calculated date of conception (ie, 280 days of pregnancy) and date of birth of the child. In the control and intervention groups,

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the mother completed the questionnaire for both maternal and paternal characteristics in 93.14% (1030/1094) and 94.65% (954/1008) of cases, respectively (P=.34).

The eHealth module contained questions regarding usability of the module, including the ease of use and whether information regarding health-related behaviors was conveyed in a pleasant manner.

Statistical Analyses

To compare the characteristics between the intervention group and the control group, we used either the Student's t-test (for continuous variables) or the chi-square test (for categorical variables) [27].

Consistent with the data analyses described by Raat et al [8], the following primary outcomes were evaluated at follow-up (ie, when the child was 36 months of age): breakfast daily, activity and outdoor play, sweetened beverages, screen time (ie, TV watching and/or computer use), BMI, and overweight/obesity prevalence. Intention-to-treat analyses were performed using generalized linear mixed models or linear mixed models.

Here, we present the results of three regressions models. The first model did not include a correction for cluster (YHC team); the second model included corrections for cluster; and the third model included corrections for cluster and covariates [28,29]. Research condition (ie, intervention vs control) was entered in the models as an independent variable. Each primary outcome was evaluated as a dependent variable in a distinct model. With respect to the model evaluating BMI at follow-up, the outcome used was the value obtained when the child was as close to 36 months of age as possible (range: 33 to 40 months). Birth weight was added to the models for predicting BMI and BMI-SDS to take into account the impact of birth weight on BMI in later life [28,30]. Where available, each model was corrected for the previous assessment of the outcome at 14 months (for details, see Multimedia Appendix 3).

The following variables were evaluated as potential confounders: (1) pregnancy duration and birth weight; (2) maternal BMI; (3) maternal HRQoL and well-being (ie, self-rated health); and (4) maternal age, education level, and ethnic background [8]. A variable was considered a potential confounding factor when it was associated with the outcome and when it was distributed unequally between the intervention and control groups [27]. Both the child's ethnic background and the mother's country of birth fulfilled the criteria for a potential confounding factor. The child's ethnic background was therefore added to the model as a covariate [27]. In addition, the models were corrected for the age of the child at the time of the follow-up assessment in order to correct for differences in the age at assessment [8,31,32].

Residuals followed a skewed distribution, and health-behavior assessments were log transformed for both the baseline and follow-up variables. Daily breakfast was dichotomized into daily breakfast yes/no because of non-normal distributed residuals after log transformation. Log transformation was performed using the natural logarithm. A constant of 0.01 was added because of zero values; activity n=1, sweet beverages n=192, and screen time n=25. The effect of research group can be interpreted by exponentiation of the coefficient as an approximate percent change in the outcome; percent change in the intervention group=100 x (exp[B]−1).

Subsequently, we evaluated moderation of the intervention effect by child's gender and ethnic background, as well as the mother's education level and weight status [8]. An interaction term between research condition and the potential moderating variable was added to the third multilevel regression model (ie, the model that was corrected for covariates) and was considered significant at P<.10 [32,33]. Stratified analyses were performed only when the interaction term reached this level of significance, and only statistically significant stratified analyses were presented. An overview of all interaction terms can be found in Multimedia Appendix 4.

In addition to the data analyses described in the study protocol [8], the following analyses were performed. Linear mixed models were used to evaluate the effect of the intervention on the longitudinal development of the child's BMI from one month until 36 months of age. The model was adjusted for birth weight, the child's age at each measurement, the child's ethnic background, and an interaction term between age and birth weight. To evaluate whether BMI developed differently between the intervention and control groups, an interaction term between age and research condition was added to the models and evaluated at P<.10. To illustrate the development of BMI over time, Multimedia Appendix 5 presents the splined average BMI of the children versus age for both study groups.

To gain insight into the characteristics of the study participants who were lost to follow-up, we used descriptive statistics to compare the age, country of birth, living situation, and education levels of the mothers who remained in the study through the follow-up measurement (n=1543) with the mothers who were lost to follow-up (n=559). In addition, to get a deeper understanding of the characteristics of the mothers who completed the eHealth module, we also evaluated the abovementioned characteristics between the mothers who completed the eHealth module (n=651) and the mothers who did not complete the eHealth module (n=357) when the child was 18 months of age.

Descriptive statistics were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.0 (IBM Corp). Generalized linear mixed models and other linear mixed models were performed using Statistical Analysis Software (SAS) version 9.4 (SAS Institute Inc).

Results

Study Population

Table 1 summarizes the characteristics of the study population. Compared with the children in the control group, the children in the intervention group were slightly but significantly older at the time of inclusion. Moreover, the intervention group contained a significantly higher percentage of children of Dutch ethnic background and a significantly higher percentage of mothers who were born in the Netherlands.

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Table 1. Characteristics of the study population at study inclusion (n=2102 parents).

Characteristics	Total study population (n=2102)	Control group (n=1094)	Intervention group (n=1008)	*P* [a]
Child characteristics				
Sex (missing n=31), n (%)				
Male	1048 (50.60)	567 (52.55)	481 (48.49)	.07
Age at inclusion in months (missing n=15), mean (SD[b])	0.51 (0.88)	0.47 (0.80)	0.55 (0.95)	.03
Age at the follow-up assessment in months (missing n=810), mean (SD)	36.84 (2.37)	36.87 (2.47)	36.81 (2.27)	.67
Birth weight in kilograms[c] (missing n=14), mean (SD)	3458.41 (525.73)	3453.60 (528.41)	3463.61 (523.03)	.66
Ethnic background[d] (missing n=4), n (%)				
Dutch	1713 (81.65)	862 (78.94)	851 (84.59)	.001
Family situation (missing n=30), n (%)				
Both parents	2029 (97.92)	1053 (97.68)	976 (98.19)	.44
Maternal characteristics				
Age in years (missing n=28), mean (SD)	30.88 (4.33)	30.99 (4.41)	30.75 (4.24)	.21
Pregnancy duration in days (missing n=66), mean (SD)	277.38 (10.72)	277.01 (10.96)	277.77 (10.44)	.11
Started breastfeeding? (missing n=34), n (%)				
Yes	1584 (76.60)	795 (73.75)	789 (79.70)	.002
BMI[e] in kg/m^2 (missing n=152), mean (SD)	25.09 (4.21)	25.26 (4.45)	24.91 (3.88)	.06
Country of birth (missing n=7), n (%)				
The Netherlands	1931 (92.17)	984 (90.36)	947 (94.14)	.001
Education level (missing n=29), n (%)				.26
Low	272 (13.12)	148 (13.77)	124 (12.43)	.15
Mid	725 (34.97)	359 (33.40)	366 (36.67)	.80
High	1076 (51.91)	568 (52.84)	508 (50.90)	.07
Employment status (missing n=67), n (%)				
Employed	1683 (82.70)	867 (82.3)	816 (83.18)	.60
Self-rated health[f] (missing n=713), n (%)				
Very good or excellent	790 (56.88)	395 (57.92)	395 (55.87)	.45

[a]The *P*-value is based on an independent Student's t-test (for continuous variables) or the chi-square test (for categorical variables) to analyze the difference between the control and intervention groups.

[b]SD: standard deviation.

[c]Birth weight was collected by the Youth Health Care professional; if missing, this value was obtained from the parent's inclusion questionnaire.

[d]Ethnic background of the child was based on the grandparents' country of birth as described by Statistics Netherlands. If one or both grandparent were born outside the Netherlands, the parents were categorized as non-Dutch. If one or both of the parents were categorized as non-Dutch, the child was also categorized as being of non-Dutch origin.

[e]BMI: body mass index.

[f]Self-rated health of the parent when the child was 36 months of age.

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Table 2. Descriptive summary of the primary outcomes measured at 14 months and at follow-up.

Primary outcomes	14 months[a]			36 months[b]		
	Control group	Intervention group	*P* [c]	Control group	Intervention group	*P* [c]
Daily breakfast 7 days/week, %	98.0	98.0	.55	96.7	98.3	.03
Activity, hours/day, mean (SD[d])	1.91 (1.30)	1.88 (1.24)	.72	2.56 (1.40)	2.68 (1.13)	.19
Sweetened beverages, glasses/day, mean (SD)	1.34 (1.16)	1.39 (1.24)	.39	2.31 (1.51)	2.10 (1.28)	.003
Screen time[e], hours/day, mean (SD)				1.22 (0.92)	1.05 (0.74)	<.001
BMI[f], mean (SD)	16.75 (1.25)	16.83 (1.24)	.18	15.66 (1.29)	15.78 (1.23)	.12
BMI-SDS[g], mean (SD)	-0.25 (0.96)	-0.17 (0.94)	.10	-0.17 (1.02)	-0.06 (1.01)	.048
Overweight or obesity[h], %				3.99	4.77	.51

[a]Number of missing values range 448 to 541

[b]Number of missing values range 559 to 915

[c]*P* value from independent t-test for continuous variables and chi-square tests for categorical variables.

[d]SD: standard deviation.

[e]Not assessed before 36 months.

[f]BMI: body mass index.

[g]BMI-SDS: body mass index-standard deviation score.

[h]Percentage of overweight and obesity defined by the international age-and gender specific cutoff values; cannot be defined before the age of 24 months.

Primary Outcome Measures

Table 2 summarizes the descriptive results and statistical analyses of the health-related behaviors, BMI, and the prevalence of overweight/obesity among the children in the intervention and control group at both 14 and 36 months of age.

At 36 months of age, significantly more children in the intervention group ate breakfast daily (*P*=.03) as compared with the control group. In addition, children in the intervention group drank less sweetened beverages (*P*=.003). Moreover, children in the intervention group had less screen time compared with the children in the control group (*P*<.001).

At 36 months of age, the BMI of children in the control group and the intervention group was 15.66 (SD 1.29) and 15.78 (SD 1.23), respectively (*P*=.12). Children in the intervention group had a BMI-SDS closer to the reference population as compared with the children in the control group (−0.06, SD 1.01 vs −0.17, SD 1.02, between group difference *P*=.048). The percentage of children classified as being overweight or obese was similar between the two study groups (*P*=.51).

The results of the regression analyses are summarized in Table 3, in which we evaluated the effect of the E-health4Uth Healthy Toddler intervention compared with the control group at 36 months of age. Without correction for cluster or covariates, children in the intervention group decreased 13.06% in screen time at follow-up compared with the control group (95% CI −20.55 to −3.92, *P*=.005); after correction for cluster and covariates the coefficient was no longer significant. No significant effects were found with respect to the other health-related behaviors.

With regard to BMI the third model (ie, the model corrected for potential covariates) revealed a beta value for BMI at follow-up of .10 (95% CI −0.15 to 0.36) for the children in the intervention group as compared with the children in the control group; for BMI-SDS, beta was .12 (95% CI −0.091 to 0.33). With respect to overweight/obesity, the odds ratio at 36 months for the children in the intervention group was 0.79 (95% CI 0.44-1.43) compared with the children in the control group.

Longitudinal Development of BMI

In addition, we analyzed BMI and BMI-SDS longitudinally. The interaction term between the study group and age was not significant for either BMI or BMI-SDS (*P*=.27 and *P*=.39, respectively), indicating that the relationship between BMI and age did not differ significantly between the intervention and control group. Multimedia Appendix 5 shows the splined average BMI values of the children in the intervention and control groups.

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Table 3. Results of the three models evaluating primary outcomes among the children at 36 months of age.

Primary outcomes at 36 months	Model 1[a,b]		Model 2[c,b]		Model 3[d,b]	
	Intervention group[e]	*P*	Intervention group[e]	*P*	Intervention group[e]	*P*
Daily breakfast (yes), OR[e] (95% CI)[f]	1.55 (0.74 to 3.25)	.25	1.55 (0.72 to 3.34)	.25	1.31 (0.56 to 3.10)	.52
Activity and outdoor play[g], hours/day, beta (95% CI)	.04 (−0.02 to 0.10)	.18	.04 (−0.05 to 0.13)	.38	.05 (−0.04 to 0.15)	.29
Sweetened beverages[g], glasses/day, beta (95% CI)	−.14 (−0.31 to 0.03)	.11	−.14 (−0.31 to 0.03)	.11	−.16 (−0.34 to 0.03	.10
Screen time[g], hours/day, beta (95% CI)	−.14 (−0.23 to −0.04)	.005	−.09 (−0.27 to 0.08)	.30	−.07 (−0.25 to 0.12)	.47
BMI[h], beta (95% CI)	.11 (−0.03 to 0.25)	.13	.11 (−0.15 to 0.36)	.40	.10 (−0.15 to 0.36)	.43
BMI-SDS[i], beta (95% CI)	.11 (0.00 to 0.22)	.06	.12 (−0.09 to 0.33)	.26	.12 (−0.09 to 0.33)	.28
Overweight or obesity[j], OR (95% CI)	0.83 (0.48 to 1.46)	.52	0.83 (0.46 to 1.49)	.52	0.79 (0.44 to 1.43)	.43

[a]Model 1: corrected for the previous assessment of the outcome (where available).

[b]Models evaluating BMI, BMI-SDS and % overweight or obesity are corrected for birth weight of the child.

[c]Model 2: corrected for cluster Youth Health Care (YHC) team and the previous assessment of the outcome (where available).

[d]Model 3: corrected for cluster (YHC team), the previous assessment of the outcome (where available), the child's ethnic background, and the child's precise age at follow-up.

[e]OR: odds ratio.

[f]The estimated coefficients and their 95% confidence interval (95% CI) are given for the children in the intervention group relative to the children in the control group.

[g]The previous assessment of the outcome (where available) and the outcome at follow-up were log transformed

[h]BMI: body mass index.

[i]BMI-SDS: body mass index-standard deviation score.

[j]Percent overweight or obese is based on the definition reported by Cole et al [7].

Evaluation of Moderating Factors

After observing a significant interaction term between potential moderators and the study groups, we performed stratified analyses. Our analysis revealed that the boys in the intervention group were more likely to eat breakfast daily compared with the boys in the control group at follow-up (OR 10.20; 95% CI 1.75-88.60). Non-Dutch children in the intervention group were 25.86% more active at follow-up compared with the non-Dutch children in the control group (95% CI 0.80-56.83, *P*=.04). Children with low educated mothers in the intervention group decreased 46.74% in screen time as compared with children of low educated mothers in the control group (95% CI −70.48 to −4.88, *P*=.03). Children of mothers with a BMI categorized as "normal" in the intervention group drank 36.24% less sweet beverages at follow-up compared with the children of "normal" weight mothers in the control group (95% CI −54.16 to −10.42, *P*=.009). Children of mothers with a BMI classified as overweight or obese in the intervention group showed 26.11% less screen time at follow-up compared with children of mothers with a similar BMI categorization in the control group (95% CI −46.74 to −2.96, *P*=.03).

Other Outcome Measures

Parents' Evaluation of the Intervention

The eHealth module was completed primarily by the mother when the children were 18 and 24 months of age (626/651, or 96.2%, and 610/638 missing n=2, or 95.9%, respectively). The parents also reported that they found the eHealth module easy to use (470/651 missing n=81, or 82.5%, and 469/638 missing n=67, or 82.1%, when the children were 18 and 24 months of age, respectively). At 18 months, 60.1% (342/651 missing n=82) and 61.6% (350/651 missing n=83) of parents appreciated receiving information regarding physical activity and nutrition, respectively, via the eHealth module.

Evaluation of the Characteristics of Parents Who Were Not Lost to Follow-Up and Parents Who Completed the eHealth Module

On an average, the mothers who participated through to the follow-up time point were older than the mothers who were lost to follow-up (31.11, SD 4.18 vs 30.24, SD 4.65 years, respectively; *P*<.001). In addition, a higher percentage of these mothers were born in the Netherlands (93.05%, 1433/1543 vs 89.73%, 498/559, respectively; *P*=.009) and lived with their partner (98.55%, 1499/1543 vs 96.19%, 530/559, respectively; *P*=.001). Finally, a higher percentage of these mothers had a higher level of education (56.04%, 858/1543 vs 40.22%, 218/559, respectively; *P*<.001).

In total, 651 out of 1008 (64.58%) parents completed the eHealth module when their child was 18 months of age, compared with 357 out of 1008 (35.42%) parents who did not complete the eHealth module at this time point. On an average, the mothers who completed the eHealth module at this time point were older than the mothers who did not complete the module (31.06, SD 4.06 vs 30.19, SD 4.50 years, respectively; *P*=.003). In addition, a higher percentage of these mothers were born in the Netherlands (95.4%, 621/651 vs 91.8%, 326/355, respectively; *P*=.17) and had a high level of education (58.7%, 380/647 vs 36.5%, 128/351, respectively; *P*<.001).

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Discussion

Principal Findings

In this study, we evaluated the effects of the E-health4Uth Healthy Toddler intervention on the child's health-related behaviors and BMI [8]. The E-health4Uth Healthy Toddler intervention provided parents with personalized advice regarding overweight-related health behaviors for their child at the ages of 18 and 24 months. This advice was then discussed between the parent and YHC professional during a regular face-to-face well-child visit. Our analysis revealed no significant effect of the intervention on health-related behaviors, BMI, BMI-SDS, or the prevalence of overweight/obesity. Significant interaction terms indicated that the intervention had positive effects on subgroups of children, namely boys, non-Dutch children, children of low educated mothers, and children from mothers with a "normal" and overweight and obese classified BMI. The intervention was generally appreciated by the parents.

Interpretation

This study adds to the overall knowledge base regarding educating parents in order to optimize the healthy behaviors of young children [34]. This is one of the first studies to combine an eHealth intervention with personalized counseling at a YHC setting, particularly with respect to both diet and physical activity. To date, relatively few interventions have been performed among children 2 years of age or younger, and the primary focus of these studies was parental feeding practices such as breastfeeding or the management of specific problems [34,35]. Similar interventions performed in primary care settings and/or well-child clinics have been evaluated among parents of slightly older children (5-10 years of age) [21,36,37]; these studies reported small beneficial effects of the intervention on the child's health-related behaviors and BMI. Thus, in theory the relatively younger children in our study may require a longer follow-up period in order to observe significant effects, particularly given that the E-health4Uth Healthy Toddler intervention focuses on primary prevention and therefore, the promotion of healthy behaviors and BMI. Interventions specifically designed for young children who are at a risk for becoming overweight—or are already overweight or obese—may benefit from such an intervention at an earlier age.

Our results show that at baseline and at 36 months of age, the children in the intervention group had a higher BMI as compared with the children in the control group; we currently have no explanation for this finding. In fact, compared with the age- and gender-matched reference population measured in 1980, the children in the entire study sample had relatively healthier BMI-SDS values. It is important to note that the Dutch reference population values from 1980 were measured just before the overweight epidemic [1]. On an average, the age-and gender-corrected standardized BMI values of the children in our study were only slightly higher than the reference values. Interestingly, the children in our sample were generally taller than the children in the 1980 reference population; however, van Dommelen et al [38] reported that taller children tend to be overweight more often than shorter children. Another explanation might be the fact that our sample contained a relatively higher number of mothers with high education; such parents tend to have less overweight children [39]. The finding of this relatively healthy sample, however, would not necessarily influence the results obtained between the two groups, although it could have limited the potential effects that could have been observed. Nevertheless, the need for an intervention that is independent of the child's weight status is supported by the prevalence of unhealthy lifestyle behaviors among the children in our sample.

The importance of factors in early life that determine the development of overweight among children reflects the need to further develop and optimize interventions designed specifically for parents of young children [34,39,40]. In this respect, some of the elements in the E-health4Uth Healthy Toddler intervention may be helpful. In order to be feasible for use in a wide range of YHC settings, and to minimize the burden on the parents, a relatively low-intensity intervention was designed; this intervention includes two eHealth modules, with personalized advice for parents and a discussion of this advice during the two regular well-child visits at a YHC organization. This approach has two advantages. Firstly, the combination of Web-based personalized advice together with a face-to-face well-child visit at the YHC organization might increase the intervention's effectiveness [9-11,41]. Importantly, the E-health4Uth intervention provides the parents with information regarding their child's health-related behaviors before the well-child visit. Thus, the parents can read the information in advance at their leisure, which may increase the likelihood that the information will be well-received during the well-child visit [42]. Secondly, if the YHC professional utilizes the advice that the parents received before the well-child visit, the visit can be designed more efficiently to discuss the child's most relevant health-related behaviors. The personalized advice is based on the parents' knowledge, and the child's health-related behavior. Because the YHC professional receives a copy of the advice given to the parents, this information can be used to customize the information provided to the parents during the well-child visit [42,43]. During the well-child visit, motivational interviewing techniques are used by professionals to help the parents effect change in the child's behavior; the use of these techniques may contribute to the effectiveness of interventions [44,45]. Finally, the intervention focuses on the child's health-related behaviors rather than the child's weight status. Interventions performed in primary care (or comparable) settings often encounter difficulty with respect to motivating the parents to change their health-related behaviors, usually due to the fact that many parents either underestimate or overestimate their child's weight status [42,43,46,47]. Moreover, many parents cannot remember the information and/or advice that was provided after their child's height and weight were measured [42]. Therefore, the focus on the child's health-related behaviors in the E-health4Uth Healthy Toddler intervention is another possible advantage and may create a reason to discuss the child's overweight status, if needed.

Other elements of the E-health4Uth Healthy Toddler intervention can be optimized and/or revised. For example, to increase its effectiveness, the intervention can be revised to give specific advice to parents of children beyond 24 months and/or

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to at an earlier age (ie, before 18 months) [48,49]. Providing parents with information regarding healthy lifestyle behaviors can have long-term benefits with respect to the targeted health-related behavior, as shown previously by Talvia et al [50]. Such a continuum of interventions focusing on parents from the birth of their child through childhood seems promising and is well-suited to the early life systems approach, which includes interventions during pregnancy, infancy, and the toddler years [40]. In this type of approach, one of the key pathways includes the behavior, policy, and practice of health care providers to promote a healthy lifestyle [40,51] by targeting several risk factors for overweight (eg, maternal smoking, overweight, and sleeping patterns) [39,52]. In this respect, the E-health4Uth Healthy Toddler intervention meets the criteria for an early life systems approach.

The E-health4Uth Healthy Toddler intervention offers the opportunity to provide parents with important messages that are strengthened by personal counseling with the YHC professional [10]. Such messages can be delivered to parents more effectively when professionals use motivational interviewing techniques [45]. However, to ensure the adequate and proper use of these techniques, continuous practice by the professional and repeated training sessions can help improve future interventions [45,53]. Also, the integrity of the use of motivational interviewing techniques may be evaluated more closely using specific instruments such as the Motivational Interviewing Treatment Integrity Code [54].

Future studies should be designed to test potential beneficial effects of combining an eHealth module with face-to-face counseling among various subgroups such as children of less-educated parents, children of non-Dutch ethnic background, and gender subgroups. Therefore, the E-health4Uth Healthy Toddler intervention can be easily adapted for use in these subgroups [46,55]. Moreover, the intervention can be revised in order to improve other characteristics of the target population. For example, advice regarding physical activity can be optimized by providing parents with local outdoor play opportunities for their children based on their zip code and/or geographic region. This type of specific, personalized advice could be added to the eHealth module; alternatively, it could be provided during the counseling session with the YHC organizations themselves, as these organizations operate within local communities and are keenly aware of local activities such as after-school physical activity programs.

Strengths and Limitations

The strength of our approach was our collaboration with the Dutch YHC organizations, which enabled us to perform a large-scale cluster RCT using Web-based eHealth combined with face-to-face counseling by community-based pediatric health care professionals engaged in daily practice. This approach also provided the opportunity to obtain a large dataset of objectively measured height and weight outcomes for the children whose parents participated in the study. In addition, the response rate among the parents was relatively high (approximately 75%), enabling us to conduct a relatively thorough evaluation of the intervention's effects on health-related behaviors and BMI.

A limitation of the study was the transformation of outcome variables, namely activity, sweetened beverages, and screen time. We performed sensitivity analyses using the dichotomized version of these primary outcome variables (data not shown) and similar results, that is, no significant differences between intervention and control group, were observed. Another possible limitation of this study was the use of self-report questionnaires, in which parents may have underestimated or overestimated their child's behavior. However, given that the same assessment materials were used in both the intervention and control groups, this effect—if present—would not likely have affected our results. Moreover, parents with a higher education were more likely to participate in the follow-up measure and in the intervention. Even though the sample may not perfectly represent the general population in the Netherlands, the sample size was sufficiently large for us to evaluate the potential moderating effects among higher and lower educated parents. Regardless, future research and implementation of these types of interventions should emphasize on hard-to-reach lower educated parents. One option for reaching these parents is to provide the eHealth module in the waiting room when the parents arrive for their well-child visit; this approach would also create an opportunity for parents to ask questions to the nurse and/or physician directly after completing the eHealth module.

Conclusions

This large cluster RCT evaluated the E-health4Uth Healthy Toddler intervention, which combines an eHealth module with face-to-face interaction between parents and YHC professionals. Our analysis revealed limited evidence with regard to health behavior and overweight prevention in young children. However, some indications for effects among subgroups of parents and children, such as less-educated parents, were observed. The E-health4Uth Healthy Toddler intervention is relatively easy to implement in community medicine and preventive pediatric practice and can serve as an important addition to current medical guidance and health-promoting practices. This low-intensity intervention can be added to regular care and may save health care professionals valuable time that can be used to focus on health-related behaviors that are determined to be most relevant by the eHealth module. The combination of personalized advice and face-to-face counseling likely increases the effectiveness of this type of intervention [11]. The results of our analysis suggest that some elements of the E-health4Uth Healthy Toddler intervention can be improved further. For example, the intervention can be adapted for parents of children younger than 18 months and children older than 24 months [40]. Thus, information regarding the child's healthy lifestyle behaviors will be conveyed to parents repeatedly, potentially improving its long-term benefits [48]. The intervention can be offered in a pediatric setting, as well as in other settings such as general practice. Importantly, the advice provided to the parents should be specific to the age of the child. In summary, this eHealth module can be adapted relatively easily to reach out to a wide range of parents, thereby contributing to reducing the prevalence of childhood overweight and obesity.

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Acknowledgments

This study was funded by a grant from ZonMW, the Netherlands Organization for Health Research and Development (grant number 50-50110-96-491) and a grant from NWO, the Netherlands Organization for Scientific Research. These funding sources had no role in the design or conduct of the study; in the collection, analysis, or interpretation of the data; or in the preparation, review, approval, or submission of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

E-health4Uth Healthy Toddler intervention example advise sweetened beverages.

[JPG File, 152KB - jmir_v19i7e268_app1.jpg]

Multimedia Appendix 2

E-health4Uth Healthy Toddler intervention example advise activity.

[JPG File, 165KB - jmir_v19i7e268_app2.jpg]

Multimedia Appendix 3

Summary of the items for assessing the children's health-related behaviors.

[PDF File (Adobe PDF File), 28KB - jmir_v19i7e268_app3.pdf]

Multimedia Appendix 4

Overview of interaction terms.

[PDF File (Adobe PDF File), 23KB - jmir_v19i7e268_app4.pdf]

Multimedia Appendix 5

Splined average of the BMI values in the intervention and control group.

[PNG File, 62KB - jmir_v19i7e268_app5.png]

Multimedia Appendix 6

CONSORT E-HEALTH checklist (V1.6.1).

[PDF File (Adobe PDF File), 519KB - jmir_v19i7e268_app6.pdf]

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Abbreviations

BMI: body mass index
BMI-SDS: body mass index-standard deviation score
HRQoL: health-related quality of life
OR: odds ratio
RCT: randomized controlled trial
SAS: Statistical Analysis Software
SD: standard deviation
SPSS: Statistical Package for the Social Sciences
TV: television
YHC: youth health care

Edited by G Eysenbach; submitted 20.12.16; peer-reviewed by JR Bautista, G Pietrabissa; comments to author 13.02.17; revised version received 01.05.17; accepted 02.05.17; published 27.07.17.

Please cite as:
van Grieken A, Vlasblom E, Wang L, Beltman M, Boere-Boonekamp MM, L'Hoir MP, Raat H
Personalized Web-Based Advice in Combination With Well-Child Visits to Prevent Overweight in Young Children: Cluster Randomized Controlled Trial
J Med Internet Res 2017;19(7):e268
URL: http://www.jmir.org/2017/7/e268/
doi:10.2196/jmir.7115
PMID:28751299

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Review

Web-Based Interventions to Improve Mental Health, General Caregiving Outcomes, and General Health for Informal Caregivers of Adults With Chronic Conditions Living in the Community: Rapid Evidence Review

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Abstract

Background: Most adults with chronic conditions live at home and rely on informal caregivers to provide support. Caregiving can result in negative impacts such as poor mental and physical health. eHealth interventions may offer effective and accessible ways to provide education and support to informal caregivers. However, we know little about the impact of Web-based interventions for informal caregivers of community-dwelling adults with chronic conditions.

Objective: The purpose of this rapid evidence review was to assess the impact of Web-based interventions on mental health, general caregiving outcomes, and general health for informal caregivers of persons with chronic conditions living in the community.

Methods: A rapid evidence review of the current literature was employed to address the study purpose. EMBASE, MEDLINE, PsychInfo, CINAHL, Cochrane, and Ageline were searched covering all studies published from January 1995 to July 2016. Papers were included if they (1) included a Web-based modality to deliver an intervention; (2) included informal, unpaid adult caregivers of community-living adults with a chronic condition; (3) were either a randomized controlled trial (RCT) or controlled clinical trial (CCT); and (4) reported on any caregiver outcome as a result of use or exposure to the intervention.

Results: A total of 20 papers (17 studies) were included in this review. Study findings were mixed with both statistically significant and nonsignificant findings on various caregiver outcomes. Of the 17 included studies, 10 had at least one significant

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outcome. The most commonly assessed outcome was mental health, which included depressive symptoms, stress or distress, and anxiety. Twelve papers examined the impact of interventions on the outcome of depressive symptoms; 4 found a significant decrease in depressive symptoms. Eight studies examined the outcome of stress or distress; 4 of these found a significant reduction in stress or distress as a result of the intervention. Three studies examined the outcome of anxiety; 2 of these found significant reductions in anxiety. Other significant results of the interventions were seen in the outcomes of caregiver gain (ie, positive aspects of caregiving), knowledge, bonding, reduction of anger-hostility, and negative mood. Based on this review, it is not possible to determine which interventions were most effective since studies differed in their design, sample, and intervention. Study results suggest that Web-based interventions may result in reduced depressive symptoms, anxiety, and stress or distress among informal caregivers of adults with chronic conditions in the community.

Conclusions: This is the first review assessing the impact of Web-based technologies on mental health, general caregiving outcomes, and general health for caregivers of adults with chronic conditions living in the community. Further rigorous research is needed that includes adequately powered studies examining the critical components of the intervention and the dosage needed to have an effect.

(J Med Internet Res 2017;19(7):e263) doi:10.2196/jmir.7564

KEYWORDS

Internet; review; chronic disease; adult; caregivers

Introduction

The number and proportion of adults living with chronic conditions is increasing globally. These adults are likely to live at home and rely on informal caregivers for support. Although informal caregivers experience rewards associated with caregiving, they also experience negative impacts such as burden, distress, and poor mental and physical health. Web-based programs may offer effective and accessible supports to improve caregiver outcomes. The purpose of this rapid evidence review was to assess the impact of Web-based interventions on mental health, general caregiving outcomes, and general health for informal caregivers of persons with chronic conditions living in the community.

Longer life expectancies and an aging population mean that an increasing number of adults are likely to develop chronic conditions and need complex care now and into the future. Globally, 68% of all deaths in 2012 were due to noncommunicable diseases such as cardiovascular disease, cancer, and diabetes [1]. In the United States in 2012, half of all adults had one or more chronic conditions and these were the leading cause of death and disability [2]. Increasingly, adults have multiple (two or more) chronic conditions (MCC). These individuals often experience poor health-related quality of life, are at increased risk for adverse events, and use more health services compared with those with a single condition [3]. For many individuals with chronic conditions, such as the estimated 228,000 Ontarians living with dementia, there are long-term health and social impacts of illness [4]. Unlike other health issues, chronic diseases are generally slow progressing, making their impact on society longstanding, expensive, and complex.

Most adults with chronic conditions live at home and rely on informal caregivers such as spouses, children, or other family or friends for support. Reasons for this reliance on informal caregivers include the limited hours of available home care, difficulty accessing services, and resistance to accepting outside help. Informal caregivers play a critical role in helping care recipients live with the complex issues of chronic conditions in their own homes rather than institutions [5,6].

In 2012, over one-quarter of Canadians aged 15 years and older (8.1 million individuals) provided care to a chronically ill, disabled, or aging family member or friend in the previous 12 months [7]. Caregiving tasks include providing transportation, housework and house maintenance, scheduling and coordinating medical appointments, help with finances, emotional support, and personal care. The median time spent on caregiving was 3 hours per week and for spousal caregiving, 14 hours per week [7]. The estimated economic contribution to the Canadian health care system of unpaid caregivers for older adults in 2009 was Can $25 billion [8]. Caregivers have multiple responsibilities in addition to their caregiver role, with 60% working at a paid job and 28% having children under the age of 18 years [7].

Although there are rewards associated with caregiving, caregivers have reported negative outcomes such as poor mental and physical health [7]. A meta-analysis of 84 studies found that caregivers have statistically significant higher levels of stress and depression and lower levels of subjective well-being, physical health, and self-efficacy compared with noncaregivers [9]. Furthermore, a prospective population-based cohort study found that, among older caregivers, a state of mental or emotional strain was associated with a 63% higher risk of mortality compared with noncaregivers [10]. Although these conclusions need to be carefully considered with respect to health care context and current understanding, it does illuminate the burden that caregivers may face. Caregiving may also result in disruptions to work routines [7]. Given the negative impacts of caregiving, caregivers may require support to ensure their own well-being.

Many interventions designed to support informal caregivers have been evaluated and have the potential to improve caregiver outcomes. A recent systematic review of systematic reviews on interventions for caregivers of persons with chronic conditions found that education and support interventions improved caregiver quality of life [11]. Most caregiver support interventions are offered face to face. eHealth interventions may offer efficient, less costly, and more accessible ways to provide education and support to informal caregivers [12]. Web-based

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interventions may be more easily accessed by caregivers from their own homes or workplaces.

There has been a rapid growth in the use of the Internet in the past 15 years, with 84% of American adults and 88.5% of Canadians using the Internet [13-15]. Although variable rates occur between socioeconomic and age groups, Canada leads Web-based engagement, with the average Canadian spending over 41 hours on the Web each month [13]. The fastest growing demographic for Internet use is in adults aged 55 years and above [13]. Furthermore, 80% of Internet users go on the Web to seek health information [5]. The Internet has become a valuable tool to provide information and connect people with others who are experiencing similar health issues and "enables new pathways for patients to find and help each other" (p. 6) [5]. In addition, caregivers of people with chronic disease often seek information and support on the Web [5]. Twenty-six percent of adult caregiver Internet users went on the Web to find other individuals who were caring for loved ones [5]. One of the groups most likely to look on the Web for health information comprises adults who have provided unpaid caregiving within the past 12 months [5]. Given this high Internet use and the potential for gaining valuable health information and support, Web-based interventions may play an integral role in decreasing caregiver burden and distress and improving their health outcomes.

Multiple systematic or other reviews of technology interventions (eg, the Web and telephone) to support informal caregivers of adults in the community have been noted in the literature [16-25]. These reviews examined the impact of the interventions on a variety of caregiver outcomes such as mental health (eg, stress, depressive symptoms, and anxiety), burden, quality of life, and social support. Most reviews concluded that there were mixed findings of the impact of the interventions; studies demonstrated positive, none, or negative effects on caregiver outcomes. Overall, mixed results were reported, due primarily to a combination of limited methodological quality (eg, weak design and small sample sizes).

Only 3 reviews focused specifically on Web-based interventions designed for caregivers [18,23,25]. Most reviews were specific to certain caregiving groups, primarily caregivers of persons living with dementia [16-22], cancer [23], and stroke [24]. One review included caregivers of persons with both acute and chronic conditions, as well as a study of caregivers of children [25]; it is not clear how similar or different the experiences, impacts, or effectiveness of technology interventions are among these different subgroups. Two reviews included only randomized controlled trials (RCTs) and controlled clinical trials (CCTs) [19,24]. Other reviews included studies of lower methodological quality than RCTs and CCTs, such as pre-post design studies. Many reviews examined the impact of Web-based technologies on specific outcomes such as caregiver stress [25] or burden [17]. None of the reviews focused specifically on the impact of Web-based interventions on mental health, general caregiving outcomes, and general health for informal caregivers of adults with chronic conditions living in the community.

Methods

Design

We used a rapid evidence review approach [26]. These reviews are a streamlined alternative to standard systematic reviews and meet the needs of faster-paced health care decision-makers [27]. This approach was well suited to the current work as the review was conducted in response to a request from policy decision makers for a synthesis of knowledge related to the impact of Web-based interventions on caregiver outcomes. Consistent with rapid evidence review approaches, we limited the review in selected ways, specifically (1) including only RCTs and CCTs representing the highest quality of study design, (2) including only papers published in English and excluding conference abstracts and dissertations, (3) omitting personal communication with experts as a search strategy, and (4) not including a quality assessment of the included studies.

Search Strategy

A peer-reviewed search strategy was developed by two research librarians at McMaster University. EMBASE, MEDLINE, PsychInfo, CINAHL, Cochrane, and Ageline were searched covering all studies published from January 1995 to July 2016. Reference lists of systematic reviews were searched for relevant studies not captured by our search. Once the search was completed and uploaded, duplicates were removed, and the citations were uploaded to a secure Web-based platform. More detailed information about the search terms is available in Multimedia Appendix 1.

Selection of Studies

The titles and abstracts of papers were reviewed by two members of the synthesis team who collectively have 30 years of experience following Cochrane systematic review methods; any article marked for inclusion by either team member went on to full text rating. Full text inclusion was done independently by two people. All disagreements were resolved through discussions rather than relying on a particular level of kappa score to indicate when discussions were no longer necessary. The inclusion results were reviewed by a third person who was also a member of the synthesis team.

For each study, one team member completed full data extraction using electronic forms. A second team member then verified all extracted data; disagreements were resolved through discussion or third party consultation when consensus could not be reached. For each study, review team members extracted data about the population, the study design, the intervention, and the results for outcomes of interest using a standardized data extraction form. Details of the interventions were extracted based on the Template for Intervention Description and Replication Checklist [28].

Papers selected for this review were any study which included a Web-based modality to deliver an intervention (either stand alone or multi-modal) and met the following criteria: (1) included informal, unpaid adult caregivers of adults (≥ 18 years of age) who were living in the community with a chronic condition or health issue; (2) was either an RCT or a CCT; and (3) reported on any caregiver outcome as a result of use or

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exposure to the intervention. RCTs are trials where the groups compared were established by random allocation, whereas CCTs are trials where the method of allocation of participants to groups was not necessarily random [29].

Results

Search Results

The database search identified 10,047 journal articles and a further 2 articles were identified from other sources (see Figure 1). After duplicates were removed, 7121 articles remained. After additional screening, 6852 articles were excluded, leaving 269 articles for assessment of eligibility. From these, 249 additional articles were then excluded resulting in 20 papers from 17 unique studies that met the inclusion criteria. Of the 20 papers, 19 reported caregiver outcomes. For 1 study, 2 papers reported on caregiving outcomes [30,31], and 1 paper reported on methods [32]. See Multimedia Appendix 2 for a detailed description of the included studies (19 papers that include caregiver outcomes are presented). Of the 17 studies included in this review, 11 were RCTs, 5 were CCTs [12,33-36], and 1 was a combination of both RCT and CCT [37]. Sample size ranged from 19-299 caregivers. Overall, 11 studies were completed in the United States [30,31,33,35,36,38-43], 2 in Canada [34,44], and 1 in both the Netherlands and France, respectively [45,46]. The remaining studies were completed across several countries including the Netherlands and the United Kingdom [47]; Germany, Netherlands, and Belgium [37]; Puerto-Rico, United States, and Mexico [12]; and the United Kingdom, Spain, and Greece [48].

Interventions were targeted at diverse groups of caregivers including caregivers of persons with (1) Alzheimer disease, dementia, or neurodegenerative disease [12,34,37-39,44-48]; (2) cancer [30,31]; (3) stroke [41-43]; (4) heart transplant [33]; (5) traumatic brain injury [40]; (6) chronic disease [36]; and (7) at least one health or safety concern, regardless of their diagnosis [35]. The mean age of caregiver participants in studies reporting the mean (n=16) was 57.72 years. Of the remaining 3 studies, one reported 48% of caregivers were aged 50+ years, another reported 39.8% of caregivers were aged 51+ years, and one stated that >50% of caregivers were aged 55 years and above. Of the 14 studies that reported on caregiver gender, 74.29% of caregivers were female. Two studies specifically targeted employed caregivers [35,36].

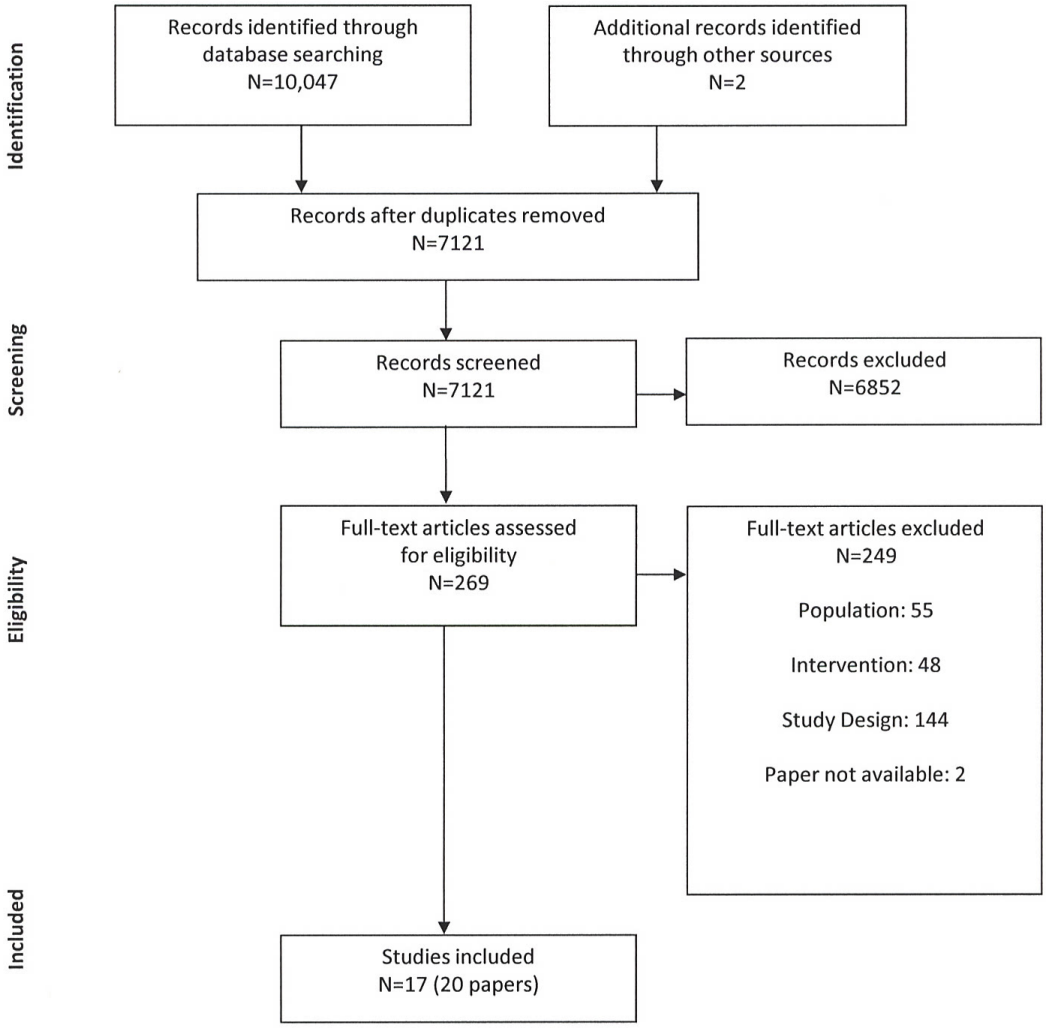
For 17 of the 19 studies that included outcome data, the comparison was between the intervention and a control group; 2 of the CCTs [34,35] compared 2 different interventions. Control groups (described in Multimedia Appendix 2) were (1) provided with usual care only [37,41,43,46,48], (2) provided with usual care plus minimal information (ie, e-bulletins, pamphlets, and newsletters) [12,30,31,39,40,42,45], or (3) wait listed 30-120 days to receive the intervention [38,47]. In one study, the control group consisted of people who did not have access to the website who were part of other longitudinal studies [33]. Three CCTs compared variations with their intervention; one compared being in a Web-based chat support group with a Web-based videoconferencing support group [34], whereas another gave enrolled participants the option of “high tech” or “low tech” support due to concerns over equal access in a work environment [35]. The last CCT used a control group of nonactive participants who posted or read fewer than 4 messages on the online support group [36].

Many caregiver outcomes were assessed across the studies, as indicated in Multimedia Appendix 3. The most common outcomes included (1) mental health outcomes such as depressive symptoms (n=12), stress or distress (n=8), and anxiety (n=3); (2) general caregiving outcomes such as burden (n=5), mastery or self-efficacy (n=5), and social support (n=4); and (3) general health outcomes such as quality of life (n=6) and overall health (n=4).

Based on the results of the literature search, we classified the study interventions into the following categories that were adapted from Jackson et al [16]: (a) single component interventions (information/education) and (b) multicomponent interventions including: (1) information/education plus peer psychosocial support; (2) information/education plus professional psychosocial support; (3) information/education plus peer and professional psychosocial support; (4) information/education plus monitoring plus professional psychosocial support; and (5) monitoring plus peer and professional psychosocial support.

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Figure 1. Study flow diagram.



Single Component Interventions: Information or Education

Three Web-delivered interventions were RCTs categorized as information or education only interventions [38-40]. The intervention, Caregiver's Friend: Dealing with Dementia, included text and videos to support employed caregivers of persons with dementia [38]. The iCare Stress Management program aimed to teach coping skills to caregivers of persons with dementia [39]. The Brain Injury Partners website provided text and video to teach advocacy skills to caregivers of persons with brain injury [40].

Two studies found statistically significant lower stress scores as a result of receipt of the intervention. Beauchamp et al [38] found a reduction in stress after 30 days using a two-question scale (P<.001); Kajiyama et al [39] found a reduction in stress using the Perceived Stress Scale (PSS) following 3 months of the intervention (P=.02). Beauchamp et al found a small reduction in depressive symptoms in the intervention group compared with the control group (P=.009) using the Center for Epidemiological Studies Depression Scale (CES-D). Kajiyama et al also assessed depression using the CES-D but did not find a statistically significant reduction in depressive symptoms (P=.26). One study found statistically significant lower scores for anxiety and caregiver strain, as measured by the State-Trait Anxiety Inventory (P=.03) and Caregiver Strain Instrument (P=.03), respectively, as well as improved scores for self-efficacy in the intervention compared with control group (P=.02) [38]. Finally, a study using Web-based training in family advocacy found statistically significant higher scores for knowledge of (P=.03), ability to apply (P<.001), and intention to use (P<.001) advocacy skills but no difference in satisfaction with life (P=.05) as a result of the intervention [40]. Overall, the three single component Web-based information or education RCT interventions demonstrated mixed findings, with some improvements in mental health and caregiver outcomes reported.

Multicomponent Interventions: Information or Education Plus Peer Psychosocial Support

Two studies, both RCTs, used a combination of information or education and peer psychosocial support offered through the Web [46,47]. The Diapason program, aimed at caregivers of persons with Alzheimer disease, consisted of a website with 12 educational sessions and a private forum for caregivers to interact with peers to share experiences [46]. The Skills Training and Reskilling (STAR) course was a Web-based portal containing eight modules to support caregivers of persons with

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dementia in the Netherlands and the United Kingdom [47]. STAR also offered linkages to communities of other caregivers via Facebook.

In both studies, there were no significant differences between groups on caregiver burden, as measured by the Zarit Burden Interview (ZBI) (*P*=.74) [46] and a single question to assess burden (not reported) [47]. In the Diapason program, no significant differences were found at 6 months between the intervention and control groups in caregiver stress (PSS; *P*=.98), self-efficacy (Revised Scale for Caregiving Self-Efficacy [RSCS], *P*=.52), reaction to problem behavior (Revised Memory and Behavior Problems Checklist [RMBPC]; *P*=.66), depressive symptoms (Beck Depression Inventory; *P*=.56), or self-perceived health (Nottingham Health Profile; not reported). There were no differences between groups at 6 months on the outcomes of knowledge (about Alzheimer disease), stress, self-efficacy (for coping with the illness), or quality of relationship (between caregiver-person with dementia), as measured by a Visual Analog Scale.

In the STAR program [47], there were statistically significant changes from baseline to 2-4 months after the intervention between the intervention and control groups on empathy subscales, as measured by the Interpersonal Reactivity Index (*P*=.003): intervention participants reported that they felt less distressed in tense situations, had more empathy for the well-being of others, and were better able to understand others' situations and actions. There were no statistically significant differences between groups on quality of life (*P*=.97). However, there was a negative effect noted following the completion of the course on one's sense of competence (*P*=.02), where course participants felt less competent to fulfill caregiving roles after the course [47]. Overall, the two multicomponent interventions including information or education plus peer psychosocial support demonstrated minimal impact on caregiver outcomes.

Multicomponent Interventions: Information or Education Plus Professional Psychosocial Support

One RCT comprised an intervention called Mastery over Dementia [45] that included a Web-based course of 8 lessons over 5 to 6 months, homework following each lesson with feedback provided electronically by a coach (psychologist), as well as a final booster session guided by the coach. The course was designed to reduce caregiver depression and anxiety. The intervention group showed statistically significant lower depressive symptoms (CES-D 20) (*P*=.02) and anxiety (Hospital Anxiety and Depression Scale; *P*=.008) from baseline to 5-6 months, noting the effect size for anxiety was moderate (0.48) and small for depressive symptoms (0.26) [45].

Multicomponent Interventions: Information or Education Plus Peer and Professional Psychosocial Support

Ten separate studies (11 papers total) described the impact of multicomponent interventions that included a combination of information or education, plus peer and professional psychosocial support. Two papers reported on an RCT of a Web-based lung cancer information, communication, and coaching system for caregivers called Comprehensive Health Enhancement Support System (CHESS) [30,31]. CHESS comprised information (eg, frequently asked questions, resource directory, and Web links), communication services (eg, discussion board monitored by a professional facilitator and online groups for caregivers), and coaching and training services (eg, data about the patient's health status, decision aids, and coping supports for distress). Following 6 months, the intervention group had statistically significant lower levels of burden, measured with the Caregiver Quality of Life-Cancer scale (CQOLC) burden scale (*P*=.02) and negative mood, measured by the Short Version Profile of Mood States (*P*=.006) than the control group who received only access to websites on lung cancer [30]. However, there were no differences between groups on disruptiveness (ie, the degree to which caregiving tasks interfere with regular daily routines), as measured by the Disruptiveness subscale of the CQOLC (*P*=.15) [30]. In a secondary analysis of the data, Namkoong et al found that the CHESS intervention group perceived higher bonding with other caregivers than the control group, as measured by a 5-item scale (*P*=.04) and that bonding was positively associated with caregivers' coping strategies [31].

Two papers reported on an RCT of Caring~Web [41,43], a Web-based intervention that offered education and support for caregivers of stroke survivors. The Caring~Web program provided access to linked websites about stroke and caregiving, educational information specific to caregivers' needs, an email forum linked to a nurse specialist and rehabilitation team members, and a nonstructured email discussion group of caregivers facilitated by the nurse [41,43]. These studies reported that after 1 year, there were no significant differences between the intervention and control groups on depressive symptoms (CES-D; *P*=.48), life satisfaction (Satisfaction with Life Scale; *P*=.90) [41], caregiver self-rated health as measured by the Multidimensional Functional Assessment of Older Adults, and receipt of emotional support or physical help from family or friends [43].

Using an RCT design, Smith et al [42] adapted the Caring~Web intervention to include a professional guide to facilitate educational modules, 11 educational videos, and chat room sessions. Caregivers in the intervention group reported statistically significant lower depressive symptoms on the CES-D scale (*P*<.01) than the control group [42]. However, there were no differences between groups on mastery, self-esteem, or social support when assessed with the Mastery Scale, Self-Esteem Scale, and the MOS Social Support Survey, respectively [42].

Four studies reported on Web-based supports for caregivers of persons with dementia or neurodegenerative disease [12,34,44,48]. Marziali and Donahue [44] used an RCT to assess the impact of a website, Caring for Others, aimed at caregivers of persons with neurodegenerative disease such as Alzheimer, stroke, and Parkinson. The website included links to information, email, and a videoconferencing link. The videoconferencing link supported participation in a 10-session psychosocial support group, followed by 12 additional online sessions facilitated by a group member. After 6 months, there were no statistically significant reductions following the intervention in depressive symptoms (CES-D), health-related quality of life measured by

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the Health Status Questionnaire, stress experienced in relation to performing activities of daily living (ADL) or instrumental ADL (IADL) for the care recipient, reaction to problem behaviors (RMBPC), or social support as measured by the Multidimensional Scale of Perceived Social Support (MDSPSS). When the authors combined the two stress measures (ADL and IADL) and managing difficult behaviors, they found a statistically significant decline in stress in the intervention group (P<.004) [44].

In a multi-site, CCT study, Marziali and Garcia [34] compared two interventions: (1) a Web-based chat support group plus 6 dementia care educational videos and (2) a Web-based videoconferencing support group facilitated by a health professional. After 6 months, both interventions showed significant improvements in self-efficacy (RSCS; P ≤.04) compared with baseline measures. The videoconferencing support group showed significantly lower distress scores associated with managing deterioration in mental function of the care recipient, measured with the Functional Autonomy Measurement System (P<.02) and a greater improvement in mental health, as measured by the Health Status Questionnaire (P<.02). However, the Web-based chat group had lower distress scores related to managing IADL of the care recipient than the videoconferencing group (P<.02). There were no differences between groups on depressive symptoms (CES-D) or social support (MDSPSS) [34].

Using a CCT design, Pagan-Ortiz et al [12] examined the impact of a website, Cuidate Cuidador, for Spanish-speaking caregivers in three countries: Puerto-Rico, United States, and Mexico. The website included information about Alzheimer disease and related dementias, strategies for managing dementia-related behaviors, a section to interact with other caregivers, and an Ask an Expert resource section. After 1 month, there were no statistically significant differences between the intervention and control group (who received educational materials) on depressive symptoms (CES-D; P=.93), sense of self-mastery (Personal Mastery Scale; P=.17), sense of social support (Lubben Social Network Scale; P=.98), or caregiver burden (ZBI; P=.77) [12].

Torkamani et al [48] used an RCT to test the impact of a computerized platform called ALADDIN (A technology pLatform for the Assisted living of Dementia elDerly INdividuals and their carers) in three countries: United Kingdom, Spain, and Greece. ALADDIN had four key features: (1) ALADDIN TV to provide information and educational material; (2) a social networking forum to connect with other carers; (3) a My Tasks distant monitoring feature where caregivers completed questionnaires about their own health and that of the care recipient, and responses were monitored by clinicians who intervened as needed; and (4) a contact us feature that alerted a request from a clinical site for contact [48]. The ALADDIN group had higher quality of life than the control group at 6 months, as measured by the EuroQol (P=.03); there was no difference in quality of life as measured by the Quality of Life scale (P=.56). There were no statistically significant differences between the ALADDIN intervention group and control group on burden or distress, as measured by the ZBI (P=.19) and the Neuropsychiatric Inventory (P>.05); impact on depressive symptoms was not assessed due to missing data.

One study in this category specifically tested Web-based interventions to support employed caregivers [36]. This CCT compared two types of interventions for caregivers of persons with chronic disease: an online support group professionally facilitated by a clinical nurse specialist, a moderated or peer-directed support group, and a control group which comprised nonactive participants of an online group (posted and viewed less than 4 messages) [36]. At 12 weeks, caregivers in both the professionally facilitated and moderated or peer-directed groups had statistically significant lower depressive symptoms (CES-D; P=.04 and P=.03, respectively) and higher quality of life, as measured by the Caregiver Quality of Life Index than the nonactive participants (P=.01, P=.008) [36]. There were no differences between intervention groups and the control group on caregiver strain (CSI) nor were there differences between the two intervention groups on depressive symptoms (P=.52) or quality of life (P=.71).

Another CCT examined the impact of a Web-based intervention for caregivers of heart transplant recipients compared with people without access to the website [33]. The intervention included “HeartNet” website comprising information on transplant-related health issues, stress and medical regimen workshops, access to electronic communication with the transplant team, and monitored discussion groups. Study participants were assessed 4 to 6 months later and the intervention group caregivers had statistically significant lower anger-hostility symptoms (P=.03), as measured by the Symptom Checklist-90 subscales for anger-hostility, compared with the control group; however, depressive symptoms (P>.05) and anxiety scores (P=.05) were not different between the groups [33].

Overall, the 10 multicomponent interventions involving information or education plus peer and professional psychosocial support showed mixed findings. Some interventions had a positive impact on mental health, caregiving, and general health outcomes, whereas others showed no differences in outcomes between intervention and control groups.

Multicomponent Interventions: Information or Education Plus Monitoring Plus Professional Psychosocial Support

The CCT in this category was the second study to specifically test Web-based interventions to support employed caregivers [35]. Working caregivers received access to either an online caregiver support group moderated by a geriatric or psychiatric nurse, Web-based information and Web-based consultation with a geriatrician, or a remote monitoring system for the older adult to wear at home. The monitoring system provided Web-based status reports and email or pager alerts when activity parameters of the care recipient were exceeded. Following 6 months, results suggested that caregivers in both intervention groups experienced reduced caregiver stress, increased morale, and increased worker productivity, but given the small sample size (N=19), statistical significance was not assessed.

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Multicomponent Interventions: Monitoring Plus Peer and Professional Psychosocial Support

One study (completed in three countries using both RCT and CCT designs) used a combination of the Web plus telephone as the intervention modality compared with usual care that included home care [37]. The Rosetta system involved the home installation of sensors and cameras to support the person with dementia with navigation, an early detection surveillance system that warned carers of changes in day-to-day patterns and activities, as well as a monitoring system to alert in times of emergencies (ie, falls). At the end of the study, approximately 4 months post baseline assessment, there were no significant differences between caregivers who used Rosetta and the usual care group (eg, home care services) on the outcomes of quality of life (P=.37), as measured by the Quality of Life in Alzheimer Disease Scale and feelings of competence (P=.11) using the Short Sense of Competence Questionnaire.

Website Use and Influence on Outcomes

Of the 17 included studies, 11 provided some information about the use of the intervention website (see Multimedia Appendix 4 for details), 5 assessed the impact of website usage on outcomes, 1 reported a significant correlation between time spent on the website and a composite outcome measure [38], 1 found greater website use was correlated with greater improvement on a quality of life domain [33], 1 found a significant correlation between more time on the website and change in knowledge [40], and 2 found no association between website use and outcomes [39,46].

Pragmatic Quality Review of Studies

We used a pragmatic approach consistent with rapid evidence review approaches to identify higher quality studies (without doing a more comprehensive quality assessment which is planned for future work). First, we included only those studies using an RCT design (and excluded the 6 studies using a CCT design). Next, we excluded studies that reported their work as pilot studies; this left us with 7 studies. Finally, we excluded studies that did not provide a sample size calculation; this left us with 2 studies (4 papers) [30,31,41,43]. These two RCTs have been described earlier as the CHESS [30,31] and the Caring~Web studies [41,43] (see Multimedia Appendix 2). Both studies involved multiple components, specifically information or education plus psychosocial support provided by both peers and professionals. The CHESS study included 285 patient-caregiver dyads of persons with advanced nonsmall cell lung cancer and the Caring~Web study included 73 caregivers of first-time stroke survivors. The outcomes of these two higher quality studies were mixed with both statistically significant and nonsignificant findings, similar to the overall review results. The CHESS study found reduced caregiver burden and negative mood, as well as improved bonding but no group differences on coping after 6 months [30,31]. The Caring~Web study found no group differences in depressive symptoms, satisfaction with life, health, emotional support, or physical help after 1 year [41,43]. This analysis of 2 higher quality studies suggests that further research is needed to understand the impact of such interventions.

Discussion

Principal Findings

This is the first known review assessing the impact of Web-based technologies, designed for use by caregivers of adults with chronic conditions living in the community, on caregiver outcomes, specifically mental health, general caregiving outcomes, and general health. This review included only RCTs and CCTs, constituting the most rigorous designs. The findings across studies were not comparable due to variations in design, sample, and interventions. In this review, more than 35 different measures were used to assess intervention outcomes, with the most commonly used tool being the CES-D to assess depressive symptoms (see Multimedia Appendix 3). This heterogeneity of outcome measures limits the ability to conduct comparison across studies. Five studies used nonvalidated tools or items to assess outcomes. The follow-up periods ranged from 1-12 months, with 9 studies having a somewhat limited follow-up of less than 6 months. The included papers provided minimal description of usual care.

Results show a mix of statistically significant and nonsignificant findings on various outcomes of the interventions (see Multimedia Appendix 2). The most important results were related to the positive impact of interventions on mental health: (1) 4 out of 12 studies examining the outcome of depressive symptoms found a statistically significant decrease in depressive symptoms in the intervention group, (2) 4 out of 8 studies examining the outcome of stress or distress found a significant reduction in stress or distress for the intervention group, and (3) 2 of 3 studies that examined the outcome of anxiety found a significant reduction due to the intervention.

General caregiving outcomes were also commonly assessed with mixed findings: (1) 2 of 5 studies found improved mastery or self-efficacy, (2) 1 of 5 studies found reduced burden, (3) 1 of 2 studies found reduced strain, (4) none of 3 studies found improved reaction to care recipient problem behaviors, (5) neither of 2 studies found improved coping as a result of the intervention, and (6) none of 4 studies found improvements in social support. In terms of general health (1) 2 out of 6 studies found an improvement in quality of life, (2) none of 4 studies found improved overall health, and (3) none of 2 studies found improved life satisfaction. Individual studies reported on a variety of other outcomes with mixed findings (see Multimedia Appendix 3).

There were mixed findings across types of interventions (Table 1). Of the 3 studies involving Web-based information or education only, 1 study found primarily positive impacts on mental health and general caregiving, one study found no impact on general health, and a third study found both positive and no effects on mental health outcomes and no impact on general caregiving. Of the 2 studies examining information plus peer support, one found no effect on general caregiving, general health, and mental health outcomes, and a second study found some general caregiving and mental health outcomes were positively impacted, and others had no change. The one study involving information or education and professional support demonstrated improved mental health outcomes. Studies

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including monitoring as part of the intervention found no impact on quality of life [37] or stress [35]. Ten studies (11 papers) included a combination of information or education, peer and professional support. Five of these 10 studies examining a mental health outcome demonstrated an improvement. Only 2 of 8 studies found an improvement in general caregiving outcomes, and 2 of 6 studies found improvement in general health.

Six of the interventions had components that were tailored to the unique needs of caregivers [30,35,38,42,47,48]. Tailoring included, for example, an assessment of baseline knowledge and confidence to help guide the caregiver on which educational module to start with [47]. All but one of these studies demonstrated positive impacts on either mental health, caregiving, or general health outcomes. Previous studies have shown the value of tailoring interventions for behavior change [49].

Two recent systematic reviews of caregiver interventions have compared the impact of Web-based or remote interventions to other types of interventions [16,50]. A systematic review of four types of social support interventions (ie, befriending and peer support, family support and social network, support group, and remote interventions including the Web and phone) for caregivers of persons with dementia concluded that there was insufficient evidence on which intervention type works best to improve social support [50]. However, the authors noted that all intervention types resulted in positive but inconsistent effects on caregiver outcomes such as depression, burden, and quality of life and that multicomponent interventions were more effective than single component interventions. Another review of interventions for caregivers of persons with dementia found that combined telephone and Web-based interventions were more effective than telephone or Web-based interventions alone on outcomes such as depression, burden, and self-efficacy [16]. Both reviews concluded that included studies had important methodological limitations and sources of bias and that further research is warranted to improve the evidence base in this area.

Although there were very few studies (n=17) that met the inclusion criteria and they had mixed findings and diverse types of interventions, this rapid evidence review found that Web-based interventions may result in improvements in mental health outcomes such as depressive symptoms, anxiety, and stress. Furthermore, Web-based interventions that are tailored to the unique needs of caregivers may hold promise for improving caregiver outcomes.

Whereas we did not conduct a formal quality assessment of included studies, our data extraction revealed a number of methodological limitations, similar to other reviews of Web-based interventions to support caregivers [23]. Six studies had very small numbers of study completers (n<50 participants) [12,35,37,42,44,46], which may have resulted in nonsignificant findings; in 2 of those studies which were evaluating feasibility of the intervention, some outcomes could not be evaluated due to small sample size [35,37] (see Multimedia Appendix 2).

Some studies reported high dropout rates of caregivers and limited use of the Web-based intervention; for example, Blom et al [45] reported that almost 40% of caregivers dropped out of the intervention before the end of the study mainly due to lack of time or energy, use of other services, the intervention being less suitable, or a change in the care recipient status. Nonuse in the intervention group could have an impact on the dosage or the amount of the intervention that was needed to have an impact on outcomes. In a review of Web-based interventions for caregivers of persons with cancer, authors identified the limited information available about the dose of Web-based interventions [23]. It is recommended that studies describe the critical components of the intervention and the dosage needed to have an effect [51]. Furthermore, Web-based program developers should consider acceptability of the program to potential users through, for example, codesign efforts.

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Table 1. Outcomes by intervention types.

Outcomes	Intervention Types											
	Information or education only n=3		Information or education plus peer support n=2		Information or education plus professional support n=1		Information or education plus peer and professional support n=11		Information or education plus monitoring and professional support n=1		Monitoring plus peer and professional support n=1	
	Sig[a]	NS[b]	Sig	NS	Sig	NS	Sig	NS	Sig	NS	Sig	NS
Mental health outcomes[c]												
Decreased depressive symptoms	[38]	[39]		[46]	[45]		[42] [36]	[41] [44] [34] [12] [48][d] [33]				
Reduction in stress or distress	[38] [39]		[47]	[46]			[34]	[44] [48]		[35][d]		
Reduction in anxiety	[38]				[45]			[33]				
General caregiving outcomes[e]												
Improved mastery or self-efficacy	[38]			[46]			[34]	[42] [12]				
Reduced caregiver burden				[46] [47]			[30]	[12] [48]				
Reduced strain	[38]							[36]				
Improved reaction to care recipient problem behaviors		[39]		[46]				[44]				
Improved coping		[38]						[31]				
Increased social support								[42] [34] [12] [44]				
General health outcomes												
Improved quality of life		[39]		[47]			[36] [48][f]	[44] [48][f]				[37]
Improved overall health		[40]		[46]				[43] [34]				
Improved life satisfaction		[40]						[41]				
Other outcomes[h]	See details below											

[a]Sig: significant.

[b]NS: Not significant.

[c]Other mental health outcomes: anger-hostility [33][a], negative mood [30][a].

[d]Unable to evaluate.

[e]Other general caregiving outcomes: caregiver gain [38][a], emotional support [43][b], empathy [47][a], reaction to problem behavior and stress measures combined [44][a], self-esteem [42][b]; and sense of competence [37,47][b,g]

[f]Separate tools used for measurement.

[g]Statistically significant negative result.

[h]Other outcomes: ability to apply advocacy skills [40][a], attitudes [47][b], bonding [31][a], disruptiveness [30][b], increased knowledge [40,47][a], intention to use advocacy skills [40][a], perspective [47][a], physical help [43][b], Visual Analog Scale (knowledge, stress, self-efficacy, and quality of relationship) [46][b].

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Overall, there was great heterogeneity in study design (ie, population characteristics, sample size, and randomization) as well as intervention, which may explain some of the variability in the outcomes. However, without conducting further analysis (eg, regressions to control for these variations), any thoughts on the cause of the differences in outcomes would be speculative. Our research team is currently updating the literature review and plans to conduct a meta-analysis, where we will examine differences in outcomes based on factors such as study design and study quality.

Study results suggest that further research is needed in this relatively new area. First, rigorous, well designed, and adequately powered studies are needed to test the impact of Web-based interventions for caregivers. Research should more carefully describe and assess the components and dose of the intervention that are needed to result in improved outcomes. Future research should examine the impact of Web-based interventions on different groups of caregivers [23] and the role of tailoring interventions. Since the impact of caregiving varies among caregivers, it is likely that the impact of interventions aimed at reducing the negative effects of caregiving will vary. Research is also needed to describe the impact of the interventions on caregivers of persons with not just one but multiple chronic conditions, given the high prevalence of multimorbidity among older adults and the complexity experienced by caregivers in supporting these individuals [52].

Study Strengths and Limitations

There are a number of strengths of this review. First, there was a very broad search for relevant papers in 6 key databases and over 10,000 records were reviewed based on a rigorous search strategy developed by two librarians. Second, only studies with the strongest designs, RCTs, and CCTs were included. Third, even though this was a rapid evidence review, a rigorous review approach was maintained, including (1) two expert librarians developed the search strategy; (2) citations in relevant systematic and narrative reviews were assessed for possible papers for inclusion; (3) titles and abstracts of papers were reviewed by two team members; (4) full text inclusion was conducted independently by two people with experience in conducting high quality systematic reviews, and included studies were reviewed by a third person who was also a member of the synthesis team; and (5) one team member completed full data extraction, and this was verified by a second person.

There are also a number of review limitations. First, only English language papers published in peer reviewed journals were reviewed. Second, the search did not include contact with experts, so some relevant studies may not have been included. Third, a formal quality assessment of the included studies was not conducted. This would have provided more detail on some of the methodological strengths and limitations of included studies. This area of study, Web-based interventions for caregivers, is not yet a robust field, and whereas we tried to ensure the highest possible rigor of studies by including only RCTs and CCTs, there was certainly variability in the degree of previous work completed on these interventions. Some interventions were clearly in the pilot phase, whereas others were further along in development and testing. Future research of such interventions should consider fidelity to the intervention and the implementation process.

Conclusions

Web-based interventions to support caregivers of persons with chronic conditions are a relatively new but promising addition to the currently offered caregiver supports. This rapid evidence review suggests that Web-based interventions may result in improved mental health, general caregiving, and general health outcomes, although effects and improvements on study outcomes varied. Based on this review, it is not clear which types of Web-based interventions are most effective and for whom. Further work needs to be done and our team plans to complete an update of the literature and meta-analysis of the data to further add to this discussion. Important potential benefits of Web-based interventions are that they may be less costly than those involving face-to-face support from professionals, and they may be more accessible to caregivers. However, further rigorous research is needed that includes adequately powered studies examining the critical components of the intervention and the dosage needed to have an effect.

Acknowledgments

This project was funded by the Ontario Ministry of Health and Long-Term Care. This project was also supported by the Aging, Community and Health Research Unit, School of Nursing, McMaster University. The authors would like to thank Laura Banfield and Jo-Anne Petropoulos for developing the search strategy and Donna Fitzpatrick-Lewis for her data abstraction assistance.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search terms.

[PDF File (Adobe PDF File), 36KB - jmir_v19i7e263_app1.pdf]

Multimedia Appendix 2

Characteristics of outcome studies.

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[PDF File (Adobe PDF File), 108KB - jmir_v19i7e263_app2.pdf]

Multimedia Appendix 3

Outcome measures.

[PDF File (Adobe PDF File), 64KB - jmir_v19i7e263_app3.pdf]

Multimedia Appendix 4

Website use and influence on outcomes.

[PDF File (Adobe PDF File), 48KB - jmir_v19i7e263_app4.pdf]

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Abbreviations

ADL: activities of daily living
ALADDIN: a technology pLatform for the Assisted living of Dementia elDerly INdividuals and their carers'
CCT: controlled clinical trial
CES-D: Center for Epidemiological Studies Depression Scale
CHESS: Comprehensive Health Enhancement Support System
IADL: instrumental activities of daily living
MCC: multiple chronic conditions
MDSPSS: Multidimensional Scale of Perceived Social Support
PSS: Perceived Stress Scale
RCT: randomized controlled trial
RMBPC: Revised Memory and Behavior Problems Checklist
RSCS: Revised Scale for Caregiving Self-Efficacy
STAR: Skills Training and Reskilling
ZBI: Zarit Burden Index

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Edited by G Eysenbach; submitted 23.02.17; peer-reviewed by E Marziali, P Klemm, D Gustafson; comments to author 30.03.17; revised version received 11.05.17; accepted 07.06.17; published 28.07.17.

Please cite as:
Ploeg J, Markle-Reid M, Valaitis R, McAiney C, Duggleby W, Bartholomew A, Sherifali D
Web-Based Interventions to Improve Mental Health, General Caregiving Outcomes, and General Health for Informal Caregivers of Adults With Chronic Conditions Living in the Community: Rapid Evidence Review
J Med Internet Res 2017;19(7):e263
URL: http://www.jmir.org/2017/7/e263/
doi:10.2196/jmir.7564
PMID:28754652

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Original Paper

Direct-to-Consumer Promotion of Prescription Drugs on Mobile Devices: Content Analysis

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Abstract

Background: US Food and Drug Administration (FDA) regulations state that any prescription drug promotion that presents drug benefits to consumers must also disclose certain information about the drug's risks in a similar manner. Nearly three-quarters of all US mobile phone subscribers use a smartphone, and over half report receiving mobile advertisements on their device.

Objective: The objective of this project was to investigate how prescription drugs are being promoted to consumers using mobile technologies. We were particularly interested in the presentation of drug benefits and risks, with regard to presence, placement, and prominence.

Methods: We analyzed a sample of 51 mobile promotional communications and their associated linked landing pages. We assessed the content and format of the mobile communications and landing pages with regard to presentation of drug benefits and risks.

Results: Of the 51 mobile communications we coded, 41% (21/51) were product claim communications (includes the drug name, benefits, and risks), 22% (11/51) were reminder communications (includes drug name only), and 37% (19/51) were help-seeking communications (includes information about the medical condition but not the drug name). Some of the product claim communications (5/21, 24%) required scrolling to see all the benefit information; in contrast, 95% (20/21) required scrolling to see all the risk information. Of the 19 product claim communications that presented both benefits and risks, 95% (18/19) presented benefits before risks and 47% (9/19) used a bigger font for benefits than for risks. Most mobile communications (35/51, 69%) linked to branded drug websites with both benefits and risks, 25% (13/51) linked to a landing page with benefits but no visible risks, and 6% (3/51) linked to a landing page with risks but no visible benefits. Few landing pages (4/51, 8%) required scrolling to see all the benefit information; in contrast, 51% (26/51) required scrolling to see all the risk information. Of the 35 landing pages with both benefit and risk information, 71% (25/35) presented benefits before risks and 51% (18/35) used a bigger font for benefits than for risks.

Conclusions: These results indicate that, while risks and benefits are both represented in mobile communications and their associated landing pages, they are not equally prominent and accessible. This has implications for compliance with FDA fair balance regulations.

(J Med Internet Res 2017;19(7):e225) doi:10.2196/jmir.7306

KEYWORDS

direct-to-consumer promotion; direct-to-consumer advertising; mobile devices; prescription drugs

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Introduction

Information, entertainment, and advertisement consumption has been steadily moving away from print and network television stations to more specialized and targeted digital outlets, including Internet and mobile devices. By 2012, half of all mobile subscribers in the United States owned a smartphone [1], jumping to nearly three-quarters within 3 years [2]. In 2013, 57% of US smartphone owners reported receiving mobile ads at least once a day [3]. Prescription drug direct-to-consumer (DTC) promotion expenditure on the Internet experienced triple-digit growth between 2005 and 2009, compared with a decrease in other media channels [4]. One report [5] estimated that 3 billion to 7 billion pharmaceutical and drug promotional messages were being delivered online each month. Another noted that US health care and pharmaceutical advertisers spent US $373 million on mobile formats in 2014 [6]. Nevertheless, prescription drug promotion, while well represented on the Internet in the form of websites, has been slower to branch into mobile promotion beyond paid searches. One possible cause of this could be the issuance of US Food and Drug Administration (FDA) "enforcement" warning and untitled letters about sponsored links on Internet search engines in 2009 [7], which stated that online promotion is subject to existing laws and implementing regulations [8,9]. In particular, the US Food, Drug, and Cosmetic Act and implementing regulations state that any prescription drug promotion that presents drug benefits to consumers must also disclose certain information about the drug's risks in a similar manner. This concept of "fair balance" may be challenging in mobile promotional communications (hereafter referred to as "mobile communications"), where there are often limitations on the amount of information that can be presented.

Content analyses have found fair balance lacking in DTC marketing in print [10-12], television [11,13-15], websites [16-18], social media sites [19], and Internet banners [20]. It is also important to have an accurate picture of the mobile promotion landscape in order to make informed decisions about mobile DTC promotion. The purpose of this content analysis was to explore the presentation of drug benefits and risks in (1) mobile communications and (2) landing pages (ie, the first page of the website to which the communication linked).

Methods

After evaluating the capabilities of several companies, we chose to use a commercially available dataset of mobile-enhanced DTC promotional communications from Competitrack (Market Track, LLC, Chicago, IL, USA). Competitrack monitors 100 leading apps and mobile-optimized websites, including mobile devices—specifically, iPhones, Android phones, iPads, and Android tablets—by sampling hundreds of top-rated apps and websites to identify those that carry the most distinctive and requested consumer advertising. This media universe is reviewed on a regular basis to identify emerging apps and websites with relevant advertising. Competitrack's database includes information about the type of device used to find the ad, jpg files of the ads, ad landing pages, URLs (if available), and general information (eg, site or app where the ad was found, and type [news, weather, shopping, health], date, and brand). We used Competitrack's database to download general information about prescription drug communications, static images of the full communication, and images of the landing pages (jpg files). Although a few of the mobile communications were interactive, we chose to use a "snapshot in time" approach to capture and code communications and landing pages at 1 point in time to avoid problems of replicability. This method allowed 2 coders to analyze identical ads and landing pages to calculate interrater reliability. We identified 266 mobile communications from May 2012 to May 2014.

We selected eligible mobile communications using the following criteria: (1) the communication and the landing page had to be viewable, (2) only 1 communication per brand could be included, (3) the promoted branded prescription drug had to be regulated by FDA's Center for Drug Evaluation and Research (CDER) [21], and (4) the communication had to be directed at consumers. We excluded 178 duplicates, plus 22 that were not prescription products regulated by CDER, and 9 due to landing page or mobile screenshot viewing issues. We excluded an additional 6 communications during coding: 4 targeted health care providers rather than consumers, 1 had no mobile communication included, and 1 had no landing page. This resulted in a sample of 51 mobile communications (Table 1).

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Table 1. Sample characteristics of mobile communications promoting prescription drugs (N=51).

Drug name	Source	Source type	Device	Year
Abilify	CBS News	App	iPhone	2013
Androgel	CNN	Website	iPad	2013
Axiron	Fox News	Website	iPad	2012
Botox	WeatherBug	App	iPhone	2013
Bydureon	AroundMe	App	Android Phone	2014
Celebrex	Fox News	App	iPhone	2013
Chantix	About.com	Website	iPad	2013
Cialis	WeatherBug	Website	Android Phone	2012
Complera	CNBC	Website	Android Phone	2013
Copaxone	eHow	Website	iPhone	2014
Cymbalta	CNN	Website	Android Phone	2013
Dexilant	Dictionary.com	App	Android Phone	2013
Diclegis	TheStreet	App	Android Phone	2013
Dulera	Weatherbug	Website	Android Phone	2012
Eliquis	Fox News	Website	iPad	2013
EpiPen	eHow	Website	iPhone	2013
Evista	Weather.com	Website	iPad	2013
Finacea	About.com	Website	iPad	2014
Gilenya	MSNBC	Website	iPad	2013
Horizant	About.com	Website	iPad	2013
Incivek	About.com	Website	Android Phone	2012
Intermezzo	New York Times	Website	iPad	2013
Intuniv	Learn Spanish Vocabulary Lite	App	Android Phone	2013
Isentress	About.com	Website	iPad	2013
Januvia	WeatherBug	Website	iPad	2013
Latuda	CareerBuilder.com	Website	iPad	2014
Lovaza	Fox News	Website	iPhone	2013
Lunesta	WeatherBug	App	Android Tablet	2013
Mirena	Fox Sports	Website	iPad	2013
Myrbetriq	eHow	Website	Android Phone	2013
Nasonex	AccuWeather	App	iPad	2012
Nexplanon	Craigslist Mobile	App	Android Phone	2013
NuvaRing	WeatherBug	App	iPhone	2012
Nuvigil	Fox Sports	Website	iPad	2013
ParaGard IUD	Dailymotion	Website	Android Phone	2012
PlanB	TweetCaster	App	Android Phone	2012
Staxyn	Fox News	Website	iPad	2013
Stelara	The Weather Channel	App	iPhone	2013
Strattera	Expedia	Website	iPhone	2013
Stribild	About.com	Website	iPad	2013
Suboxone	Fox News	App	iPhone	2013
Symbicort	Weather.com	Website	iPhone	2013

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Drug name	Source	Source type	Device	Year
Synthroid	About.com	Website	iPad	2013
Tamiflu	CBS Local YourDay	App	iPhone	2012
Velcade	New York Times	Website	iPhone	2013
Vesicare	eHow	Website	iPhone	2013
Viagra	NFL.com	Website	iPad	2013
Vyvanse	Craigslist Mobile	App	Android Phone	2013
Xarelto	AOL	Website	iPad	2013
Xeljanz	CNN	Website	iPad	2013
Zetonna	AccuWeather	App	iPad	2013

Two raters independently double coded 10% of the sample (5 mobile communications and their related landing pages) to refine the coding scheme, and double coded an additional 10% of the sample to determine interrater reliability (κ=.92 for mobile communication codes and κ=.83 for landing page codes). Disagreements were resolved through discussion. We coded the type of mobile communications and landing pages, the prominence and placement of benefit and risk information, and the presence of links. The type and amount of risk and benefit information in each communication was determined by examining the FDA-approved product labeling for that product. We coded the part(s) of the landing page that were viewable on the screenshot (see Multimedia Appendix 1 for examples). In cases where partial information was visible and ended mid sentence or a capture included additional information that could be accessed through scrolling, as indicated by the presence of a scroll bar, we made the reasonable assumption that it continued below the available screenshot.

Results

Mobile Communication Content and Format

Of the 51 mobile communications we coded, 41% (21/51) were product claim communications, 22% (11/51) were reminder communications, and 37% (19/51) were help-seeking communications (see Multimedia Appendix 2 for examples). Scrolling was needed to see all the benefit information on 24% (5/21) of the product claim mobile communications. In contrast, scrolling was needed to see all the risk information on all but 1 of the product claim mobile communications (20/21, 95%). Of the 21 communications, 2 (10%) had additional benefit information available with a link or tab, and 1 (1/21, 5%) had additional risk information available with a link or tab. Of the 19 product claim communications that presented both benefits and risks, 95% (18/19) presented benefits before risks, 47% (9/19) used a bigger font for benefits than for risks, 16% (3/19) used a bigger font size for risks, and 37% (7/19) used the same size font for both.

Of the 51 mobile communications, 37 (72%) included links or tabs to access additional information. The most common link or tab we coded was to the FDA-approved prescribing information [22] (Tables 2 and 3).

Landing Page Content and Format

The majority of the mobile communications (35/51, 69%) linked to product claim websites, 25% (13/51) linked to landing pages with the drug name and benefit information without visible risk information, and 6% (3/51) linked to landing pages with the drug name and risk information without visible benefit information. Some help-seeking and reminder communications linked to landing pages with the drug name and benefit information without visible risk information (Table 4).

Table 2. Types of links and tabs (N=51).

Type of link or tab	Definition	Mobile promotional communication, % (n)	Landing page, % (n)
Prescribing information	A compilation of information about the product, written for the health care practitioner audience, approved by the FDA[a], based on the agency's thorough analysis of the new drug application or biologics license application submitted by the applicant. This labeling contains information necessary for safe and effective use.	37 (19)	82 (42)
MedGuide	FDA-approved information that comes with some prescription medicines, determined to pose a serious and significant public health concern. The MedGuide is designed to help patients avoid serious adverse events. MedGuides are a specific category of Patient Labeling.	22 (11)	53 (27)
FDA website	www.fda.gov or www.fda.gov/medwatch	14 (7)	16 (8)
Patient information	Labeled as information for patients, patient information, or patient package insert.	6 (3)	29 (15)

[a]FDA: US Food and Drug Administration.

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Table 3. Types of links and tabs by type of mobile promotional communication.

Type of link or tab	Type of communication, % (n)		
	Product claim (n=21)	Reminder (n=11)	Help seeking (n=19)
Prescribing information	81 (17)	18 (2)	0 (0)
MedGuide	52 (11)	0 (0)	0 (0)
FDA website	33 (7)	0 (0)	0 (0)
Patient information	14 (3)	0 (0)	0 (0)

Table 4. Type of mobile promotional communication by type of landing page (N=51).

Type of communication	Type of landing page, % (n)			Total
	Product claim (name, benefits, and risks)	Drug name and benefits	Drug name and risks	
Product claim	29 (15)	12 (6)	0 (0)	41 (21)
Reminder	14 (7)	6 (3)	2 (1)	22 (11)
Help seeking	25 (13)	8 (4)	4 (2)	37 (19)
Total	69 (35)	25 (13)	6 (3)	100 (51)

Nearly all (48/51, 94%) of the landing pages had visible benefit information, and 88% (45/51) had additional benefit information available with a link or tab. Approximately three-quarters of landing pages had visible risk information (38/51, 74%) and 86% (44/51) had additional risk information available with a link or tab. Scrolling was needed to see all the benefit information on 8% (4/51) of the landing pages. In contrast, scrolling was needed to see all the risk information on 51% (26/51) of the landing pages.

Of the 35 landing pages with both benefit and risk information, 71% (25/35) presented benefits before risks, 51% (18/35) used a bigger font for benefits than for risks, 3% (1/35) used a bigger font size for risks, and 46% (16/35) used the same size font for both.

Nearly all the landing pages (48/51, 94%) included links or tabs to access additional information. The most common link or tab we coded was to the FDA-approved prescribing information (Table 2).

Discussion

DTC marketing can affect important public health outcomes [23-25], and mobile DTC promotion continues to increase exponentially [26]. Therefore, it is important to understand the content of this promotion. Surprisingly, 22% of mobile communications were reminder communications, a higher proportion than expected given the scarcity of reminders overall. An informal survey of DTC television ads reveals almost no reminder ads in that medium, which may be a direct result of the Pharmaceutical Research and Manufacturers of America DTC guidelines that encourage DTC ads that name a product to also include both risk and indication information [27]. Reminder communications may be suited to the mobile space because they do not have to accommodate benefit and risk information. Enforcement in other space-limited Internet venues likely also affected the types of mobile communications used [28]. Despite FDA guidance in this area [9], sponsors who remain unsure about how to implement a fairly balanced product claim promotion in this medium may opt instead to use a reminder communication to link to the drug's promotional website [29].

When mobile communications included both benefits and risks, benefits appeared to be more prominent and easily accessible than risks, although we did not test for significant differences. This echoes prior research across a broad range of marketing platforms and raises concerns about whether fair balance requirements are being met in the mobile marketing of prescription drugs in the United States. Similarly, and consistent with past research, benefits also appeared to be more prominent than risks on landing pages [18,20]. It may be that the apparent difference in scrolling needed is because there is often more information in the risk section of approved labeling than in the indication section. Regardless, if risk information is available only through scrolling or a link, consumers may be less likely to access it and may miss important information [30]. Sponsors should ensure that benefit and risk information in mobile communications and on landing pages is equally prominent and accessible to address fair balance.

Some help-seeking and reminder communications linked to a website with the drug name and benefit information but without visible risk information. The FDA has expressed concerns about linking a drug to an indication without accompanying risk information [31]. Moreover, research has shown that consumers confuse disease information with branded prescription drug information when the two are presented together [32] or associated by link [33]. Situations where reminder or help-seeking communications are linked to full product claim websites may require extra care to ensure the information is truthful, balanced, and nonmisleading.

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Limitations

First, the dataset we used consisted mostly of static screenshots. Thus, we could not code interactive features or information that could be viewed only by scrolling. If the screenshot consisted only of the "above the fold" section of a landing page, we could not determine whether risks or benefits were presented "below the fold." Second, content analysis allows for in-depth analysis of information, but it cannot provide information on how often consumers view mobile communications, what information they understand, or how often they view the landing page. Third, Competitrack did not have an established protocol regarding the orientation of the device. This was done at the discretion of the capture person, but some apps presented the page in landscape by default. As a result, there could potentially be differences in what was captured in a screenshot depending on the device.

Conclusions

Consumers are increasingly going online for health information, and as digital marketing for prescription drugs is increasing, consumers are more likely to encounter these mobile communications. At the same time, lack of fair balance generally, and minimization of risk information in particular, continue to be frequently cited in FDA letters [34]. Our findings suggest that sponsors continue to struggle with these issues across promotional platforms. Recent FDA guidance on character space-limited platforms [8,9] may help sponsors navigate these issues. The results of this analysis, particularly with respect to the persistent lack of fair balance, may provide useful information to regulators as they consider the available data applicable to policy. Additionally, continued surveillance of DTC marketing online and in mobile communications is needed to ensure that consumers have access to fairly balanced, accurate, and nonmisleading information about medical products.

Acknowledgments

The study was supported by the Office of Prescription Drug Promotion, US Food and Drug Administration. We would like to thank Lisa Gilbert for her contributions to designing the study.

Authors' Contributions

KA and HS contributed to study design, methodology, data analysis, and manuscript preparation. LS, ML, and DS contributed to methodology and data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Landing page examples.

[PDF File (Adobe PDF File), 463KB - jmir_v19i7e225_app1.pdf]

Multimedia Appendix 2

Type of mobile promotional communication in sample.

[PDF File (Adobe PDF File), 187KB - jmir_v19i7e225_app2.pdf]

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Abbreviations

CDER: Center for Drug Evaluation and Research
DTC: direct-to-consumer
FDA: US Food and Drug Administration

Edited by L Buis; submitted 18.01.17; peer-reviewed by D DeAndrea, C Adams, BL Rollins, E Doran; comments to author 16.02.17; revised version received 03.04.17; accepted 05.06.17; published 04.07.17.

Please cite as:
Aikin KJ, Sullivan HW, Dolina S, Lynch M, Squiers LB
Direct-to-Consumer Promotion of Prescription Drugs on Mobile Devices: Content Analysis
J Med Internet Res 2017;19(7):e225
URL: http://www.jmir.org/2017/7/e225/
doi:10.2196/jmir.7306
PMID:28676469

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Original Paper

Youth Oriented Activity Trackers: Comprehensive Laboratory- and Field-Based Validation

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Abstract

Background: Commercial activity trackers are growing in popularity among adults and some are beginning to be marketed to children. There is, however, a paucity of independent research examining the validity of these devices to detect physical activity of different intensity levels.

Objectives: The purpose of this study was to determine the validity of the output from 3 commercial youth-oriented activity trackers in 3 phases: (1) orbital shaker, (2) structured indoor activities, and (3) 4 days of free-living activity.

Methods: Four units of each activity tracker (Movband [MB], Sqord [SQ], and Zamzee [ZZ]) were tested in an orbital shaker for 5-minutes at three frequencies (1.3, 1.9, and 2.5 Hz). Participants for Phase 2 (N=14) and Phase 3 (N=16) were 6-12 year old children (50% male). For Phase 2, participants completed 9 structured activities while wearing each tracker, the ActiGraph GT3X+ (AG) research accelerometer, and a portable indirect calorimetry system to assess energy expenditure (EE). For Phase 3, participants wore all 4 devices for 4 consecutive days. Correlation coefficients, linear models, and non-parametric statistics evaluated the criterion and construct validity of the activity tracker output.

Results: Output from all devices was significantly associated with oscillation frequency (r=.92-.99). During Phase 2, MB and ZZ only differentiated sedentary from light intensity (P<.01), whereas the SQ significantly differentiated among all intensity categories (all comparisons P<.01), similar to AG and EE. During Phase 3, AG counts were significantly associated with activity tracker output (r=.76, .86, and .59 for the MB, SQ, and ZZ, respectively).

Conclusions: Across study phases, the SQ demonstrated stronger validity than the MB and ZZ. The validity of youth-oriented activity trackers may directly impact their effectiveness as behavior modification tools, demonstrating a need for more research on such devices.

(J Med Internet Res 2017;19(7):e250) doi:10.2196/jmir.6360

KEYWORDS

child; movement; fitness trackers

Introduction

The 2008 Physical Activity Guidelines for Americans recommend that children and adolescents engage in at least 60 minutes of physical activity (PA) daily [1]. In the United States, the prevalence of 6-11 year old children meeting this guideline was 42% and drops to 8% for adolescents [2]. This level of PA for the nation's youth was reported as a "D-" in the recent

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release of "The 2014 United States Report Card on Physical Activity in Children & Youth" [3]. A low level of PA is one of the behaviors contributing to the current US epidemic of pediatric obesity and to high levels of risk factors for a number of chronic diseases [1].

Exploring novel resources and tools for promoting youth PA are needed. In adults, pedometers and other commercially available PA tracking devices (eg, FitBit, JawBone UP, Misfit Shine) have gained considerable popularity. Similar activity trackers are now being marketed for children. Several studies have now evaluated validity and reliability of adult activity trackers [4-10], but there is currently no independent research validating the output from youth-oriented activity trackers.

Activity trackers are promoted as behavior change tools to increase PA, similar to the way pedometers are used in walking-based intervention studies or community-based programs [11]. Just as pedometers have been validated to support their use as behavior change tools [12,13], these newer activity monitoring devices should also be subjected to validation testing. Use of these commercial activity trackers as behavioral monitoring tools in research interventions is increasing [14,15], with some studies also using these trackers as the assessment tool to determine effectiveness of an intervention [15]. A great degree of caution is warranted in such an approach. Whether used as an intervention or assessment tool, these commercial devices should be sensitive enough to detect different levels of activity (eg, differentiating walking from jogging) in order to provide the user with appropriate feedback. Performing a bout of activity without the activity tracker registering that movement (eg, jogging but only getting "credit" for walking) would make the device irrelevant or even demotivating.

Before being used for intervention purposes, the validity of these commercially available activity trackers needs to be established so that researchers using these devices can be confident in their utility as behavioral tracking devices. In addition, evaluating these youth-oriented activity trackers may help consumers make educated decisions regarding device selection. Therefore, the purpose of this study was to determine the ability of youth-oriented activity trackers to detect the volume of movement in 3 phases, from highly structured to unstructured: (1) using an orbital oscillator, (2) during structured indoor activities, and (3) during 4 days of free-living activity.

Methods

Devices

The ActiGraph GT3X+ (AG; ActiGraph, LLC, Pensacola, FL) accelerometer provides an objective estimate of human PA and is used in many research and clinical applications [16-18]. The AG includes a micro-electro-mechanical system (MEMS) based accelerometer with a dynamic range of ± 6 G-forces. The acceleration data are sampled by a 12-bit analog to digital converter at rates ranging from 30 Hz to 100 Hz and stored in a raw, non-filtered accumulated format (G-forces). These data are stored directly into non-volatile flash memory. Raw data are collected at the selected sampling rate and are post-processed in the ActiLife software. Users can generate files containing any desired combination of parametric data (eg, 1 s epoch, 60 s epoch) during the data processing step [19].

This study evaluated the output from 3 commercially available activity trackers (see Table 1 and Figure 1). The selection of trackers was based on an Internet search for youth activity trackers. During the time this study was initiated, these were the only devices that seemed suitable for the age range we were targeting. The Movband (MB: Movband, LLC, Brecksville, OH) is a wrist-worn activity tracker that looks like a watch and is similar to many adult-oriented activity trackers. The MB is marketed toward school classroom and Physical Education instructors and also to adult consumers. The face of the unit displays the time and "Moves" or "Steps." The MB is synced to the associated website by connecting the display piece to the user's computer via a USB cable. The Sqord (SQ: Sqord, Inc, Durham, NC) is another wrist-worn activity tracker similar to a watch but lacks a display. The Sqord wrist unit syncs the user's activity "Points" with a computer by tapping the device to a Sync Station that is connected to the computer using a USB cable. Lastly, the Zamzee (ZZ: HopeLab non-profit organization, Redwood City, CA) is a hip-worn activity tracker that uses a built in clip to attach to a user's waistband, similar to a pedometer. Like the SQ, there is no display. The user syncs the ZZ activity "Pointz" with a computer via a USB cable. All output from the activity trackers (Moves and Steps, Points, and Pointz) are the result of proprietary algorithms; raw acceleration data is not available.

Table 1. Descriptions and features of the ActiGraph accelerometer, and the Movband, Sqord, and Zamzee activity trackers.

Device	Placement	Output	Features
ActiGraph GT3X+ (ActiGraph, LLC, Pensacola, FL)	Above right hip; elastic belt	Vector Magnitude Counts from raw (30-Hz) tri-axial acceleration signal	No display; no user interface
Movband Model 2 (Movable, Inc Brecksville, OH)	Dominant wrist	"Moves" based on tri-axial accelerometer and proprietary algorithm	Display screen; upload to website for tracking and group participation
Sqord (Sqord, Inc Durham, NC)	Dominant wrist	Activity "Points" based on tri-axial accelerometer and proprietary algorithm	No display; upload to website (tracking, groups/social network, avatar, challenges)
Zamzee (Hope Lab, NPO, Redwood City, CA)	Above right hip; elastic belt	Activity "Pointz" based on tri-axial accelerometer and proprietary algorithm	No display; upload to website (tracking, groups/social network, avatar, challenges)

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Figure 1. Devices used (from left to right): ActiGraph GT3X+™, MovBand Model 2™, Sqord™, and the Zamzee™.



Phase 1: Orbital Shaker Validation

In Phase 1, criterion and construct validity were assessed by comparing activity tracker output to the oscillation frequency and to the AG output respectively. Using the orbital shaker produces a known and constant oscillation frequency, which should be detected by all activity trackers due to the uniformity of the movement. If the devices are not able to detect changes in such structured movement, it would be ill-advised to assume they would work in free-living settings. Therefore, this validation step is included as a first "hurdle" for such devices to clear. Additionally, the highly controlled oscillations allowed for the assessment of inter-unit reliability for all devices.

Procedures

An orbital shaker was used to perform electronic motion testing, which produces controlled oscillations between 0.25 and 5.00 Hz. Four trays were mounted on the base of the oscillating plate of the shaker. Each tray had 4 slots to securely position the activity trackers (one of each brand) and the AG (ie, 4 of each device were tested at the same time). All devices were spun continuously for five minutes at three frequencies (1.3, 1.9, and 2.5 Hz) that were previously used to approximate light, moderate, and vigorous intensity physical activity [20,21], and output from each device was summed over the five minutes.

Data Processing

Following each 5-minute oscillation frequency, total output for the MB was retrieved from the real-time display and output for both the SQ and ZZ were downloaded and retrieved from their websites. ActiGraph data were collected at 80 Hz, without the low frequency extension, post processed using ActiLife software (version 6.1) and aggregated into counts per second. Since the activity trackers were only able to provide output for the full duration of each activity, an analogous variable was obtained from the AG. Vector magnitude counts from the AG (counts per second output from all 3 axes) were summed over 5 min for each oscillation frequency.

Analysis

Spearman correlation coefficients (ρ) were used to assess associations between oscillation frequency and device output (criterion validity) and Wilcoxon Rank Sum tests were used to determine whether there were significant differences in mean output from each device among the 3 oscillation frequencies. In addition, inter-unit reliability was assessed with linear-mixed models to calculate the coefficient of variation in output at each oscillation frequency.

Phase 2: Structured Activities

In Phase 2, criterion and construct validity were assessed during structured indoor activities by comparing activity tracker output to energy expenditure using a portable indirect calorimetry system and to the AG output.

Participants

Children (6 to 12 years old) from the local community were recruited to participate in the validation of the activity trackers during structured activities (see Table 2). Children were included if they had no physical or mental disabilities that would interfere with the child's ability to perform physical activity or follow protocol instructions. Prior to any data collection, university Institutional Review Board approval and written parent/guardian informed consent were obtained. Children were read an assent script and then, to ensure comprehension, were asked to describe what they would be asked to do for the study.

Table 2. Descriptive information for participants in phase 2 and 3.

Participant characteristics	Phase 2: structured activities (n=14)	Phase 3: free living activity (n=16)
Age, mean (SD)	9.0 (2.0)	8.6 (1.6)
Gender (female), n (%)	7 (50)	8 (50)
Height (cm), mean (SD)	135.3 (13.57)	133.9 (12.2)
Weight (kg), mean (SD)	36.1 (10.6)	32.2 (8.4)

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Devices

In addition to the 3 activity trackers (MB, SQ, ZZ) and the AG, energy expenditure (oxygen consumption [VO_2] expressed as ml/kg/min) was measured with the Oxycon Mobile portable indirect calorimetry system (Carefusion, Inc.); serving as a criterion measure during the structured activities. The Oxycon Mobile provides breath-by-breath analysis of gas exchange and has been validated for use in children using pediatric-sized face masks and harness [22,23].

Procedures

The participants reported to the laboratory on two occasions. The child's height and weight were measured by trained research staff to the nearest 0.1 cm and 0.1 kg, respectively, using a portable stadiometer (Weigh and Measure, LLC, Olney MD) and digital scale (Seca 876, Hanover, MD). We also obtained age (from date of birth), sex, and grade level at school. Demographic data (age, sex, height, and weight) were entered into each device website as a new user account for each participant. Once in the gymnasium, participants were fitted with the Oxycon Mobile system and one set of activity trackers. The AG and ZZ were placed above the right hip bone on an adjustable belt and the MB and SQ were placed on the dominant wrist as per manufacturer recommendations. The hip-worn AG is the standard placement and has been validated previously using similar activities in similar age groups [24-26] providing the greatest ability for comparison to previous studies.

Ten activities were performed (5 activities per visit). Each activity was performed for 7 minutes, with the exception of quiet sitting, which was performed for 5 minutes. Order effects on EE levels were minimized by allowing for a 5-10 minute break between each activity and by balancing the order of presentation for moderate and vigorous intensity activities. Participants were allowed to remove the Oxycon Mobile mask during breaks and water was provided. A description of the tasks for each visit is provided in Table 3.

Table 3. Description of structured activity visits.

Visit 1	Visit 2
1. Sit[a]: quiet sitting	1. Sit: quiet sitting
2. Catch[b]: Stood and played catch, minimal movement (research staff retrieved ball)	2. Cards: sit at table and play cards
3. Self-Paced Walk • Instructed to walk at a comfortable pace; • Reminded child that there would be a slower and faster walk; • Always preceded the Slow- and Moderate-paced walks; • Research staff walked with and paced the participant to obtain a constant intensity of effort.	3. Slow Walk: 0.5 miles/hr (0.22 meters/sec) slower than Self-Paced Walk
4. Moderate and Vigorous Activities (Balanced Order) • Moderate Walk: 0.5 miles/hr (0.22 meters/sec) faster than Self-Paced Walk • Self-Paced Jog: Jog at comfortable pace participant could maintain for 7 min; Research staff jogged with and paced the participant to obtain a constant intensity.	4. Moderate and Vigorous Activities (Balanced Order) • Modified Tag: A tag game that involved one researcher playing tag with the participant with a goal to take ribbons off of the belt of the participant-researcher. • Modified Relay: 20 meter distance marked on the floor with cones; Researcher demonstrated various calisthenics and movement patterns that involved moving from one cone to the other and back; Participant copied movements; Researcher and participant took turns for duration of activity.

[a]Sit lasted 5 min; all other activities lasted 7 min.

[b]Catch was subsequently classified as moderate intensity due to children frequently not catching the ball and having to walk/jog to retrieve it.

Data Processing

After each activity, the data from the activity trackers were uploaded to the device website. Total "Moves," Points, and "Pointz" for the MB, SQ, and ZZ, respectively, were recorded for each activity. The AG accelerometer data were downloaded via the Actilife computer software (version 6.1). From the raw AG data, total vector magnitude counts for each activity were recorded (analogous to the output from the activity trackers). The Oxycon Mobile data were uploaded and summarized using the system's software. The computers used to collect the AG and Oxycon Mobile data were synchronized and the first and last minute of the AG and EE data were removed and the remaining five minutes of data was summed; all five minutes of data from the Sit condition were retained.

Analysis

Most of the data distributions from the activity trackers were not normally distributed. Therefore, Spearman rho coefficients were calculated to compare activity tracker output to the EE and the AG vector magnitude counts. Since the output variables from each device are different, comparing the absolute output values was not meaningful. Hence, within-device analyses were conducted to examine if the pattern of output from each activity tracker was similar to the pattern observed for EE and AG vector magnitude counts. To limit the number of analyses performed, activities were categorized as Sedentary (both sitting sessions, playing cards), Light (slow walk, self-paced walk), Moderate (catch, moderate walk) and Vigorous (self-paced jog, tag, relay). A repeated measures Wilcoxon Rank Sum non-parametric test

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was calculated to determine within device differences in output among the intensity categories.

Phase 3: Free Living Activity

In Phase 3, construct validity was assessed by comparing activity tracker output to the AG vector magnitude counts across all days and for each day.

Participants

The same recruitment strategy, inclusion criteria, and informed consent procedures used for Phase 2 were also used for this free living assessment.

Procedures

The same demographic and anthropometric data that were collected for Phase 2 (Structured Activities) were obtained from the Phase 3 participants and used for setting up each device. The device placements were also the same as for Phase 2. Children were instructed to wear all four devices during all waking hours for the next 4 full days, except when the devices would get completely wet (eg, showering, bathing, swimming). Participants received verbal instructions and were sent home with a sheet of instructions for all devices and contact information for study staff in the event of technical problems. The AG was initialized to begin recording data at 4:00 AM in the morning after the children received their devices. After the 4 days of wearing the device, children returned all devices.

Data Processing

Using the ActiLife software [27], non-wear time was defined as at least 30 minutes of consecutive zeros from the AG data. Data points for non-wear times were set to missing and were not included in any further data processing. Based on the remaining data points, days with less than eight hours of wear time were removed (excessive non-wear time). If a day did not meet this criterion for the AG, all data from the activity trackers were also set to missing for those days. Data points from days with at least eight hours of data were included in further processing. To obtain AG variables comparable to the output from the consumer devices, we calculated the total counts per day using all 3 AG axes (vector magnitude counts). In addition, we also processed the vertical axis AG data using cutpoints developed by Evenson et al [24] to identify total time spent in moderate + vigorous PA (MVPA), and total PA (light + moderate + vigorous). The consumer activity trackers did not allow for extraction of data from specific time points. For the MB, we extracted total "Moves" and steps per day. For the SQ and the ZZ, both provided output as Points or "Pointz" per day, respectively.

Analysis

One participant's data were removed from the data set due to excessive non-wear time on two days and very low activity levels (more than 2 standard deviations below group average) which caused significant skewness in the data. One other participant also had high non-wear time on two days and one other child's data were missing for one day. Both of these participants were retained for the analyses (removing them did not significantly affect the results). The retained data approximated a normal distribution across all output variables. Since each device uses a different algorithm to process its output, the metrics for each device were different and direct comparisons of absolute values (eg, Moves vs Points/Pointz vs Minutes of MVPA) were not possible. Pearson correlation coefficients were calculated to compare total daily metrics from each activity tracker to analogous metrics from the AG (ie, total vector magnitude counts per day; minutes of total activity and MVPA per day). Repeated measures linear models were calculated for each device separately to identify daily differences in device output.

Results

Phase 1: Orbital Shaker Testing

The output for each device was highly correlated with oscillation frequency; correlations for the AG, MB, SQ, and ZZ were .96, .99, .98 and .92, respectively. Output from each device was significantly different among the oscillation frequencies (range P=.007-.03). Linear-mixed models revealed that there were no significant inter-unit differences in device output at each frequency (Figure 2). The coefficient of variation at each oscillation frequency revealed that the SQ had the highest variability (29.8%) at the lowest frequency of 1.3 Hz (Table 4). The ZZ displayed the highest variability for oscillation frequencies of 1.9 Hz (12.1%) and 2.5 Hz (9.75%). In contrast, the AG and MB demonstrated lower variability at all oscillation frequencies compared to the SQ and ZZ.

Table 4. Coefficient of variation at each oscillation frequency across all units for each device.

Device	Frequency (Hz)		
	1.3	1.9	2.5
AG[a]	0.28	0.41	0.43
MB[b]	0.62	0.85	0.19
SQ[c]	29.8	3.85	1.93
ZZ[d]	25.5	12.1	9.75

[a]AG: ActiGraph.

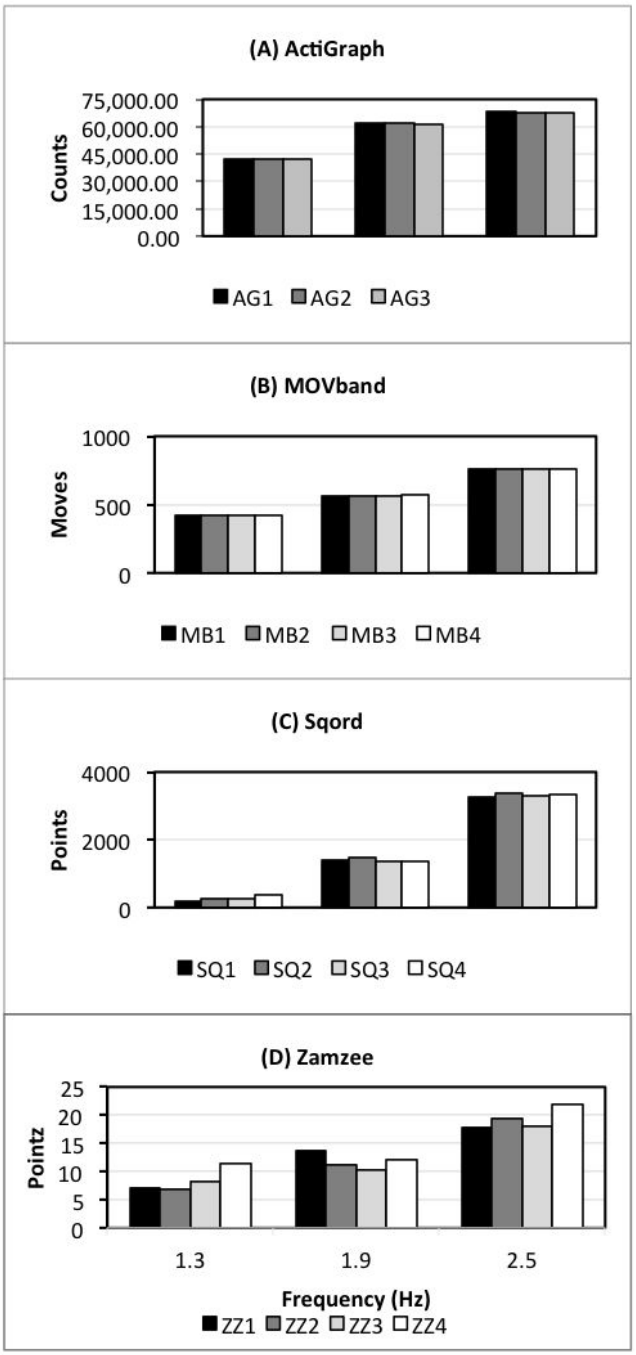
[b]MB: Movband.

[c]SQ: Sqord.

[d]ZZ: Zamzee.

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Figure 2. Output as a function of oscillation frequency for individual units of the (A) ActiGraph, (B) Movband, (C) Sqord and (D) Zamzee.

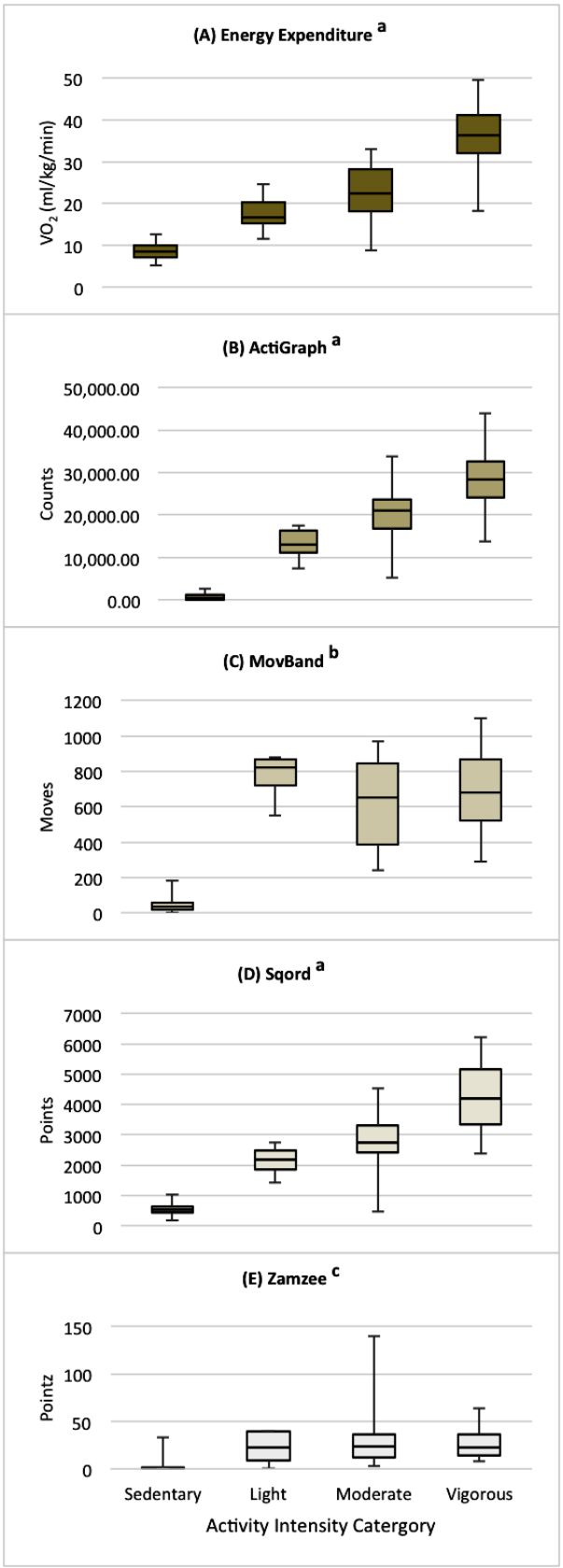


Phase 2: Structured Activities

Across all of the structured activities, Spearman correlation coefficients between EE and the AG, MB, SQ, and ZZ were .87, .61, .87, and .60, respectively. Associations among the activity trackers and the AG were .66, .90, and .66 for the MB, SQ, and ZZ, respectively. With activities categorized by intensity (sedentary, light, moderate, and vigorous), EE and AG counts increased in a step-wise fashion (Figure 3 shows Panels A and B, all categories significantly different from each other, $P \leq .002$). Similarly, the SQ demonstrated a step-wise increase in activity points with increasing intensity category (all categories significantly different, $P<.001$, see Figure 3, Panel D). In contrast, the MB differentiated between the sedentary and light intensity categories ($P<.001$, see Figure 3, Panel C) and between light and moderate ($P=.04$), but not between moderate and vigorous ($P=.32$). Of note, the median Moves for the moderate intensity activities were actually lower compared with the light intensity activities. The ZZ only differentiated between sedentary and light intensity activities ($P<.001$) with no difference in ZZ "Pointz" between light versus moderate ($P=.89$), or moderate versus vigorous intensity categories ($P \geq .67$; see Figure 3, Panel E).

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Figure 3. Box and Whisker plots for (A) Energy expenditure, and device output by activity intensity category for the (B) ActiGraph, (C) Movband™, (D) Sqord™, and (E) Zamzee™.



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Figure 4. Pearson correlation coefficients with ActiGraph vector magnitude total counts by day for the Movband™, Sqord™, and Zamzee™ activity trackers.

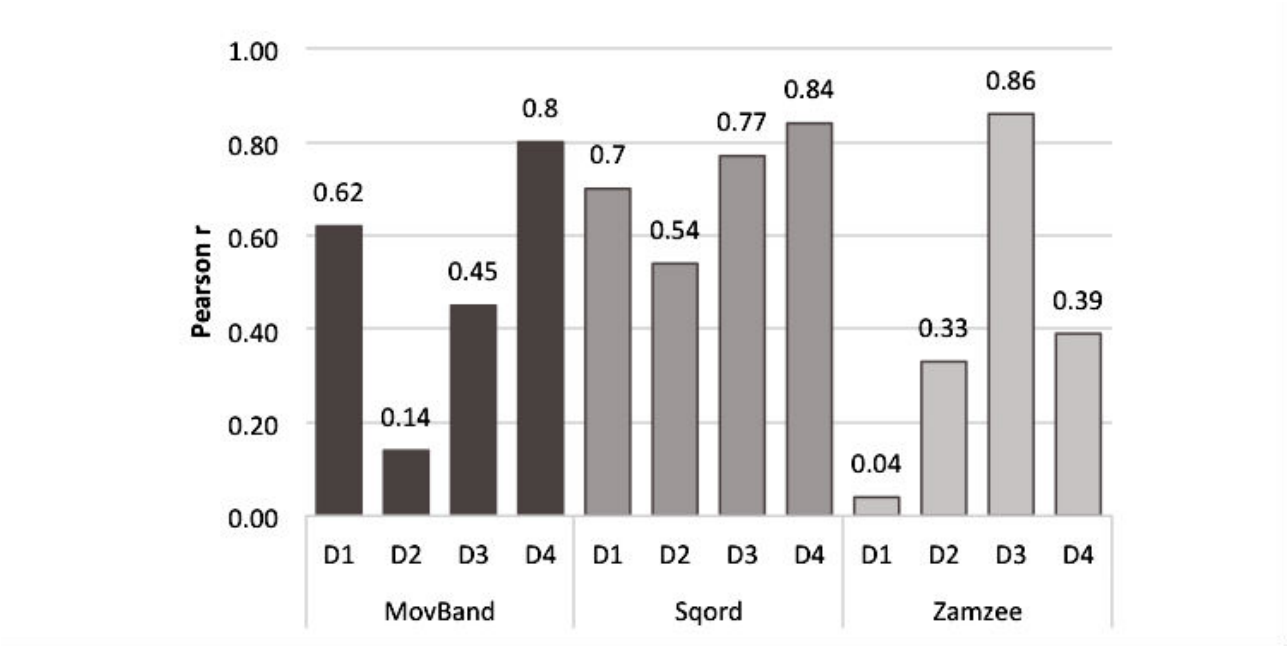


Figure 5. Device output by day. a = Day 4 significantly different from Days 1 and 2 for ActiGraph and Zamzee™ (p <0.04). Note: device output has been scaled to better present all device data in one figure

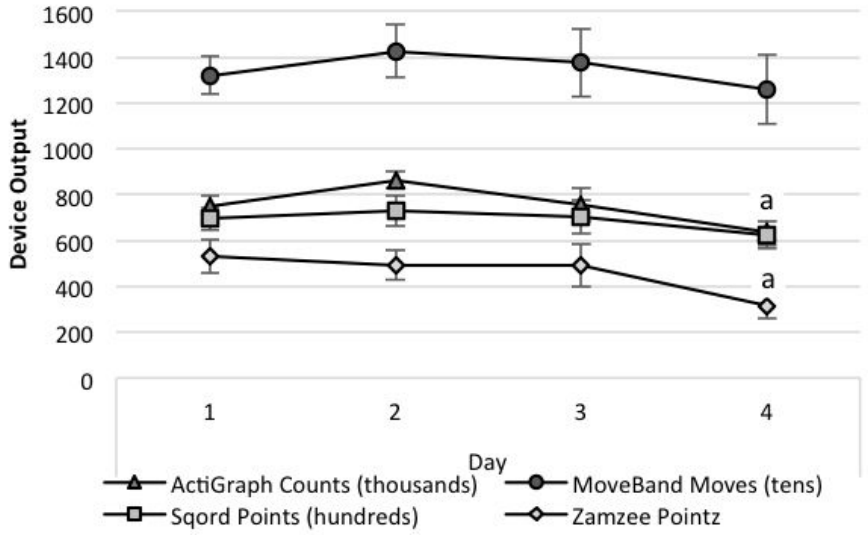


Table 5. ActiGraph minutes of MVPA and total PA per day; mean (SD).

Activity Intensity	Day			
	1	2	3	4[a]
MVPA (moderate +vigorous PA)	57.1 (18.1)	65.5 (15.6)	60.1 (28.7)	48.0 (19.6)
Total PA	157.1 (30.2)	183.1 (28.0)	168.2 (59.0)	144.4 (44.9)

[a]significantly different from Day 2, *P*=.01.

Phase 3: Free Living Activity

Total vector magnitude counts summed over all days from the AG were significantly associated with the analogous output from the activity trackers (*r*=.76, .86, and .59 for the MB, SQ, and ZZ, respectively). Correlation coefficients between total minutes of MVPA from the AG and the main output variables from the activity trackers were also significant (*r*=.73, .75, .65

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for the MB, SQ, and ZZ, respectively). The correlation between output from the MB and SQ, both wrist-worn activity trackers, was high (r=.90) while output from the ZZ was more modestly associated with output from the MB (r=.71) and SQ (r=.73) (all correlations are $P \leq .005$). Day-to-day associations between the AG vector magnitude counts and the output from the MB, SQ, and ZZ ranged from r=.14 to .80, r=.54 to .84, and r=.04 to .86, respectively (see Figure 4).

The total number of steps across all days estimated by the MB was significantly associated with the step estimate from the AG (r=.79) and ranged from r=.09 for Day 2 and r=.68 to .89 across the other 3 days. Compared to the AG, the MB overestimated the total number of steps (AG 34,393 (7128); MB 42,504 (13,764), P=.004) and average steps per day (AG 8,865 (1,796); MB 11,055 (2,897), P=.03).

The within device repeated measures analyses indicated that for AG and ZZ, the output was significantly greater on days 1 and 2, compared to day 4 ($P \leq .04$). No other day-to-day differences were detected (see Figure 5). Similar results were obtained when performing the same analyses calculated for the minutes per day of MVPA and total PA from the AG. For both variables, day 2 was significantly greater than day 4 (both P=.01); no other significant differences were detected (see Table 5).

Discussion

Principal Findings

The purpose of this study was to evaluate the validity of 3 youth-oriented commercially available activity trackers using 3 approaches: (1) orbital shaker testing, (2) human testing during structured activities, (3) four days of free-living activity. The major finding of this study was that no consumer device was consistently superior across all 3 approaches to device validation. The SQ, however, performed consistently well during the structured and free-living activities. Compared to the SQ and ZZ, the MB demonstrated the lowest inter-unit variability across all frequencies during the orbital shaker testing; the ZZ demonstrated the greatest inter-unit variability. The ZZ was also less sensitive to the higher intensities performed during the structured activities, and demonstrated lower overall and more variable day-to-day associations with the AG during the free-living phase of this study. However, the ZZ was the only activity tracker that identified lower activity on day 4, compared with days 1 and 2 which was similar to the analysis of the AG counts. With the increased popularity of consumer activity trackers, the use of these devices in research interventions is looming, although based on these findings, caution is warranted. For use by consumers or researchers, activity trackers should be able to differentiate between distinct intensity levels of effort. Performing 30 minutes of vigorous intensity activity but the tracker only registering some or none of the time as vigorous could de-motivate many individuals.

Comparison With Prior Work

Orbital Shaker Testing

Inter-unit variability is an important instrument characteristic when considering the use of these devices in group settings and for tracking intervention progress or change in PA. Since the activity trackers were tightly secured in the orbital shaker, the variability observed is not a function of human variability in movement for a given activity. The greater inter-instrument variability observed for the ZZ will reduce the ability to identify differences between groups or group-level changes over time, requiring larger sample sizes in order for those differences to attain statistical significance. This inter-instrument variability might not be of major concern when examining intra-individual changes. However, these devices are currently being used in group settings (classrooms, physical education) that typically lead to comparisons among children. Thus, two children may perform the same activity but the devices may record different amounts of movement. The relatively high coefficient of variation for the SQ output during the lowest oscillation frequency would indicate that the SQ may not be sensitive to detecting light intensity movements; an important consideration since increasing evidence implicates excess sedentary time as an unhealthy behavior distinct from physical activity [28,29]. During the structured activities, however, the SQ was able to distinguish between the sedentary behaviors (resting, playing cards) and light intensity movement (slow walk).

Structured Activities

During the structured activities, the MB and ZZ trackers demonstrated a ceiling effect such that as the intensity of activity increased (according to indirect calorimetry and AG) the output from the trackers plateaued. This could be due to the detectable range for the accelerometer that is used in each device, the sampling and filtering of the raw acceleration signal, and/or the proprietary algorithms used to produce their output (Moves and “Pointz”, respectively). Because these issues are internal to the devices, we are only able to speculate on these issues. Alternatively, the large inter-quartile and overall ranges in the device output for each intensity category indicates substantial inter-individual variability in the output from these devices for the same activities. For example, the self-paced walking and jogging paces were maintained consistently by participants, although each participant’s pace was individualized. Therefore, the inability of the MB and ZZ to distinguish among light, moderate, and vigorous activities may be due, in part, to inter-individual variability, rather than a tracker hardware or software issue. However, the MB and the SQ were both worn on the same wrist with an intensity-related increase observed for the SQ Points but not for the MB Moves. Similarly, while the AG counts increased with activity intensity the ZZ “Pointz” did not increase correspondingly, even though both devices were worn on the hip.

These findings are in contrast to the one other validation study of youth activity trackers. Guthrie et al [30] performed a similar semi-structured protocol with 31, 12-14 year old children (54% female) performing nine activities across a range of intensities while wearing the ZZ and an RT3 research accelerometer. There was a strong association between ZZ and RT3 output (Spearman

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r=.94-.97) and no evidence of systematic bias. The different accelerometer and older age of the children used by Guthrie et al, compared to the current study, may have contributed to some of the between-study differences. One considerable methodological difference between the studies is that Guthrie et al had access to the raw acceleration data from the ZZ allowing them to post-process the raw acceleration data into 10-second epochs for comparison with the RT3 data. This 10-s data is not available with the commercial units used for the current study, thus the reliance on recording total output from the ZZ after each activity. Relying on output metrics based on proprietary algorithms limits our ability to determine if a device is truly valid, since there is no frame of reference for those metrics (eg, Points, Pointz). Having access to the raw data collected by these consumer activity trackers would allow researchers to develop more precise and accurate algorithms, providing information for researchers and users with feedback that would be specific to meeting or not meeting national physical activity recommendations.

Free Living Activity

The associations between the activity tracker output and the AG during the four days of free living activity were low and inconsistent for the MB and ZZ, while relatively high and stable for the SQ. One major limitation of all the trackers was that none provided output for minutes per day spent in MVPA, which is the variable that would allow examination of attainment rates for PA guidelines [1,31]. The MB does provide steps per day, and after inputting participant information for device setup, all children were given a 10,000 steps per day goal that could be tracked via the website. The MB also set a 12,000 “Moves” per day goal, although it is not clear if this directly compares to the youth PA recommendation (60 minutes of MVPA per day).

The low and variable day-to-day correlations between the AG and the MB and ZZ trackers may be a reflection of improper device placement and/or inconsistent wear time, although the SQ demonstrated higher and more stable daily associations with the AG. Participants were provided their devices and instructed to wear all 4 consistently at the same time for all 4 days. Access to each activity tracker website was provided as a means of encouraging children to wear the devices each day. However, some participants may have taken off the MB and ZZ to synchronize with the associated website and may not have put it back on in the proper place or may have forgotten to put it back on right away. Additionally, children may not have reattached all of the devices after sleep time. Therefore, the total and pattern of wear time for each tracker and the AG may have been different. Although we provided each participant and his/her parent/guardian with a log sheet to record times when the devices were removed, these were not completed consistently, and some families did not complete it at all. While the ZZ needed to be removed and connected to a USB port to check on progress, neither the MB nor SQ needed to be removed for this task. The periodic removal of the ZZ may have led to children forgetting to put the ZZ back on, leading to wear times that were not consistent with the other devices. Indeed, this participant compliance limitation is present in all free-living studies. Therefore, using a semi-structured protocol would allow an assessment of criterion and/or construct validity by, for example, directly observing children in natural settings (eg, home, playground) while they wear the activity trackers and the AG or other research-grade accelerometer [32].

While the ZZ demonstrated low and variable associations with the AG, it was the only tracker that identified less activity on the fourth day of wear compared to days one and two; similar to the AG. It is likely that the larger variability in the daily values from the MB and SQ limited our ability to detect statistically significant day-to-day differences for these consumer devices. This may be an important consideration if the goal is to use these devices to track changes in activity at the group level, especially for smaller groups of children where inter-individual variability may overwhelm the ability to detect any statistically significant differences between groups or changes over time.

Strengths and Limitations

To our knowledge, this is only the second study to provide validation results for commercially-available youth-oriented activity trackers [30]. There is a growing body of literature performing similar work with adult activity trackers (eg, FitBit, Misfit, and Jawbone) [4-10]. Given the public health importance of promoting active lifestyles for the nation’s youth, more attention to activity trackers marketed for use by children is needed. To our knowledge, no research has attempted to validate adult-oriented activity trackers worn by children. However, this line of research may be limited since there are additional child protection regulations required for youth activity trackers (eg, the Federal Trade Commission’s Children’s Online Privacy Protection Rule). An additional strength of this study is the comprehensive validation procedures; encompassing orbital shaker testing, and human testing in structured activities and multiple days of free-living activity. We identified potential strengths and weaknesses of each device. Unfortunately, we were not able to accurately assess fidelity with device placement and simultaneous wearing of the devices during the free-living phase of the study. As a result, devices may not have been worn properly, indicating a need for additional research in semi-structured settings. A limitation with all of the trackers is that they employ proprietary algorithms to produce their output and therefore, it is not possible to directly compare output among devices and limits the ability to gauge attainment of PA recommendations.

A limitation endemic to research with activity trackers is the lack of a common metric for direct comparisons among devices. This is due to the proprietary algorithms employed by the device manufacturers. Another possible limitation is the relatively small sample (n=14 and n=16) for the testing of human subjects. Despite this, we were able to observe the expected differences in device output for the ActiGraph, our criterion measure, indicating that we had adequate statistical power to detect meaningful differences. A post-hoc power analysis was performed using G*Power (version 3.1) [33] based on performing Wilcoxon Rank Sum Tests to detect differences between adjacent intensity categories for the structured activities protocol (Phase 2). For the ActiGraph, Sqord, and Zamzee, 80% power was obtained with N=4 to 10 participants, N=4 to 15 participants, and N=11 to 450 participants, respectively.

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Therefore, the current sample size, while relatively small, was adequate for our purposes.

In summary, all of the activity trackers distinguished between frequencies on the orbital shaker with limited inter-unit variability for the MB and SQ whereas the ZZ units displayed the greatest amount of inter-unit variability. During the structured activities, the SQ was able to distinguish between all of the activity intensity categories, similar to the criterion measures (weight relative energy expenditure and AG vector magnitude counts), while the MB and ZZ did not discriminate among light, moderate and vigorous activity intensity. During the 4 days of free-living activity, the ZZ was the only activity tracker to identify the activity level on the fourth day to be lower than the first and second day, similar to the AG. Visually, the pattern of output from the MB and SQ also resembled that from the AG, but high levels of inter-individual variability prevented the detection of those patterns as statistically significant.

Conclusions

Of the devices tested, the Sqord demonstrated stronger validity compared with the Movband and Zamzee across study phases. Youth activity tracker manufacturers may use this information to assist with product development and refinement. Interventionists can use this information to assess the utility of these youth-oriented activity trackers as behavior change tools. Physical activity researchers may use this information to conduct additional investigations of other youth- and adult-oriented activity trackers. Future research studies should assess the validity of youth activity trackers in larger, more diverse samples and assess the reliability of these trackers over longer periods of use, which would be important if such devices are to be used as behavioral modification tools.

Acknowledgments

This study was funded by the Reebok Foundation.

Conflicts of Interest

None declared.

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Abbreviations

AG: ActiGraph
MB: MovBand
SQ: Sqord
ZZ: Zamzee
EE: energy expenditure
PA: physical activity
MVPA: moderate + vigorous physical activity

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Edited by G Eysenbach; submitted 15.07.16; peer-reviewed by R Furberg, J Schrager, D Donaire-Gonzalez; comments to author 19.11.16; revised version received 11.03.17; accepted 27.03.17; published 19.07.17.

Please cite as:
Sirard JR, Masteller B, Freedson PS, Mendoza A, Hickey A
Youth Oriented Activity Trackers: Comprehensive Laboratory- and Field-Based Validation
J Med Internet Res 2017;19(7):e250
URL: http://www.jmir.org/2017/7/e250/
doi:10.2196/jmir.6360
PMID:28724509

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Original Paper

Smartphone-Based Monitoring of Objective and Subjective Data in Affective Disorders: Where Are We and Where Are We Going? Systematic Review

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Abstract

Background: Electronic mental health interventions for mood disorders have increased rapidly over the past decade, most recently in the form of various systems and apps that are delivered via smartphones.

Objective: We aim to provide an overview of studies on smartphone-based systems that combine subjective ratings with objectively measured data for longitudinal monitoring of patients with affective disorders. Specifically, we aim to examine current knowledge on: (1) the feasibility of, and adherence to, such systems; (2) the association of monitored data with mood status; and (3) the effects of monitoring on clinical outcomes.

Methods: We systematically searched PubMed, Web of Science, PsycINFO, and the Cochrane Central Register of Controlled Trials for relevant articles published in the last ten years (2007-2017) by applying Boolean search operators with an iterative combination of search terms, which was conducted in February 2017. Additional articles were identified via pearling, author correspondence, selected reference lists, and trial protocols.

Results: A total of 3463 unique records were identified. Twenty-nine studies met the inclusion criteria and were included in the review. The majority of articles represented feasibility studies (n=27); two articles reported results from one randomized controlled trial (RCT). In total, six different self-monitoring systems for affective disorders that used subjective mood ratings and objective measurements were included. These objective parameters included physiological data (heart rate variability), behavioral data (phone usage, physical activity, voice features), and context/environmental information (light exposure and location). The included articles contained results regarding feasibility of such systems in affective disorders, showed reasonable accuracy in predicting mood status and mood fluctuations based on the objectively monitored data, and reported observations about the impact of monitoring on clinical state and adherence of patients to the system usage.

Conclusions: The included observational studies and RCT substantiate the value of smartphone-based approaches for gathering long-term objective data (aside from self-ratings to monitor clinical symptoms) to predict changes in clinical states, and to investigate causal inferences about state changes in patients with affective disorders. Although promising, a much larger evidence-base is necessary to fully assess the potential and the risks of these approaches. Methodological limitations of the available studies (eg, small sample sizes, variations in the number of observations or monitoring duration, lack of RCT, and heterogeneity of methods) restrict the interpretability of the results. However, a number of study protocols stated ambitions to expand and intensify research in this emerging and promising field.

(J Med Internet Res 2017;19(7):e262) doi:10.2196/jmir.7006

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KEYWORDS

review; mood disorders; smartphone; ecological momentary assessment

Introduction

Unipolar depressive disorder is one of the leading chronic medical conditions in Europe, accounting for 13.7% of the disability burden [1], and is projected by the World Health Organization to become the second highest condition leading to burden of disease by 2030 [2]. International lifetime prevalence rates of depression range from 6.3-10.3% [3], and comorbidity [3] and mortality [4,5] are common; these disorders also incur a considerable economic burden [6]. Unipolar depression often takes a chronic recurrent course, with more than 70% of patients suffering several episodes throughout their lifetimes [7,8]. Bipolar disorder affects 2-2.5% of the adult population [9,10] and is considered a chronic disorder [11]. Both unipolar and bipolar affective disorders have severe consequences on functioning and quality of life [12]. Although effective treatment is available [13], it is estimated that at least 50% of patients with depression receive no treatment at all [14,15]. Furthermore, most patients do not adhere to medication regimens and referrals [16,17]. Barriers for help-seeking and treatment adherence include stigmatization, fear of discrimination, and an unavailability of services [18,19].

Electronic mental health (e-mental health) interventions represent a promising means of overcoming such barriers and increasing the capacity for patients' self-management of depression [20]. Using the Internet to deliver treatment for affective disorders has been shown to be an effective option for reaching patients who were not able to receive face-to-face treatment due to geographical or other situational barriers [21], or to augment face-to-face therapy [22]. Internet availability in developed countries has expanded rapidly and now reaches individuals in nearly all social, age, ethnic, and education-level groups [23]. It is of promise for e-mental health interventions that people suffering from mental disorders actively use the Internet just as often as those in the general population who do not have mental illnesses (80%) [24]. A newer technological development is the rapid spread and technological improvement of smartphones. In the first quarter of 2016, there were 7.4 billion mobile phone subscriptions worldwide, of which 3.4 billion were for smartphones [25]. These numbers are estimated to reach 9 billion mobile phone and 6.3 billion smartphone subscriptions by the year 2021 [25]. Over 80% of the general population in Western countries already use mobile phones [23], thereby passively collecting an extensive amount of data that is not yet sufficiently used for medical and scientific purposes.

Capitalizing on these technological advances, a novel approach in e-mental health has emerged with the development and testing of several technology-enhanced systems for affective disorders that rely on combinations of subjective (ie, self-reported) and objective data, measured by sensors embedded within (or connected to) smartphones. When considering subjective self-ratings, smartphone apps result in better adherence and less missing data compared with paper-pencil or personal computer-based questionnaires or diaries [26]. However, the strongest asset of smartphone-based systems may be their high suitability for collecting objective data from behavioral and physiological monitoring. Differences in subjective (ie, psychological) and objective (ie, behavioral or physiological) data are a common finding (eg, pronounced differences in self-ratings on sleep quality compared to objectively recorded sleep quality are often seen in subjects with sleep disorders, such as insomniac patients who typically overestimate their actual wake times during the night). This issue has sparked a discussion about whether or not both approaches are alternatives or complement each other by capturing different aspects of the respective construct (a detailed discussion of this topic can be found in Tams et al [27]). Using both self-reported and objectively measured data derived from the smartphone-based systems may help to better monitor disease progression and optimize self-management approaches. Modern smartphones are able to incorporate a large number of various sensors (eg, global positioning system [GPS], Bluetooth, accelerometers, microphones), are carried mostly close to the body, have long lasting batteries, and contain large memory storage and powerful central processing units for recording and processing information [28,29]. Mobile technology has the vast advantage that it can be easily integrated into patients' lives as a comfortable, simple, time-unconstrained, user-friendly, economical, and noninvasive method of registering and monitoring relevant signs and symptoms. Such technologies can be used to provide continuous self-management and psycho-educational content tailored to the specific needs of each individual on the basis of data registered on their own smartphones [23].

Using objective data for symptom monitoring is especially relevant for affective disorders, in which reliable diagnostic and predictive biomarkers are still lacking and self-reported symptoms are not only influenced by recall bias, but also by a mood-state associated bias. Therefore, it is an important question whether long-term continuous monitoring of subjective and objective parameters combined with a time-series analysis could provide earlier and more reliable predictors and indicators of mood changes. Such findings could be helpful for the individual patient to improve their self-management and prevent relapses [23]. Although there is already an ever-growing number of systems (usually smartphone apps) focusing on monitoring depressive symptoms, as well as collection of objective data from smartphone or external sensors, only a small portion of these have been evaluated regarding feasibility, efficacy, and safety [23]. Considering the importance of this emerging field, the speed of innovations and new developments, it was our aim to review the state-of-the-art knowledge about smartphone-based monitoring systems for affective disorders and their benefits for treatment.

Objective

The aim of this systematic review is to examine the literature on smartphone-based systems that combine subjective ratings with objectively measured data for the self-monitoring of depressive symptoms. The following aspects will be covered: (1) feasibility and adherence, (2) the association of monitoring data with mood status, and (3) effects on clinical outcome.

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Methods

Overview

Literature was systematically reviewed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines [30]. This systematic review has been registered in the PROSPERO international prospective register of systematic reviews (registration number CRD42017058539). A PRISMA checklist is presented in Multimedia Appendix 1.

Information Source

In February 2017, the search for relevant articles published in the last ten years (2007-2017) was conducted in the following bibliographic databases: PubMed, Web of Science, PsycINFO, and Cochrane Central Register of Controlled Trials. Additional articles were identified via pearling, author correspondence, selected reference lists, and trial protocols.

Search Strategy

The search strategy was developed by three of the authors and included combinations of the search terms, such as *affective disorder*, *ecological momentary assessment*, *smartphone*, *e-mental health*, and *self-monitoring*. The search took place in six content-related categories and the application of iterative combinations of these categories by employing the Boolean search operators (see Multimedia Appendix 2 for the full search strategy).

Eligibility Criteria

Titles and abstracts were screened for eligibility and were included if: (1) abstracts were published in English or German, (2) any form of smartphone-assessed self-monitoring of depressive symptoms was mentioned, and (3) adult study participants with depressive symptoms (but not postpartum/postnatal depression or pregnant women) were investigated. In cases of insufficient information to determine eligibility, papers were nonetheless subjected to further screening. Considering the novelty of this research area, the review was planned to be as inclusive as possible. Therefore, experimental and observational studies were included.

Selection of Studies

We obtained full reports of all potentially relevant papers. Articles were discarded if they met at least one of the following exclusion criteria: (1) review papers only; (2) study protocols or descriptive planned studies or future study intents; (3) descriptive studies that did not include participants diagnosed with affective disorders (apart from postpartum/postnatal depression); (4) studies that did not monitor objective data involving a smartphone/mobile device (eg, computerized/Internet-delivered or Internet-based Cognitive Behavioral Therapy interventions or Ecological Momentary Assessment [EMA] studies in which only subjective ratings were obtained); or (5) other reasons (eg, comments, letters, poster abstracts, articles not written in English). Additional information from study authors was obtained when necessary to resolve questions about eligibility. Four authors (ED, EK, CS, and XW) screened the full text reports and decided whether these papers met the inclusion criteria. Records were originally split among the four reviewers, each of whom made independent decisions regarding exclusion. Uncertainties and disagreement were resolved through discussion (ED, EK, CS, and UH). Reasons for excluding articles were recorded (including multiple assignments to exclusion criteria, if applicable). Finally, all exclusion assignments were reviewed and each record was allocated to one exclusion criteria (CS, XW, and EK).

Assessment of Methodological Quality

The Downs and Black Instrument [31], which is recommended for both randomized and nonrandomized studies, was used for assessing the quality of included studies. This 27-item checklist rates studies on the following subscales: reporting, external validity, internal validity-bias, internal validity-confounding (selection bias), and power. The total maximum score that can be achieved with this instrument is 32. High internal consistency, as well as good inter-rater variability and test-retest-reliability, were reported [32]. For the purpose of this study, the last question was modified by changing the score from 0-5 to a dichotomous score (0/1) equivalent to the procedure outlined by Hootman et al [32]. If a sample size or power calculation was provided, the final item was scored as 1. The item was scored 0 if sample size and power calculations (or explanations about the appropriateness of the sample size) were missing. Thus, the total maximum score of this modified checklist is 28.

Data Synthesis

Due to the novelty of the approach/research field and the heterogeneous nature of the included studies, a quantitative data synthesis (meta-analysis) has not been performed, since there was an insufficient amount of data to calculate effect sizes. Standardized forms were developed for data collection purposes and two authors (ED and EK) were trained to use and apply them. Piloting of the extraction forms with a subsample of randomly selected included studies also took place. To ensure consistency between reviewers, calibration exercises took place before starting the review. Data extraction was performed in duplicate by two authors (ED and EK), disagreement was resolved by discussion, and another author (CS) verified the information to reduce bias and errors in data extraction. We contacted study authors to resolve any uncertainties or for clarification, if needed. A systematic narrative synthesis will be provided with information presented in the text and tables to summarize and explain the characteristics and findings of the included studies.

Results

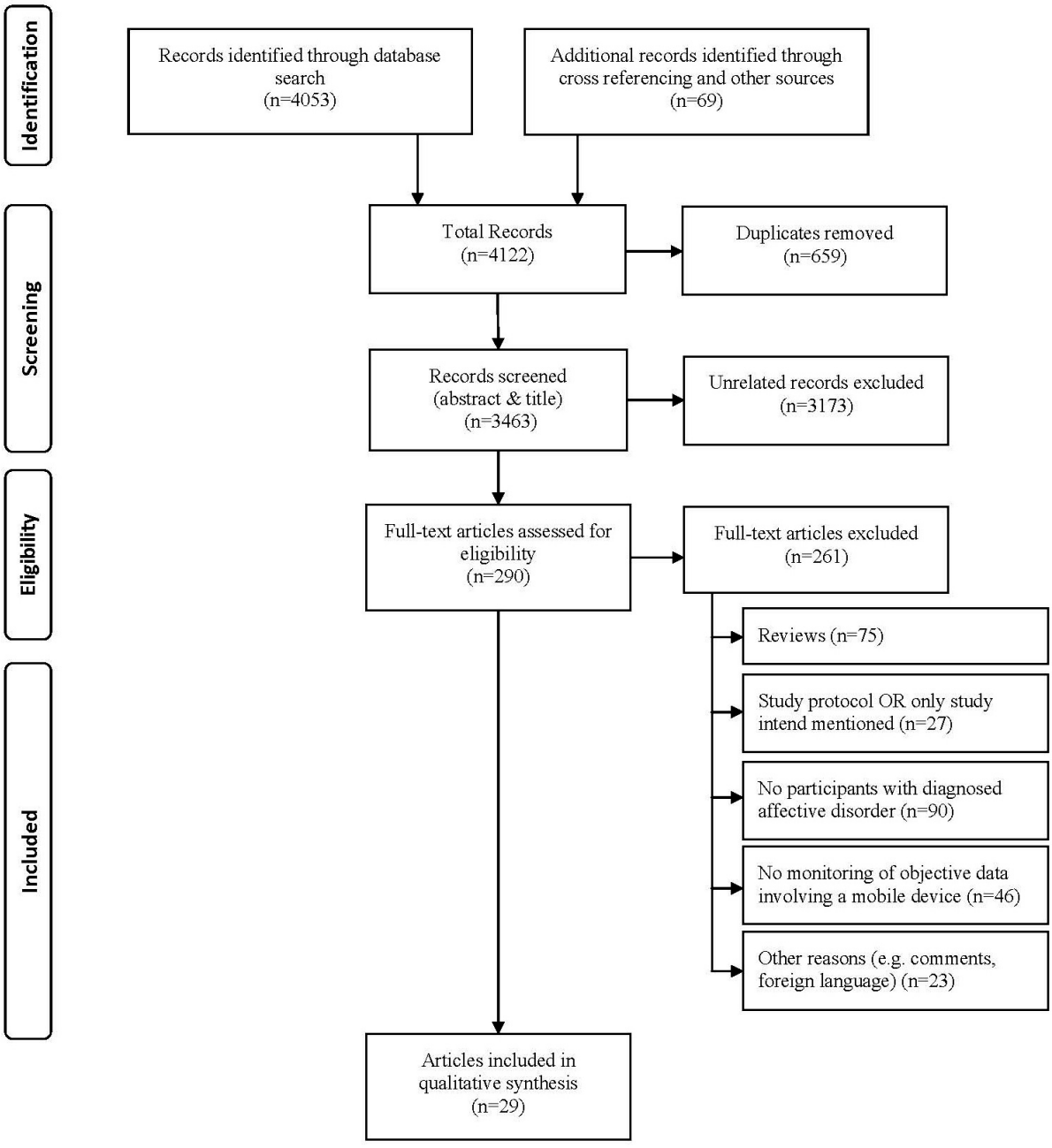
After the description of the selection process and characteristics of included systems and studies are detailed, the results section is structured according to the objectives of the review. The *Association of Monitoring Data With Mood Status* section lists the different parameters recorded by the smartphone-based systems included in the review and, where applicable, is extended by further evidence.

The electronic database search resulted in a total of 4122 records (PubMed, n=650; PsycINFO, n=378; Web of Science, n=1534; Cochrane Central Register of Controlled Trial, n=1491; and

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n=69 identifications by cross-referencing), of which 3463 were unique articles. In the first selection step (abstract screening), 3173 records were excluded after it was determined that they did not meet inclusion criteria based on information in the abstract. The majority of these studies were excluded because they only contained descriptions of online/computerized Cognitive Behavioral Therapy systems, descriptions of pure online interventions, or self-monitoring or screening tools (using only subjective assessment and self-monitoring or smartphone-based ecological momentary assessments). A total of 290 full text papers were retrieved for further consideration. After reviewing these full texts, an additional 261 records were excluded. Figure 1 depicts a flowchart of the screening process (see Multimedia Appendix 3 for the list of excluded full text articles).

Figure 1. PRISMA Flow chart.



Characteristics of Included Systems and Studies

Twenty-nine studies were included for qualitative synthesis in this review. Although the search range spanned from 2007 to 2017, the included studies were all published after 2010, attesting to the novelty of the research field. Table 1 provides an overview of all systems that were described within the included articles. Most systems incorporated different data sources: in all cases, subjective ratings were required by the users (eg, ratings on mood, estimates on sleep, or information

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on medication). These data were complemented by different bio-parameters (eg, electrocardiogram [ECG], respiration, skin conductance), which were either recorded by the smartphone itself (eg, accelerometer, microphone) or by additional wearables. Smartphone usage was monitored by many of the included systems, although different parameters were used (eg, screen state, number of incoming and outgoing calls). Smartphone sensors also provided information about context and environmental conditions that were taken into account (eg, light sensor, GPS).

A detailed description of the included studies is provided in Multimedia Appendix 4. Studies were conducted in the following countries: United States/England (n=10), Austria/Germany (n=8), Denmark (n=8), and Italy/France (n=3). The majority of included studies used an observational design (n=27), as most were pilot or feasibility studies focusing on feasibility of, and adherence to, the respective monitoring systems, or were aimed at investigating the association of monitored data with clinical mood state. Only three studies [33-35] provided data on effects of monitoring on clinical outcomes; of those, only one used a randomized controlled trial (RCT) design [35]. Accordingly, the sample sizes ranged from 1 to 78. While 4 studies included patients with diagnosed major depression, 24 studies were conducted with patients with bipolar affective disorder. Two studies [36,37] also included schizophrenia patients in their study population with affective disorders.

Table 1. Overview of smartphone-based systems that combine subjective mood ratings and objective assessment of physiological and behavioral parameters for the monitoring of affective symptoms.

	Self-Report Data	Physiological Data	Behavioral Data			Context and Environmental Data		Type of clinical trials
			Phone Usage	Physical Activity	Voice features	Light Exposure	Location	
Empath [38]	+	+	-	+	+	-	-	Case Study
FINE [39]	+	-	+	+	-	-	+	Feasibility Study
MedLink [33][a]	+	-	-	-	-	-	-	Pilot Study
Mobilyze! [34]	+	-	+	+	-	+	+	Feasibility Study
MONARCA [26,35,40-44]	+	-	+	+	+	+	+	Feasibility Study, Pilot Study, RCT
MoodRhythm [45]	+	-	+	+	-	+	-	Pilot Study
PSYCHE [46-48]	+	+	-	+	+	-	-	Pilot Study
SIMBA [49]	+	-	+	+	-	-	+	Pilot Study
Unnamed System [50][b]	+	+	+	+	-	-	-	Feasibility Study
Unnamed System [36]	+	+[c]	-	+	-	-	-	Pilot Study

[a]Objective monitoring of medication adherence using a *Wisepill bottle*.

[b]System was utilized in an Automated Monitoring of Symptom Severity (AMoSS) study.

[c]An ingestion sensor was used for gathering the physiological data.

Results on Methodological Quality Assessment

According the Downs and Black instrument, the methodological quality scores of the studies ranged from 5 [44] to 22 [35]. Methodological bias of the included studies is presented in Multimedia Appendix 5. In most cases the included studies had low scores, as they were mostly conducted as single-arm observational trials, feasibility studies, or pilot studies, and were not randomized trials. In addition, studies reporting only qualitative data [37,39,50,51] also scored lower. Except for one study [36], no adverse effects were reported in the selected studies.

Results on Feasibility and Adherence

Among the included studies, large variations in drop-out rates were reported, ranging from 0% [26,33,39,44,46,48,50,52-56] to 22% [45]. Technical problems, including inappropriate operating systems [34,40,45,57], were reported to be the most common reason for discontinuation. Several articles reported on feasibility and discussed aspects of improving adherence. Prociow et al [51] reported large initial interest when approaching self-support groups and charities, but only three patients were willing to participate in their feasibility trial, of which two withdrew before a second visit. Compared to their healthy participants who were described as being “accustomed with mobile technology”, the patient (although being euthymic during the study duration) adhered only poorly to the monitoring regimen due to self-reported difficulties with the management of the unfamiliar technology. The system in this study was comprised of environmental as well as wearable sensors, with the latter causing a higher level of discomfort.

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In a field trial of MONARCA 1.0 [40] the adherence rates for phone-based and paper-based self-assessments were found to be comparable. Moreover, high compliance scores of the four mandatory self-assessment parameters by phone-based self-assessment were reported. The patients in this field trial also rated the system usability and usefulness on a Likert scale from 1 (strongly agree) to 7 (strongly disagree). Average rates for these scores were: overall satisfaction=2.6, system usefulness=1.93, information quality=3.32, interface quality=2.71, usefulness of the system for disease management=3.16, and perceived usefulness for disease management=2.16. Taking into account the days on which the system was working, an adherence rate of 87% was reported for this field trial, with an increased adherence (91%) being reported for MONARCA 2.0 [44].

Beiwinkel et al [49] reported a compliance rate of 55.7% for filling in self-reporting data, with no decline over time, during an average study duration of 12 months. In a pilot study (n=28) assessing feasibility of a digital health feedback system using an ingestion sensor for physiologic assessments and confirmation of tablet ingestions, a medication adherence rate of 74% was documented [36]. Among the participants who completed the study (n=27), the concept was found easy to understand by 70%, 89% reported that the system might be useful for them, and 78% indicated that they would prefer to receive reminders on their smartphones in case of forgetting to take the medications [36]. In the pilot study (n=8) of the Medlink system [33], medication adherence was assessed through the *Wisepill bottle* which produces a signal when it is opened, thus providing real-time information about patient pill-taking activity. According to data gathered from the pillbox, 72.5-100% of doses were taken by study participants [33]. On a scale from 1 (strongly disagree) to 7 (strongly agree) the average rating for satisfaction was found to be 4.8 (standard deviation [SD]=0.8). Ease of use was rated 5.7 (SD=1.1), while learnability scored 6.1 (SD=1.5) and an average rate of 4.6 (SD=1.0) was found for usefulness.

The overall satisfaction of users with smartphone-based systems is reported to be rather positive (eg, the satisfaction with the Mobilyze! intervention was reported to be 5.71 [SD=1.38] on a scale ranging from 1 [strong disagreement] to 7 [strong agreement]) [34]. However, the usage pattern in this study showed a constant decline over time with participants using their phone 15.3 times (SD=8.3) during the first week of the intervention, 9.0 (SD=6.5) during the fourth week, but only 4.8 times (SD=4.6) during the eighth week [34]. In a post-study usability survey of MoodRhythm, the average System Usability Scale rating among participants was found to be 85.94 (SD=10.43) out of 100 [58].

Patient compliance was reported as a limitation in several studies [39,41-43,45,49,51,52,54,55,59], as it could not completely be controlled if participants carried their smartphone with them all the time, did not share their phone with others, or did not turn it off occasionally during the monitoring phase. In the study by Muaremi et al [60], 6 of 12 included participants were excluded for mood state classification analyses due to either not experiencing mood state changes, or data incompleteness caused by not using the study smartphones for phone-calls or switching it off for several days. Maxhuni et al [53] also used information from only 5 of 10 participants due to the lack of data gathered from phone calls. As a precaution, Faurholt-Jepsen et al [26] did not include participants who were not willing to use the study smartphone regularly.

Reporting experiences from a first field trial of their FINE app prototype, Dang et al [39] stated that patients provided information about using the study smartphone only irregularly. However, the patients shared that they would be interested in using the device in addition to their conventional treatment if transparency concerning the recorded data and its further use was given [39]. Participants also criticized not being allowed to disable the background data logging, specifically mentioning GPS tracking [39]. Saunders et al [50] interviewed 21 patients that had participated in a self-monitoring study and found that patients considered it very important that assessment devices look normal to avoid drawing attention in public. Wrist-worn actigraphy devices and a daily mood rating were considered tolerable; a higher frequency of assessments (in the study, up to 10 mood samples during a day were collected) was considered inconvenient [50]. All but one patient was willing to share their data with others, especially since most considered this to be beneficial for the decision making of their psychiatrists; however, patients also stated that they would be interested in giving context explanations to their data to avoid misinterpretations [50]. The size of wrist-worn actigraphy devices was also rated favorably by the participants of the Naslund et al study [37]. Wearing the device was considered uncomplicated, yet some participants with limited prior experience with mobile technology experienced operating with the unfamiliar smartphone technology as distracting and discouraging [37].

Results on Association of Monitored Data With Mood Status

At present, most empirical data exist on the association between objectively recorded data and clinical state or symptom changes (self-reported or rated by clinicians). Therefore, the following section summarizes results obtained with the different (bio-) parameters. If applicable and relevant, additional evidence from nonincluded publications is given to provide a comprehensive overview. Based on our results, no cumulative statements about the direction and/or magnitude of effect sizes can be drawn, since all studies differed concerning selected features, statistical approaches, and handling of ground truth (classification of affective states) for mood state prediction. Overall, the prediction accuracy depended largely on the methodological approach and the respective affective states as outcome measures (eg, depression versus euthymic state compared to depression versus [hypo]mania).

Many of the included studies reported results on a small number of subjects. However, when individual time-series are to be analyzed, a sufficient recording duration for the individual patients seems to be more desirable than a larger number of subjects. Twenty-five studies monitored data for several months or weeks, three of which still had to exclude subjects from the final analysis, as they did not experience any changes in mood

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states, and thus associations between mood states and objective parameters could not be analyzed [54,55,60].

Self-Assessment/Self-Report

Self-assessment or subjective rating of mood status via different assessment methods is an integral part of nearly all included studies and systems currently being tested. The superiority of EMAs in mental health versus standard paper-pencil questionnaires has been proved by many studies [61]. Among the selected studies, 20 [26,33-36,38-45,49,50,52,53,55,57,60] provided a self-assessment option. Mood agenda, sleep agenda, and diary have also been included in the PSYCHE platform [46], but no findings were reported in that context.

The content of self-monitored items varies from system to system. Within the MONARCA system, self-assessment of mood, sleep length, medication adherence, irritability, activity, mixed mood, cognitive problems, stress, alcohol consumption, menstruation for women, and individualized early warning signs are requested [62]. In the system used by Grünerbl et al [57], information about the activities of daily living as well as psychological state, physical state, and amount of activity were assessed daily. Within the SIMBA system, there were only two questions about mood and energy [49]. Several systems use established questionnaires. In the MoodRhythm system the Social Rhythm Metric (SRM-5) is used [45]; the FINE app monitors mood through administration of the Patient Health Questionnaire (PHQ-9) [39], and within the MedLink system, mood was assessed with PHQ-9 [33]. The Center for Epidemiologic Studies Depression Scale is administered weekly in the Empath system [38], and in the system used for the AMoSS study *Mood Zoom* was used for daily mood monitoring while the *True Colours* system was selected for weekly mood measurements [50]. In the pilot study of a digital health feedback system using an ingestion sensor for confirmation of medication ingestion and measurement of physical metrics, a self-assessed sleep quality questionnaire was used [36]. Additionally, in some systems there are extra self-assessment opportunities, such as notes or diary sections that are incorporated [45]. However, in the field trial of MONARCA 1.0 [40] it was reported that participants did not use the optional text entry on the phone.

Self-assessments may serve different purposes: they provide a continuous support to individuals (eg, supportive monitoring) and also allow for a better estimation of individuals' need for support, and may serve as an underlying information system to guide and tailor care accordingly (eg, by detecting symptom deterioration or early warning signs for change in moods states) [63]. This longitudinal technology-enhanced assessment of symptoms and behaviors (eg, outcome monitoring and EMA) can help to improve our understanding of illness development and recovery, and can further optimize care by integrating self-monitoring systems into specific e-mental health interventions and apps. In the study of Mobilyze! [34], self-reported items were used for individualizing prediction models. Frost et al [44] showed in the field trial of MONARCA 2.0 that self-reported activity, stress, and sleep were among the three ranked parameters according to the correlation between Impact Factor and the mood score. Faurholt-Jepsen et al [26] showed that there was a significant correlation between Hamilton Depression Rating Scale, 17 item version (HDRS-17) scores and self-rated mood in adjusted (for age and sex) and unadjusted models. Another study by Faurholt-Jepsen et al [43] showed significant positive correlations between self-monitored mood rate and HDRS-17 in adjusted and unadjusted models (n=29). In relation to manic symptoms, the Young Mania Rating Scale (YMRS) correlated significantly and positively with self-monitored data on mood in adjusted and unadjusted models. Maxhuni et al [53] reported that adding information from questionnaires to the information from accelerometer and audio features improved the overall accuracy results of classifying bipolar disorder episodes; however, they emphasized that precision and recall results were very similar with and without questionnaires.

Physiological Parameters

According to Valenza et al [64], studying mood swings over time shows that changes in mental status have intrinsic dynamics, which suggests a link between autonomous nervous system dynamics (a division of peripheral nervous system) and bipolar disorders. These changes can be shown in physiological parameters such as respiration activity, heart rate variability (HRV), and electrodermal activity. Physiological parameters were assessed in four of the included studies [36,46,48,50]. Since two of the studies did not report any association with the mood states, only the other two will be discussed.

Using the PSYCHE platform, ECG/HRV and respiration activity were gathered using a sensorized t-shirt [46]. Additionally, an accelerometer for measuring physical activity was included in the wearable system. The collected raw data was preprocessed and feature extraction was performed to determine data series for the HRV and respiratory rates. Studies using the PSYCHE platform to identify and predict mood states indicated that HRV series can be employed for classification of mood states: after analyzing HRV series Lanata et al [46] suggested that sample entropy of these series can be regarded as a marker for clinical severity in bipolar disorders. In a study analyzing long-term HRV dynamics in eight patients with bipolar disorder, Gentili et al [48] found that HRV features that were normalized using information from future and past mood states provided a significantly higher classification accuracy (mean=99.52) compared with other HRV-features, which were normalized using other procedures or were not normalized at all. The authors claimed that the results of this study show the high accuracy of HRV features in labeling of mood states [48].

Phone Usage

During a depressive phase, the desire and ability for social interaction is mostly reduced, whereas during the (hypo)manic phase it is increased [59]. The included studies measured social interaction through duration and number of incoming and outgoing phone calls and number of incoming and outgoing short messaging system (SMS) texts per day as a behavioral marker. Nine of the included studies [26,34,42,43,49,52,57,59,60] reported the association between social interactions with mood states.

According to Grunerbl et al [57] the length and number of phone calls increase in mild depressive phases compared to severe

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depression or a normal mood state. In another study by the same group [59], it was reported that behavioral data only from phone call features did not provide high recognition rate. Muaremi et al [60] examined phone call features in three groups: phone call statistics (eg, number of calls/day), social signal processing (eg, average speaking length), and acoustic emotion recognition (eg, pitch frequency). The average mood state prediction performance of phone call statistics was lower than other features [60].

Within the MONARCA project, significant positive correlations between the number and duration of incoming and outgoing calls per day and scores on YMRS, and between scores on the HDRS-17 and duration of incoming and outgoing calls per day, were found; additionally, a significant positive correlation between scores on the YMRS and the number of outgoing text messages per day was shown [42]. In another study from this group [26] with bipolar patients (n=17) there was no significant correlation between affective symptoms assessed with HDRS-17 and YMRS and the number of outgoing text messages. In another study with 29 participants [43] HDRS-17 scores were found to be significantly and negatively correlated with numbers of incoming text messages per day as well as numbers of outgoing calls per day, whereas positive correlations were shown between numbers of incoming calls and missed calls per day and HDRS-17 scores. In relation to manic symptoms, YMRS scores were found to be significantly and positively correlated with numbers of outgoing text messages per day and daily duration of phone calls in adjusted models [43]. Furthermore, daily duration of outgoing calls, as well as number of characters in incoming text messages, were significantly and negatively correlated with YMRS scores [43].

Beiwinkel et al [49] found a negative association between number of outgoing SMS texts and HDRS-17 scores in within-patient analyses and between-patient analyses. As duration of calls did not show any significant relationships with YMRS and HDRS, the number of calls made was positively associated with manic symptoms, assessed via YMRS in between-patient analyses [49].

Phone usage patterns including screen state and usage of apps might provide information about patients' current mood state. Alvarez-Lorenzo et al [52] reported that self-reported mood level showed a negative correlation with the amount of time the phone screen is on, the percentage of social apps, the percentage of entertainment apps, as well as the amount of time patients interact with the smartphone, respectively (n=18). Conversely, positive correlations between average number of apps and self-reported mood level, as well as between browser apps (eg, Chrome, Firefox) and self-reported mood level, were reported [52]. For 17 bipolar patients, no significant correlation between the amount of time the screen was on and affective symptoms (assessed with HDRS-17 and YMRS) was reported by Faurholt-Jepsen et al [26]. However, in another study by this group [43], duration of screen-on per day was found to be positively and significantly correlated with HDRS-17 scores in unadjusted as well as adjusted models.

Physical Activity

Patients with affective disorder tend to have lower acceleration and activity energy expenditure compared to healthy individuals [65]. Furthermore, a lower activity energy expenditure per day and acceleration have been demonstrated in bipolar patients compared to patients with unipolar depression [65]. By gathering the physical activity data continuously, it is possible to observe the effects of physical activity on mental health more comprehensively. Among the included studies, physical activity was measured mainly with accelerometers incorporated in the smartphones. In the PSYCHE project [46], the accelerometer was integrated into a wearable system.

Eight of the selected studies reported on the relationship between affective states and physical activity [38,45,49,53-55,57,59]. In a study with 12 bipolar patients, the average precision/recall values (for state change detection) were approximately 60% for acceleration [55]. Conversely, in a study with 10 bipolar patients an average recognition accuracy of 70% for movement features (measured with accelerometers) was reported by Grünerbl et al [59]. This finding was supported by results from an older study by this group [57], in which an increase in motion ratio occurred with improved mood state. Furthermore, the authors pointed out that in manic patients the trend was reversed: with the progression from manic to normal state, a decrease of 33.7% in the amount of movement was detected [57]. Abdullah et al [45] pointed out that nonsedentary duration was weakly correlated with mood pattern. Beiwinkel et al [49] reported that device activity (measured by accelerometers) did not have a significant relationship with clinical symptoms in between-patient analyses. Osmani et al [54] reported a correlation between the overall physical activity level and the patients' state. Furthermore, this study found a much stronger correlation between the physical activity divided in daily intervals and patient's state than there was for the overall physical activity levels [54]. Maxhuni et al [53] reported that using accelerometer features recorded during telephone conversations have accuracy results over 80% for classifying bipolar disorder episodes. According to these analyses, the frequency domain feature showed better performance in comparison to the time domain feature [53]. However, Dickerson et al [38] could not find a significant relationship between mood levels and a movement factor.

Location

Changes in travel patterns (eg, distance travelled per day, location changes), which can be gathered through GPS, Bluetooth (via detection of other wireless devices), cell tower identification (ID) and WiFi, may provide information about patients' mood states. For example, it is expected that people in a depressive phase travel and stay outside less often [55]. Eight studies [26,34,43,45,49,55,57,59] investigated the association between travel patterns and mood states. Promising accuracy rates for state recognition by using travel patterns were shown in two studies [55,59]. Grünerbl et al [57] found an increase of 200% in the average time spent outside from a depressive state to normal state. Beiwinkel et al [49] reported that the amount of movement between cell towers (indicating changes of location) did not have a significant relationship with

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clinical symptoms but distance travelled showed significant negative association with clinical manic symptoms in between-patient analyses. Additionally, in within-patient analyses a negative relationship between the increase in cell tower movements and clinical manic (as well as depressive) symptoms was found [49]. Conversely, changes in distance travelled were not significantly related to symptom change [49]. Faurholt-Jepsen et al [26] reported a significant correlation between the higher score on HDRS-17 and lowered number of changes in cell tower ID per day in their unadjusted model; however, in their adjusted model the correlation was borderline significant. In another study using MONARCA system [43], Faurholt-Jepsen et al reported significant positive correlations between cell tower ID changes per day and both rating scale scores (YMRS and HDRS-17). In the study by Abdullah et al [45], a significant positive correlation between location clusters and trend of self-assessed energy scores was found, while location clusters had the second highest ranking among distance travelled, nonsedentary duration, and conversation frequency in stable and unstable status classification.

Light Exposure

Light density in the environment can be used to provide information about patients' sleep-wake cycles, which is disturbed in unipolar depression as well as in bipolar disorder [66,67]. Differentiation between natural and artificial light can also be used to approximate time spent outdoors, which has also been shown to have a negative correlation with depressive symptoms [68]. Only three of the included studies [34,45,51] used ambient light sensors. Prociow et al [51] added a light detector as an environmental sensor in their system. The Mobilyze! app also used ambient light data to approximate environmental context, but technical problems were reported (implausible results above the maximum meaningful value were obtained by the ambient light sensor) [34]. The MoodRhythm system included light sensor data in its evaluation of sleep-wake cycles [58], while the study protocol of the MONARCA 2.0 trial categorized ambient light under phone usage information [62]. The monitoring of ambient light is also planned in the further development of the PSYCHE platform [69].

Voice Features

Analysis of speech and voice features appears to be a useful approach in predicting mood state in unipolar depression and in bipolar disorder [70,71]. Furthermore, using microphones to capture ambient sound can allow for the gathering of the number of conversations as a measure of social isolation, which is a behavioral pattern common in depression [45,59].

Eight articles [38,41,45,47,53,56,60,72] reported on relationships between voice features and affective states. The study by Gideon et al [72] dealt with a typical challenge of real-life monitoring of speech patterns: patients use different smartphones causing acoustic variations during the voice recordings. Using various approaches for preprocessing, feature extraction, and data modeling, the authors were able to increase the discriminative power of their mood state prediction algorithms [72]. However, only structured interview calls were analyzed in this study. Karam et al [56] also demonstrated that mood states of bipolar individuals can be separated based on voice recordings from clinical interactions and that hypomania can also be detected from unstructured calls, whereas their system struggled to detect depression from voice recordings during nonclinical interactions. Abdullah et al [45] reported that conversation frequency was weakly correlated with mood pattern. Within PSYCHE project, Guidi et al [47] concluded from a case report that changes in voice pitch features can be extracted via smartphones and correlate significantly with changes between euthymic, depressed, and hypomanic states in a bipolar patient.

Analyses of voice and speech features are also performed within the frame of the MONARCA project. Muaremi et al [60] extracted three types of features from phone call conversations and reported that using acoustic features (eg, kurtosis energy, pitch frequency) resulted in the best state recognition in comparison to phone call statistics (eg, number of phone calls during the day, average duration of phone calls) and social signals (eg, average speaking turn duration, average number of speaker turns). Maxhuni et al [53] reported that using audio features (emotional and spectral) resulted in accuracy results >80% for classifying the mood state of patients with bipolar affective disorder. Testing emotional and spectral features isolated and together resulted in similar accuracy [53]. Faurholt-Jepsen et al [41] reported an accuracy ranging from 0.61 to 0.74 in the classification of mood states based on voice feature. Dickerson et al [38] found speech factors and sleep factors more indicative of depression than other features measured in this case study.

Aggregation of the Data Collected From Smartphone Sensors

Most of the reviewed papers described a combination of self-reported data with behavioral and/or physiological parameters. Grünerbl et al [55,59] reported that the combination of features (eg, social behavior, travel patterns, and movement) optimized the state detection and provided better results than single sensors or fusion of only a few sensor modalities. Abdullah et al [45] also reported that combining self-reported data with data from several smartphone sensors (light sensor, accelerometer, microphone) and communication patterns resulted in reliable prediction of SRM-5 scores (75.89% of correctly classified labels had a probability >.7). Ranking the used features according to their importance for the classification of stable and unstable status (according to SRM-5 scores) showed the following order: distance travelled, location cluster, nonsedentary duration, and finally conversation frequency. Maxhuni et al [53] found only a small improvement in average classification accuracy for emotional states of their participants when audio features derived from phone conversations were combined with accelerometer features recorded during phone conversations. Faurholt-Jepsen et al [41] stated that increases in the sensitivity, specificity, and accuracy were found after combining voice features, self-monitored data, and automatically generated objective data. The Empath system described by Dickerson et al [38] also aims at combining several behavioral markers into a depression index, or a global depression risk index. However, only a single patient case study was reported, mainly dealing with feasibility issues [38]. Prociow et al [51] also introduced a system that combines environmental (motion

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detectors, light detector, microphone, door and bed sensors, remote control monitor) and wearable sensors (accelerometer, light detector, microphone, GPS).

Results on Effects on Clinical Outcome

Most of the reviewed studies did not report any results regarding the effects of smartphone-based monitoring on depressive symptoms or clinical outcomes. However, Burns et al [34] reported that during the Mobilyze! intervention program, depressive symptoms (self-reported on the PHQ-9) decreased significantly over time (t_{13}=7.02, $beta_{week}$=–.82, *P*<.001) according to intent-to-treat analyses. Moreover, this study found that evaluator-rated depressive symptoms (rated on the Quick Inventory of Depressive Symptomatology) improved (t_{13}=8.22, $beta_{week}$=–.81, *P*<.001) and it became less likely for participants to fulfill diagnostic criteria for Major Depressive Disorder (Z=2.15, $beta_{week}$=–.65, *P*=.03) [34]. Additionally, anxiety symptoms decreased (t_{13}=4.59, $beta_{week}$=–.71, *P*<.001) according to Generalized Anxiety Disorder questionnaire scores [34].

Saunders et al [50] performed qualitative interviews with a subset of participants (n=21) of the AMoSS study, which had monitored their moods using a smartphone combined with movement sensing devices. The authors reported that most patients (n=16) experienced the self-monitoring as enhancing their illness insight and that half of their patients stated that they had improved their mood due to being able to better identify their feelings [50]. Half of the patients also reported a change in behavior, in most cases related to increased exercise levels, but four patients also pointed to potential negative effects due to becoming too occupied with the monitoring [50]. Naslund et al [37] provided 11 patients with activity tracking devices combined with smartphones for a 6-month lifestyle intervention aimed at weight reduction, and then performed qualitative interviews. Participants considered the devices to be motivating and to increase awareness about their level of physical activity, thus helping them to increase their overall activity [37]. In the pilot trial of MedLink system [33] which assessed medication adherence through a *Wisepill bottle*, a decrease of depressive symptoms assessed with PHQ-9 was observed (*P*=.008). The authors suggested that lag time between monitoring and the initiation of medication can be reduced via the MedLink system [33].

Results from only one RCT were available. Faurholt-Jepsen et al [35] reported that in the MONARCA 1.0 trial patients in the intervention group showed more depressive symptoms during the trial according to HDRS-17 scores compared with the control group (B=2.02, 95% CI –.13 to 4.17, *P*=.07). Additionally, in further analyses (excluding mixed depressive and manic symptoms in both adjusted and unadjusted models) significantly more depressive symptoms were reported in the intervention group [35]. No difference in manic symptoms (based on the YMRS) was observed between the intervention and control groups (B=–.34, 95% CI –1.14 to .47, *P*=.41). However, excluding mixed depressive and manic symptoms, a trend for fewer manic symptoms in the intervention group was reported compared to the control group in the adjusted model (B=–1.07, 95% CI –2.15 to 0.005, *P*=.051) [35]. Furthermore, a trend towards a higher score of subjectively perceived stress was reported in the intervention group compared to the participants in the control group (adjusted model: B 2.40, 95% CI -.33 to 5.13, *P*=.09). No differences in psychosocial functioning, quality of life, self-rated depressive or manic symptoms, or self-rated or screened cognitive function were found between the intervention and control groups [35].

Discussion

To our knowledge, this is the first systematic review of the current scientific literature on smartphone-based systems for the subjective and objective monitoring of mood disorders and studies testing these systems. A considerable number of projects have started developing smartphone-based tools for the management and monitoring of mood disorders and have conducted promising tests of feasibility. Nonetheless, it became obvious during the review process that only a small number of systems that are currently available (or in preparation) have been described in scientific papers, let alone been subjected to empirical studies.

The results showed great potential in monitoring parameters relevant to the course of affective disorders, although most of the reviewed studies were feasibility tests or pilot trials without control groups, conducted with only a small number of participants and with short assessment periods, and did not investigating any medium- or long-term effects or possible risks of the respective applications. It is important to highlight that there are several systems described in publications that could not be included in this review due to: not meeting the inclusion criteria (eg, no monitoring of objective data [73,74]), not involving a smartphone for the objective monitoring [64,69,75-77], not having studied participants with an affective disorder diagnosis [78-81], or not having published results from trials being conducted at the time of our search [82].

Given the lack of reliable biomarkers in affective disorders, the combination of different physiological and behavioral parameters seems to be a highly promising approach [83,84]. This is especially true if time-series analyses are applied to continuously monitored behavioral and/or physiological data from individual patients to predict changes in their clinical states. It can be noted that significant heterogeneity exists with respect to how the data was analyzed across studies. Many groups developed their own data analytic approaches (eg, machine learning algorithms) in parallel to the set-up of their systems, and the chosen approaches have considerable impacts on the results of the respective studies. Those studies using such approaches could show good prediction values and probability estimations for changes in mood states or clinical outcomes [45,55,59].

The acceptance of using smartphones for continuous monitoring (of subjective and objective data) seems encouraging based on the results of this review and reflects patients' interests. However, regarding the decrease in adherence rates in several studies [34,78], some caution might be taken to ensure the continuity of usage. For instance, a promising concept for user engagement is the employment of gamification (game design elements such as infographics, feedback, activity, and progress bars [85]). Future trials should use reminders and/or other

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evidence-based patient engagement methods (eg, financial incentives, gamification, and peer mentoring) to minimize the problem of missing data that stems from nonadherence of carrying or using the smartphone for data collection.

Technical issues that might occur in this context (ie, energy management) could serve as a major obstacle. Using external sensors that do not rely on the smartphone's power source was discussed as one possible solution, but Prociow et al [51] reported that any additional devices were perceived as uncomfortable by the patients and tends to increase reluctance to use the system. It is also important to enable data collection from as many operating system as possible, since using another smartphone system was reported to be a reason to decline the participation of a study [41,43].

Only five of the reviewed articles reported on clinical outcomes [33-35,37,50]. In the pilot study of the Mobilyze! intervention program [34] the depressive symptoms were decreased during the trial. Conversely in the first RCT of the MONARCA system [35] the exploratory analyses in relation to primary outcomes revealed that electronic daily self-monitoring (including feedback to the users as well as their health care practitioners) may improve manic symptoms but also sustain depressive symptoms among some, but not all, patients. Following the authors' explanation, it can be speculated that self-monitoring increases illness insight and self-awareness, which are often lacking in phases of (hypo)mania. Therefore, patients within this mood state might benefit more than depressed patients, where a daily confrontation with their perceived shortcomings might sustain or even worsen their depression. However, the potential risks and adverse effects associated with continuous self-monitoring should be considered and carefully evaluated. Surprisingly, these aspects are highly underrepresented or even neglected in the recent literature body. Conceivably, a fragmentation of daily life, increased somatization due to continuous monitoring of biological parameters, negative effects on attention, decreased mindfulness, and social and behavioral aspects could be potential negative effects [86,87]. These considerations indicate the importance of conducting more experimental and randomized trials with larger samples sizes and longer assessment durations.

Combining smartphone-based self-monitoring with digital intervention strategies has a high potential for improving the current treatment and management of affective disorders. By investigating the efficacy of smartphone-based interventions, the notion of the "digital placebo" effect [88] should also be taken into account. High levels of expectation, trust, and personalization of smartphones influence the outcome of app-based interventions, as simply interacting with and receiving feedback from a smartphone app may already increase subjective well-being [88,89]. For example, one of the first studies on mental health apps by Kauer et al [90] showed that depressive symptom recording and self-monitoring via smartphone significantly reduced symptoms even without any direct therapeutic intervention. Not only the placebo effects, but also the adverse effects and safety issues of using digital mental health apps, are very rarely taken into account. A number of adverse effects that are unique to the use of mobile apps and the Internet have been discussed (eg, increased levels of inactivity, sleep pattern disturbances, eye strain, and reduced social skills [87]), but to date there is no information available on occurrence or frequency of risks, or whether certain mental health apps have a higher or lower risk potential than others.

Additionally, there are several ethical issues arising from continuous monitoring and the use of objective smartphone data. While some users/patients may find that remote monitoring allows them to feel more control over their illness, also opening new possibilities for patient-empowerment and self-management, others may feel overwhelmed by the added responsibility of self-monitoring, or perceive it as a constant reminder that they are ill [91]. The feeling of being watched or being under surveillance may also cause unease or even increase anxiety. Furthermore, there is a certain risk for patients and health care providers alike of placing too much trust in smartphone-based monitoring systems, especially concerning the (limited) possibilities of an adequate response in emergency situations (eg, acute suicidal ideation). The increasing usage and application of these technologies in mental health care and research poses the question of responsibility, and new ethical dilemmas will undoubtedly arise [92].

Sensitive data concerning mental health require an especially high standard of protection from security breaches due to a high risk of stigmatization and discrimination in the case of data disclosure. Patients' concerns about the security of the data monitored and recorded by the system have significant impacts on the acceptance of the apps and the readiness to use them for continuous monitoring [93]. Processing data locally on the smartphone has been suggested as one possible solution [47]. The classification of mental health apps as medical products is also of capital importance for patient safety and acceptance. When a product is considered a medical product, the respective mental-health apps (especially apps focusing on specific disorders and symptom reduction) would need to meet certain quality standards, and would have to undergo efficacy and safety trials (comparable to the approval process of drugs or physical therapies). For example, this would ensure that patients would not falsely rely on a completely ineffective app or even use an app giving them potentially harmful recommendations [89]. However, not all of the available mental health apps (especially those focusing on self-management and lifestyle) are considered medical products, and therefore do not require these defined standards. To summarize, further attention should be given to questions of data security and confidentiality, especially regarding the huge amounts of mental health apps being openly available (eg, Apple App Store, Google Play Store) that show major flaws in security settings [94].

Future Directions/Perspectives

Smartphone-based systems for managing and monitoring mood disorders present a highly promising field of innovation in health care. Simply using and carrying a smartphone on a day-to-day basis generates a larger amount of data than is typically collected in questionnaire-based studies or online interventions. Analyses of covariations of recorded bio-parameters within individual time-series and identification of individual patterns that predict state changes must be employed, in addition to group statistics. However, to identify such individual patterns, long monitoring

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durations with a certain amount of state changes are required. Most of the available studies used short or moderately sized recording durations and three of them [54,55,60] had to exclude participants from the final analyses, as they did not exhibit recognizable changes in mood state.

Apart from the continuous assessment of bio-parameters themselves, smartphone-based monitoring also allows researchers to gather information on context and environment, which could prove valuable for the interpretation of the monitored biomedical data (eg, information about weather conditions) and allow for a better interpretation of changes in body temperature or skin conductance levels (as well as locomotor activity) that might be restricted on rainy versus sunny days. Furthermore, these large amounts of data allow for the employment of data mining techniques to potentially generate and explore new hypotheses about causes and predictors of affective episodes, define individual disorder phenotypes, or analyze the consequences of changes in medication or treatment regimens, or potentially even health policy changes [94].

Continuous measurement of physiological and behavioral parameters is a valuable addition to self-reported symptoms to help complete the clinical picture, especially since there is often significant variation between measured parameters and subjective perspective of the self-reporting patient [95]. When considering disorders with impaired insight into illness, such as bipolar disorder [96], objectively measured data may provide a valuable method of tracking and predicting mood state changes. A highly valuable aspect of continuous physiological and behavioral monitoring approaches is the versatility of the usage of the resulting data: it could be used by the patients themselves to enhance self-monitoring practices and improve self-management strategies, and help clinicians adjust treatment by providing a more detailed picture of symptom trajectory. However, as of now, there is only sparse empirical evidence backing up these expectations, as most systems are currently in development and/or have only been studied within feasibility or pilot studies.

Smartphone-based monitoring systems can also be combined with electronically delivered psychotherapeutic interventions. By linking behavioral monitoring and intervention feedback loops, interventions can be delivered right-on-time at the most useful moment, in contrast to face-to-face psychotherapy mainly based on retrospective data and information [23]. However, fully relying on mental-health apps for disorder management and therapy would be placing false confidence and trust in a young technology. A broader empirical database is needed regarding effectiveness and potential adverse effects of continuous monitoring of behavioral and physiological data using smartphones. Meanwhile, an integrated treatment approach (face-to-face interaction between patients and clinicians and smartphone-based disorder management) should be preferred.

Limitations

In this review, we have presented the current state of research on smartphone-based mental-health technologies for monitoring and managing mood disorders. A limitation of this publication is that it only covers those smartphone-based systems in which studies have been conducted, and results of these studies have been published in scientific literature. We also focused on articles listed in scientific literature databases; thus, grey literature (eg, conference proceedings and abstracts) was not included. There are a great number of apps for the monitoring and management of mood disorders available to the public that have either not been subjected to a scientific study, or the results have not been published (yet). Furthermore, some publications had to be excluded due to not reporting results on patients with affective disorders, although they were also introducing smartphone-based systems for affective symptoms. Another limitation is that a number of the included studies were feasibility studies, allowing conclusions to be drawn about the practicality of a certain monitoring technology, yet not about its clinical efficacy or effectiveness. However, the results of this systematic review on the current state of smartphone-based monitoring of depressive symptoms demonstrates that using smartphone apps for EMA and management of mood disorders is a promising field, in which more and larger efficacy studies and longitudinal research regarding placebo effects, possible risks, and adverse effects are required.

Conclusion

Smartphone-based monitoring of objective and subjective data in mood disorders is a rapidly growing approach and research field. The current body of literature consists mainly of observational studies and substantiates the value of smartphone-based approaches for gathering long-term objective data (aside from self-ratings) to monitor clinical symptoms, predict changes in clinical states, and investigate causal inferences about state changes in patients with affective disorders. Although promising, a much larger evidence-base is necessary to fully assess the potential, as well as the risks, of these approaches. Fortunately, a number of study protocols stated ambitions to expand and intensify research in this emerging and promising field in the coming years.

Acknowledgments

Preparation of this work was supported by the STEADY-project sponsored by the German Federal Ministry of Education and Research within the funding program *Medical technology solutions for a digital health care* (contract number: 13GW0162B). We would like to thank Elise Kathleen Paul for proofreading the manuscript and Sabrina Baldofski for editing support.

Authors' Contributions

Authors UH, ED, and EK developed the concept of this paper and the search strategy. Authors ED, EK, and CS completed the data extraction of relevant articles. Authors ED, XW, CS, and EK wrote the first draft of the manuscript. After the critical revision

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of the manuscript by UH, the final draft of the manuscript was written by the authors, and all authors gave final approval of the submitted version of the manuscript.

Conflicts of Interest

The author UH declares several potential conflicts of interest with respect to the research, authorship, and/or publication of this article. Within the last three years, UH was: an advisory board member for Lundbeck, Takeda Pharmaceuticals, Servier, and Otsuka Pharma; a consultant for Bayer Pharma; and a speaker for Medice Arzneimittel, Novartis, and Roche Pharma. ED, XW, CS and EK declare no competing interests.

Multimedia Appendix 1

PRISMA checklist.

[PDF File (Adobe PDF File), 83KB - jmir_v19i7e262_app1.pdf]

Multimedia Appendix 2

Search strategy.

[PDF File (Adobe PDF File), 64KB - jmir_v19i7e262_app2.pdf]

Multimedia Appendix 3

Reference list of excluded full text articles with reason for exclusion.

[PDF File (Adobe PDF File), 260KB - jmir_v19i7e262_app3.pdf]

Multimedia Appendix 4

Overview of selected studies.

[PDF File (Adobe PDF File), 203KB - jmir_v19i7e262_app4.pdf]

Multimedia Appendix 5

Methodological Quality Scores.

[PDF File (Adobe PDF File), 168KB - jmir_v19i7e262_app5.pdf]

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Abbreviations

AMoSS: Automated Monitoring of Symptom Severity
ECG: electrocardiogram
EMA: Ecological Momentary Assessment
E-mental health: electronic mental health
GPS: global positioning system
HDRS-17: Hamilton Depression Rating Scale (17 item version)
HRV: heart rate variability
ID: identification
PHQ-9: Patient Health Questionnaire
PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis
RCT: randomized controlled trial
SD: standard deviation
SMS: short messaging system
SRM-5: Social Rhythm Metric
YMRS: Young Mania Rating Scale

Edited by S Kitsiou; submitted 15.12.16; peer-reviewed by T Kowatsch, M Faurholt-Jepsen, T Beiwinkel, J Apolinário-Hagen; comments to author 04.02.17; revised version received 31.03.17; accepted 15.05.17; published 24.07.17.

Please cite as:
Dogan E, Sander C, Wagner X, Hegerl U, Kohls E
Smartphone-Based Monitoring of Objective and Subjective Data in Affective Disorders: Where Are We and Where Are We Going? Systematic Review
J Med Internet Res 2017;19(7):e262
URL: http://www.jmir.org/2017/7/e262/
doi:10.2196/jmir.7006
PMID:28739561

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Original Paper

Images of Little Cigars and Cigarillos on Instagram Identified by the Hashtag #swisher: Thematic Analysis

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Abstract

Background: Little cigar and cigarillo use is becoming more prevalent in the United States and elsewhere, with implications for public health. As little cigar and cigarillo use grows in popularity, big social media data (eg, Instagram, Google Web Search, Twitter) can be used to capture and document the context in which individuals use, and are marketed, these tobacco products. Big social media data may allow people to organically demonstrate how and why they use little cigars and cigarillos, unprimed by a researcher, without instrument bias and at low costs.

Objective: This study characterized Swisher (the most popular brand of cigars in the United States, controlling over 75% of the market share) little cigar- and cigarillo-related posts on Instagram to inform the design of tobacco education campaigns and the development of future tobacco control efforts, and to demonstrate the utility in using big social media data in understanding health behaviors.

Methods: We collected images from Instagram, an image-based social media app allowing users to capture, customize, and post photos on the Internet with over 400 million active users. Inclusion criteria for this study consisted of an Instagram post with the hashtag "#swisher". We established rules for coding themes of images.

Results: Of 1967 images collected, 486 (24.71%) were marijuana related, 348 (17.69%) were of tobacco products or promotional material, 324 (16.47%) showed individuals smoking, 225 (11.44%) were memes, and 584 (29.69%) were classified as other (eg, selfies, food, sexually explicit images). Of the marijuana-related images, 157/486 (32.3%) contained a Swisher wrapper, indicating that a Swisher product was used in blunt making, which involves hollowing out a cigar and refilling it with marijuana.

Conclusions: Images from Instagram may be used to complement and extend the study of health behaviors including tobacco use. Images may be as valuable as, or more valuable than, words from other social media platforms alone. Posts on Instagram showing Swisher products, including blunt making, could add to the normalization of little cigar and cigarillo use and is an area of future research. Tobacco control researchers should design social media campaigns to combat smoking imagery found on popular sites such as Instagram.

(J Med Internet Res 2017;19(7):e255) doi:10.2196/jmir.7634

KEYWORDS

Instagram; Swisher; little cgars; cigarillos; social media; blunts; health behavior; tobacco use

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Introduction

Little cigar and cigarillo use is becoming more prevalent in the United States and elsewhere, with implications for public health [1,2]. These products deliver nicotine to users and share the same health risks as cigarettes [3,4]. However, tobacco control policies in the United States do not apply equally to cigarettes and to little cigars and cigarillos [5]. For example, little cigars and cigarillos can be sold in inexpensive packs of two, whereas cigarettes cannot be legally sold in packages with fewer than 20 cigarettes [6]. Little cigars and cigarillos are also offered in a variety of flavors such as chocolate and strawberry, unlike cigarettes. Lax sales and marketing restrictions could be one reason for the increase in little cigar and cigarillo use in the United States.

As little cigar and cigarillo use grows in popularity, big social media data (eg, Instagram, Google Web Search, Twitter) can be used to capture and document the context in which individuals use, and are marketed, these tobacco products. Big social media data may allow people to organically demonstrate how and why they use little cigars and cigarillos, unprimed by a researcher, without instrument bias and at low costs [7]. These data can be used to inform public policy and pubic health [8], and have been repeatedly used to provide rapid insights into health behaviors [9]. For example, by using these data sources, researchers have shown how hookah use is cross-promoted with alcohol [10], documented reasons for electronic cigarette use [11], and captured reactions to mass media campaigns [12,13]. A study using Twitter data suggested that individuals tend to report smoking specific brands like Swisher when posting about little cigars and cigarillos [14]. A separate study reported that over 80% of little cigar- and cigarillo-related posts on Twitter contained references to marijuana [15].

Instagram is a social media site featuring photo-based content that offers a unique opportunity to examine user-generated images of little cigars and cigarillos. It allows users to capture, customize, and post photos on the Internet. Instagram (with over 700 million active users) [16] has surpassed Twitter's popularity and is the second most used social media site among youth, behind Facebook [17]. Swisher is the most popular brand of cigars in the United States, controlling over 75% of the market share [18]. In this study, we characterized Swisher little cigar- and cigarillo-related posts on Instagram to inform the design of tobacco education campaigns and the development of future tobacco control efforts, and to further demonstrate the utility in using big social media data in understanding health behaviors.

Methods

Data Collection

We collected all data through Instagram's application programming interface (API). These data were publicly available; that is, anyone with an Internet connection could view the image at the time we retrieved it. Inclusion criteria for this study comprised an Instagram post with the hashtag #swisher. Little cigar and cigarillo products are often referred to by their brand name (eg, Swisher) by users, justifying this inclusion criterion. Participants from focus group studies who regularly used Swisher products revealed that they were unfamiliar with the terms "cigarillos" or "little cigars" [19]. We collected images from Instagram posted between March 6, 2016, and May 21, 2016. This study used a stratified sampling frame based on week, with 11 weeks in the study period, and randomly sampled from each stratum proportionate to the number of posts. A total of 7408 posts included the hashtag #swisher during the study period worldwide, and we randomly sampled 27% of posts each week, yielding 1967 posts to analyze. The authors' university's institutional review board approved all study procedures.

Coding of Themes

Two investigators worked together to become familiar with the data, then generated a coding frame and identified 5 common themes. The purpose of the approach was to condense the raw image-based data into summary format and report the underlying themes that were evident in the data. The primary mutually exclusive themes identified were as follows (1) Tobacco product or promotion: an image of a Swisher product or packaging, professional advertisement, or sponsored flyer, all without the presence of marijuana. (2) Smoking: individual(s) blowing smoke or holding a lit little cigar or cigarillo. (3) Marijuana *:* blunts or hollowed-out cigars next to marijuana on a table, bongs, pipes, joints, rolling papers, or rolled cigars visibly containing marijuana. (4) Meme: a graphic or image that encapsulates a concept, catchphrase, or piece of media [15]. (5) Other: posts that did not clearly fall into one of the above categories (eg, selfies, food, sexually explicit images). We also coded marijuana-themed images for product reference, where a code of 1 indicated that a Swisher wrapper was visible in the image (eg, a wrapper from a Swisher package was next to a hollowed-out cigar) and a code of 0 indicated that a Swisher wrapper was not visible anywhere in the image. In line with prior research using Instagram data to study tobacco-related behavior [10], we determined the presence (coded 1) or absence (coded 0) of alcohol in all images. One investigator coded all posts and another investigator coded a subsample of posts (n=200) to determine reliability. Agreements for the primary themes (90% agreement; κ=.87), product reference (98% agreement; κ=.86), and alcohol (98% agreement; κ=.66) were substantial.

Descriptive Analysis

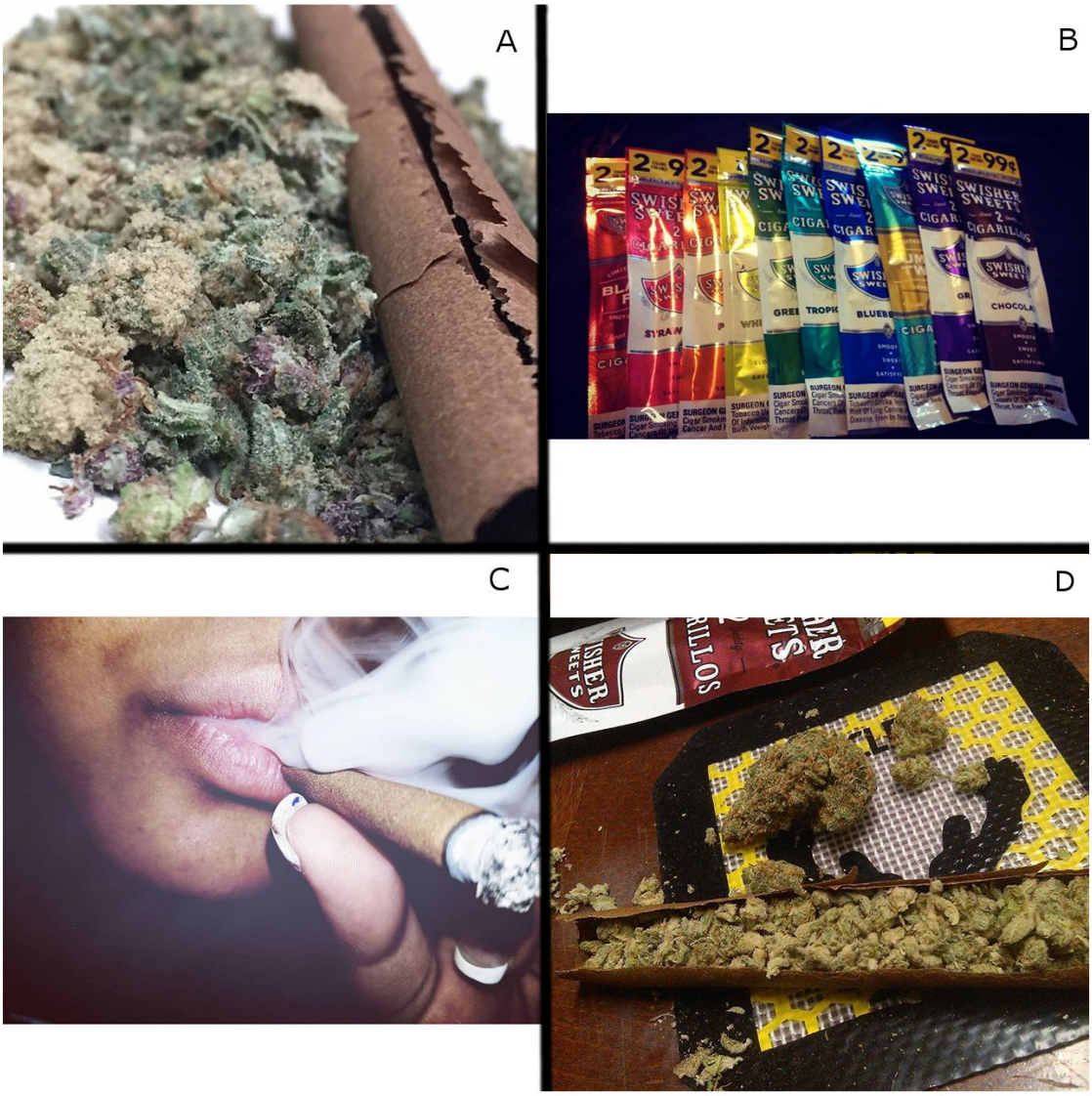
We report the percentages of themes and average number of "likes" per theme.

Results

Among the 1967 posts, 486 (24.71%) were marijuana themed (Figure 1, panel A), 348 (17.69%) were tobacco product or promotion (Figure 1, panel B), 324 (16.47%) showed smoking (Figure 1, panel C), 225 (11.44%) were meme, and 584 (29.69%) were other. Among marijuana images, 157/486 (32.3%) were coded as having a product reference (ie, a Swisher wrapper was visible; Figure 1, panel D). Among all images, 108/1967 (5.49%) showed alcohol. Memes received the highest average number of likes (mean 11, SD 15), followed by other (mean 8, SD 34), marijuana (mean 7, SD 16), smoking (mean 5, SD 9), and tobacco product or promotion (mean 4, SD 7).

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Figure 1. Images representative of themes. (A) marijuana; (B) tobacco product or promotion; (C) smoking; (D) marijuana with product reference.



Discussion

Principal Findings

To our knowledge, this study is the first to use Instagram posts to capture and document the context in which individuals use, and are marketed, little cigars and cigarillos. Images from Instagram may be used to complement and extend the study of health behaviors including tobacco use. Photos may be as valuable as, or more valuable than, words from other social media platforms alone. Posts on Instagram showing Swisher products and smoking imagery, including blunt making, could add to the normalization of little cigar and cigarillo use and should be countered by health campaigns.

We found Swisher products to be used in blunt making, which is similar to earlier reports from focus groups suggesting little cigar and cigarillo companies have developed products that facilitate blunt making [20]. Regular little cigar and cigarillo users reported that in the past, blunt making required a certain level of skill, but in today's market manufactures have simplified the blunt making process by creating tobacco leaf wraps that come apart easily [20].

Users of blunts may unknowingly expose themselves to nicotine, an issue health campaigns could address on social media. Nicotine is present in the wrapper of a cigar product even if all tobacco filler is removed prior to filling the cigar with marijuana [21]. Consequently, smoking blunts may be considered as concurrent use of marijuana and tobacco [22]. Marijuana use has been associated with substantial adverse effects among youth and young adults, including addiction to other substances, abnormal brain development, progression to use of other drugs, depression or anxiety, motor vehicle accidents, diminished lifetime achievements, and symptoms of chronic bronchitis [23]. Research has suggested that young people recognize blunts as a form of marijuana use but do not recognize it as cigar use [24]. Instagram may be an excellent social media platform to monitor the integration of marijuana with tobacco products, and thus informing new lines of inquiry.

This study found similar results to those in prior studies that used data from Instagram. The tobacco product or promotion theme constituted 17.69% of images in this study, while a

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previous study on hookah similarly reported that 18% of images showed promotional materials [10]. Among all images in our study, 5.49% showed alcohol, which is less than in prior work, where 31% of all hookah-related images showed or referenced alcohol use [10]. This finding suggests that little cigar and cigarillo use may not co-occur as often as hookah with alcohol consumption.

Photos of individuals smoking constituted 16.47% of the images in this study, while a study on marijuana-related images on Instagram reported that 13% of images pictured people smoking joints or blunts [25]. Similarly, Instagram data on electronic cigarette use or "vaping" showed that 18% of images were of individuals performing tricks with the aerosol or cloud chasing (eg, the act of blowing the largest aerosol cloud possible in a competition) [26]. Positive imagery of tobacco product or marijuana use on social media may lead priority populations such as youth and young adults to view these behaviors as social norms, thus encouraging these behaviors [27]. The impact of viewing smoking-related behaviors online should be studied to identify any possible offline consequences such as uptake of tobacco or increase in its use.

Limitations

This study relied on Instagram's API to retrieve data, which prevented access to users with private accounts. This study focused solely on images of posts and not the captions, which may have provided additional insight into little cigar and cigarillo use. Younger age groups (18-29 years) and ethnic minority groups are overrepresented among Instagram users [28]; therefore, these data were not representative of the US population or other populations of interest. However, youth, young adults, and minority groups are priority populations for tobacco-related research, suggesting that Instagram can provide substantial insight into little cigar and cigarillo use. Instagram only allows searches using hashtags, and related posts that do not use the # symbol can be missed. Additionally, Instagram posts with the hashtag #swisher may not represent all posts pertaining to other manufacturers of little cigars and cigarillos.

Despite these limitations, the little cigar- and cigarillo-related themes identified in this study could inform the design of media campaigns that aim to counter the depiction of little cigar and cigarillo use on Instagram, and the development of tobacco control efforts in the future, such as analyzing the potential of new cigar products to be unraveled for use in blunt making. Findings from this study should spur efforts to better understand the consequences of health behaviors viewed on Instagram.

Acknowledgments

Research reported in this publication was supported by grant # P50CA180905 from the US National Cancer Institute and the Food and Drug Administration (FDA) Center for Tobacco Products. Neither the National Institutes of Health (NIH) nor the FDA had a role in study design; the collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or FDA.

Authors' Contributions

JPA and PE conceived of the study. JPA and PE analyzed the data. JPA drafted the initial manuscript. JPA, PE, KHC, TBC, and JBU revised the manuscript for important intellectual content and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface

Edited by I Weber; submitted 03.03.17; peer-reviewed by J Ayers, C Pechmann, Y Kim; comments to author 05.05.17; revised version received 23.05.17; accepted 28.06.17; published 14.07.17.

Please cite as:
Allem JP, Escobedo P, Chu KH, Boley Cruz T, Unger JB
Images of Little Cigars and Cigarillos on Instagram Identified by the Hashtag #swisher: Thematic Analysis
J Med Internet Res 2017;19(7):e255
URL: http://www.jmir.org/2017/7/e255/
doi:10.2196/jmir.7634
PMID:28710057

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Original Paper

Social Media Engagement and HIV Testing Among Men Who Have Sex With Men in China: A Nationwide Cross-Sectional Survey

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Abstract

Background: Many interventions find that social media engagement with health promotion materials can translate into behavioral changes. However, only a few studies have examined the ways in which specific actions on various social media platforms are correlated with health behaviors.

Objective: The objective of this study was to examine the association between social media use and HIV testing behaviors among Chinese men who have sex with men (MSM).

Methods: In July 2016, a Web-based survey was conducted to recruit MSM in 8 Chinese cities through Blued (Blue City Holdings Ltd.), the world's largest gay mobile phone app. Data on sociodemographic variables, social media use platforms and behaviors, sexual behaviors, and HIV testing histories were collected. HIV testing–related social media use was defined as having ever engaged with HIV testing content on social media, which was further divided into observing (ie, receiving), endorsing (eg, liking and sharing), and contributing (eg, posting or commenting on HIV testing materials). Confirmatory factor analysis (CFA) was conducted to determine the best division of HIV testing–related social media use. Univariate and multivariable logistic regressions were used to examine the association between HIV testing–related social media use and HIV testing behaviors.

Results: A total of 2105 individuals participated in the survey. Among them, 46.75% (984) were under the age of 24 years, 35.43% (746) had high school education or less, and 47.74% (587) had condomless sex in the last 3 months. More than half of the respondents (58.14%, 1224/2105) reported HIV testing–related social media use. Additionally, HIV testing–related social media use, especially on multifunctional platforms such as WeChat, was found to be associated with recent HIV testing (adjusted odds ratio [aOR] 2.32, 95% CI 1.66-3.24). Contributing on social media was correlated with recent HIV testing (aOR 2.10, 95% CI 1.40-3.16), but neither observing (aOR 0.66, 95% CI 0.38-1.15) nor endorsing (aOR 1.29, 95% CI 0.88-1.90) were correlated.

Conclusions: Our data suggest that social media use, particularly on multifunctional platforms such as WeChat and with contributing behaviors, is correlated with HIV testing among MSM in China. Campaigns that promote active participant contribution on social media beyond passive observation and endorsement of promotional materials are needed. This study has implications for the design and implementation of social media interventions to promote HIV testing.

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(J Med Internet Res 2017;19(7):e251) doi:10.2196/jmir.7251

KEYWORDS

social Media; HIV; China; homosexuality; male; mobile application

Introduction

Social media components are increasingly being integrated into public health interventions. Web-based engagement with social media health promotion campaigns can translate into offline behavioral changes [1,2]. Mobile phone apps and related social media provide opportunities for men to locate potential sex partners in their vicinity; according to recent statistical data, men report opening such apps approximately 190 times per week [3]. Healthcare professionals are increasingly using social media to develop health promotion materials, distribute information, and establish peer-mentored education programs [4]. A wide range of social media interventions have been successfully implemented to improve health worldwide [5-7].

Although the effectiveness of social media interventions is well established, the relationship between social media engagement and relevant behavioral outcomes has not been fully explored [8,9]. In particular, detailed examination of the ways in which participants engage with social media platforms in public health interventions is scarce [10-12]. Functions and features vary between different social media platforms, with different platforms encouraging specific types of engagement (sharing, liking, commenting, etc). Identifying the effects of specific social media platforms and behaviors on health outcomes and taking advantage of them can help optimize health-related intervention effects [13].

For HIV prevention, low HIV testing rate is a major obstacle and a disruption to the continuum of care [14,15]. A large subgroup of men who have sex with men (MSM) and engage in high-risk sexual behaviors has never tested for HIV [16], thereby resulting in a sizable population of HIV-positive men who do not know their status [17,18]. Studies on MSM in the United States, the United Kingdom, and Thailand using social and sexual networking sites have demonstrated that social media interventions for HIV testing promotion are both feasible and effective [19-21]. Social media platforms, which are used by MSM across the world to expand social circles, help build community, find sexual partners [22,23], and allow public health practitioners to implement HIV testing promotion among MSM [12,21,24].

In China, the rise in popularity of Web-based social and sexual networking sites has coincided with an increase in the prevalence of HIV infection among MSM in recent decades [25]. Social media platforms such as Weibo, WeChat, QQ, and gay apps are providing men with social and sexual networking opportunities and mediums for learning new information. In 2015, WeChat, a multifunctional social media platform based in China, reported 549 million monthly active users [26]. Meanwhile, between 2006 and 2014, the HIV infection rate among MSM rose from 2.5% to 25.8% [27]. As social media platforms are increasingly being integrated into Chinese daily life and public health interventions, there is a clear need for greater analysis of the specific effects of various forms of social media use on offline HIV testing behaviors [27,28]. This study uses data from a cross-sectional Web-based survey to examine the association between social media use by Chinese MSM and HIV testing behaviors.

Methods

Recruitment

We conducted a Web-based survey among MSM in 8 Chinese cities: Guangzhou, Shenzhen, Zhuhai, and Jiangmen (Guangdong Province, Southern China); and Jinan, Qingdao, Yantai, and Jining (Shandong Province, Northern China) in July 2016. This was a baseline survey of an intervention study to evaluate the promotion of HIV testing among MSM in China, and these 8 cities were chosen because they were urban cities with relatively high rates of HIV prevalence [27]. Protocol of the study was registered in the Clinical Trials.gov database (NCT02796963). We followed the Checklist for Reporting Results of Internet E-Surveys for reporting the development and findings of Web-based surveys [29].The pretest survey was field tested by 30 MSM in April 2016, and their feedback was taken into account to finalize the survey questionnaire.

Participants were recruited through Blued, the world's largest gay mobile app [30]. Private short messages containing the survey link were sent to the registered Blued users in the 8 cities. The study used cellphone numbers to prevent multiple entries from the same individual. Duplicated responses were excluded from the analysis. The eligible participants included those who were born biologically male, had ever engaged in anal sex with a man, were at least 16 years of age, were currently living in one of the designated 8 cities, were willing to provide their cell phone number, and were willing to complete an informed consent procedure. All eligible participants signed an electronic informed consent form before completing the survey and received a small phone card reimbursement or WeChat Red Envelope (hongbao), equivalent to roughly US $7.5.

Measures

Sociodemographic information collected in the survey (full survey attached as Multimedia Appendix 1) included age, education, income, and marital status. Questions on sexual orientation and disclosure of sexual orientation to others were also included. Participants were asked about their sexual histories and behaviors, including the number of sex partners and condom use practices in the past 3 months. The survey also included questions on HIV testing behaviors, including past HIV testing (beforethe recent 3 months) and testing for HIV in the preceding 3 months. We focused on HIV testing in the past 3 months as outcome to reduce recall bias and to remain consistent with questions about social media use within the past 3 months. These measures had been used in previous Web-based surveys among MSM in China [31].

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The survey included a section on social media use, in which participants were asked whether they had ever engaged with any content related to HIV testing on social media in the past and, specifically, whether they had done so in the past 3 months. In this study, we defined HIV testing–related social media use as having ever engaged on a social media platform with any information or materials that mention or promote HIV testing.

Men who reported HIV testing–related social media use were further asked about specific behaviors on 4 social and sexual networking platforms: Weibo, QQ, WeChat, and gay-specific dating apps. Weibo is a Chinese microblogging platform, similar to Twitter, where users can publicly broadcast short messages (under 140 Chinese characters) to their friends and followers [32]. Both QQ and WeChat are Chinese instant messaging platforms that provide multiple functions, including communication, information, entertainment, and financial services [33]. Whereas QQ is optimized for desktop use [34], WeChat is optimized for mobile phone use [26]. Gay-specific dating and networking apps mainly refer to Blued, a Chinese app with 27 million registered users. Other gay apps included Hornet, Grindr, and Zank, which are all available on mobile phones and allow participants to meet new sexual partners [35].

In addition, men who reported HIV testing–related social media use in the past 3 months were asked whether they had ever received, liked, or commented on information related to HIV testing or whether they had ever shared materials on their own timelines, forwarded them to others, or discussed them in one-on-one or group messages on various social and sexual networking platforms. These categories of social media activities were adopted and revised from previous studies, which distinguish behaviors based on the differing levels of time investment and effort required [36,37]. In particular, specific social media use behaviors in the past 3 months were categorized into three groups: observing, which included receiving HIV testing information; endorsing, which included liking HIV testing materials, forwarding them to others, and sharing them on timelines; and contributing, which included posting original information, commenting on someone else's post about HIV testing, and participating in one-on-one or group chats [38,39].

Statistical Analysis

Descriptive statistics were used to describe men's sociodemographic information, sexual risk behaviors, and social media use. Bivariate analysis was used to examine factors associated with HIV testing–related social media use.

Confirmatory factor analysis (CFA) was conducted to confirm the division of social media use into more specific categories. The indicators of CFA included the chi-squared test of minimum discrepancy divided by degrees of freedom (CMIN/DF), goodness of fit index (GFI), adjusted goodness of fit index (AGFI), normed fit index (NFI), comparative fit index (CFI), and root mean square error of approximation (RMSEA). The CMIN/DF assesses the fit of a model in CFA and modeling in which the minimum discrepancies are divided by its degrees of freedom. The value of CMIN/DF should ideally be less than 2.0. The GFI is a measure of fit between the hypothesized model and the observed covariance matrix; the AGFI corrects GFI, which is affected by the number of indicators of each latent variable. The GFI and AGFI range between 0 and 1, with a value of over .9 generally indicating an acceptable model fit. The NFI analyzes the discrepancy between the chi-squared value of the hypothesized model and the chi-squared value of the null model. Values for the NFI should range between 0 and 1, with a cutoff of .95 or greater indicating a good model fit. The CFI analyzes the model fit by examining the discrepancy between the data and the hypothesized model while adjusting for the issues of sample size. The CFI values range from 0 to 1, with larger values indicating a better fit. A CFI value of .95 or higher is presently accepted as an indicator of good fit. The RMSEA examines the discrepancy between the hypothesized model with optimally chosen parameter estimates and the population covariance matrix. The RMSEA ranges from 0 to 1, with smaller values indicating a better model fit. A value of .06 or less is indicative of an acceptable model fit.

Logistic regressions (univariate and multivariable) were used to examine the relationship between HIV testing–related social media use and HIV testing behaviors. Multivariable logistic regression models were adjusted for potential confounding variables, including age, education, income, marital status, sexual orientation, disclosure of sexual orientation to others, partner status (primary partner, multiple partners, etc) and past HIV testing (before the recent 3 months). As social media platforms are designed for and encourage different actions and behaviors, this study controlled for platforms while examining the effect of specific Web-based actions on offline behavior [40,41].

Ethical Statement

This study was approved by the ethics review committees at the Guangdong Provincial Center for Skin Diseases and STI Control; the University of North Carolina, Chapel Hill (14-1685); and the University of California, San Francisco (14-14877) before the survey launch.

Results

Study Participants

The survey link distributed on Blued was clicked 36,863 times in 3 days, with 25,141 unique Internet Protocol addresses automatically collected by the survey tool. Of these clicks, 2112 individuals met the study eligibility criteria and completed the questionnaire in its entirety. Seven responses were deleted as duplicates. Overall, 2105 eligible men from the 8 designated cities were included in the final analysis. The percentages of participants who were from Guangzhou, Shenzhen, Zhuhai, Jiangmen, Jinan, Qingtao, Yantai, and Jining were 14.68% (309), 14.87% (313), 11.21% (236), 9.07% (191), 13.21% (278), 13.92% (293), 12.92% (272), and 10.12% (213), respectively.

Demographics and Behaviors

Of the 2105 men who participated in the survey, 46.75% (984) were under the age of 24 years, and 35.44% (746) had high school education or less. Most men (85.94%, 1809) were never married, and 61.24% of men (1289) had an annual income over US $5500.

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Table 1. Sociodemographic and behavioral characteristics of men who have sex with men in 8 Chinese cities, 2016 (N=2105).

Characteristics	Total, n (%)
Age (years)	
≤24	984 (46.75%)
>24	1121 (53.25%)
Education	
High school or below	746 (35.44%)
Some college	583 (27.70%)
College or above	776 (36.86%)
Annual income (US $)	
<2700	391 (18.57%)
2700-5500	425 (20.19%)
5501-9200	690 (32.78%)
9201-15,000	384 (18.24%)
>15,000	215 (10.21%)
Marital status	
Never married	1809 (85.94%)
Ever married	296 (14.06%)
Sexual orientation	
Gay	1524 (72.40%)
Bisexual	496 (23.56%)
Heterosexual	11 (0.53%)
Unsure	74 (3.52%)
Ever disclosed sexuality to others	
Yes	1426 (67.74%)
No	679 (32.26%)
Main partner in the past 3 months	
Yes	812 (38.57%)
No	1293 (61.43%)
Number of sexual partners in the past 3 months	
0-1	1477 (70.17%)
Multiple	628 (29.83 %)
Consistent condom use in the past 3 months[a]	
Yes	643 (52.28%)
No	587 (47.72%)
Past HIV testing before the recent 3 months	
Yes	628 (29.83%)
No	1477 (70.17%)
Tested for HIV in the past 3 months	
Yes	687 (32.64%)
No	1418 (67.36%)
Ever HIV testing–related social media use	
Yes	1224 (58.15%)
No	881 (41.85%)

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Characteristics	Total, n (%)
HIV testing–related social media use in the past 3 months	
Yes	954 (45.32%)
No	1151 (54.68%)

[a]Men who reported having sex within the past 3 months were asked about consistent condom use (N=1230).

Nearly three-fourths (72.40%, 1524) of men self-identified as gay, and over two-thirds (67.74%, 1426) had ever disclosed their sexual orientation to others. Over one-third (38.57%, 812) reported a main sexual partner in the past 3 months. Nearly one-third (29.83%, 628) had multiple sexual partners, and 47.72% (587) did not consistently use condoms among the men who had sex in the last 3 months. Nearly one-third (29.83%, 628) of respondents had tested for HIV before the recent 3 months, and 32.64% (687) had been tested in the past 3 months. Among respondents, 58.15% (1224) reported ever HIV testing–related social media use, and 45.32% (954) reported such experience in the last 3 months (Table 1).

Specific HIV Testing–Related Social Media Use Categories

CFA indicated that the model of specific social media use categories had a good fit (CMIN/DF=2.56, GFI=.99, AGFI=.98, NFI=.99, CFI=.99, RMSEA=.04). Of the three social media use categories, observing occurred most frequently on gay mobile apps (460, 48.2%), followed by WeChat (396, 41.5%). Endorsing occurred most frequently on WeChat: 26.8% (256) had liked HIV testing–related information, 17.2% (164) had forwarded such information to others, and 18.6% (177) had shared HIV-related materials on their own timelines. Contributing was a common behavior on both WeChat and QQ. Men posted original information about HIV testing on WeChat (154, 16.1%) and QQ (146, 15.3%); commented on others' posts on WeChat (186, 19.5%) and QQ (150, 15.7%); had one-on-one chats about HIV testing on WeChat (265, 27.8%) and QQ (237, 24.8%); and had group chats on WeChat (226, 23.7%) and QQ (247, 25.9%). Men tended to be least likely to use Weibo to conduct HIV testing–related behaviors (Table 2).

Correlates of HIV Testing–Related Social Media Use

In bivariate analyses, age, education, income, and marital status were not correlated with HIV testing–related social media use. Self-identified gay men reported HIV testing–related social media use in the past 3 months more frequently than heterosexual and bisexual men (74.5% vs 70.63%, χ^2_1=3.9, *P*=.047). Men who had ever disclosed sexual orientation to others were more likely to report HIV testing–related social media use (73.2% vs 63.25%, χ^2_1=23.5, *P*<.001). Men who had main partners in the past 3 months were more likely to report HIV testing–related social media use (41.8% vs 35.88%, χ^2_1=7.8, *P*=.01).

Compared with men without HIV testing–related social media use, men with HIV testing–related social media use were more likely to have had multiple sexual partners in the past 3 months (33.2% vs 27.02%, χ^2_1=9.6, *P*=.01), and have been recently tested for HIV (40.5% vs 26.15%, χ^2_1=48.6, *P*<.001) (Table 3).

Table 2. Specific social media use platforms and behaviors in the past 3 months among men who have sex with men in 8 Chinese cities, 2016 (N=954). Weibo is a Chinese microblogging platform, akin to Twitter; QQ and WeChat are Chinese instant messaging platforms, with QQ largely optimized for desktop computers and WeChat optimized for mobile phones; gay apps refer to gay-specific networking apps.

Behaviors	Weibo, n (%)	WeChat, n (%)	QQ, n (%)	Gay apps, n (%)
Observing				
Received information about HIV testing	227 (23.8%)	396 (41.5%)	318 (33.3%)	460 (48.2%)
Endorsing				
Liked information about HIV testing	180 (18.9%)	256 (26.8%)	189 (19.8%)	240 (25.2%)
Forwarded information about HIV testing to others	120 (12.6%)	164 (17.2%)	139 (14.6%)	141 (14.8%)
Shared information on timeline about HIV testing	108 (11.3%)	177 (18.6%)	134 (14.0%)	146 (15.3%)
Contributing				
Posted original information about HIV testing	90 (9.4%)	154 (16.1%)	146 (15.3%)	138 (14.5%)
Commented on others' post about HIV testing	103 (10.8%)	186 (19.5%)	150 (15.7%)	179 (18.8%)
One-on-one chatted about HIV testing	101 (10.6%)	265 (27.8%)	237 (24.8%)	206 (21.6%)
Group chatted about HIV testing	85 (8.9%)	226 (23.7%)	247 (25.9%)	175 (18.3%)

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Table 3. Comparison of sociodemographic and behavioral characteristics between men with HIV testing–related social media use and men without among men who have sex with men in 8 Chinese cities, 2016 (N=2105).

Sociodemographic and behavioral characteristics	Men with HIV testing–related social media use (N=954), n (%)	Men without HIV testing–related social media use (N=1151), n (%)	Chi-square	*P* value
Age, in years				
≤24	433 (45.4)	551 (47.87)	1.3	.26
>24	521 (54.6)	600 (52.13)		
Education				
High school or below	305 (32.0)	441 (38.31)	9.2	.01
Some college	278 (29.1)	305 (26.50)		
College or above	371 (38.9)	405 (35.19)		
Annual income (US $)				
<2700	165 (17.3)	226 (19.64)	5.8	.21
2700-5500	195 (20.4)	230 (19.98)		
5501-9200	313 (32.8)	377 (32.75)		
9201-15,000	169 (17.7)	215 (18.68)		
>15,000	112 (11.7)	103 (8.95)		
Marital status				
Never married	813 (85.2)	996 (86.53)	0.8	.21
Ever married	141 (14.8)	155 (13.47)		
Sexual orientation				
Gay	711 (74.5)	813 (70.63)	4.0	.047
Others[a]	243 (25.5)	338 (29.37)		
Ever disclosed sexuality to others				
Yes	698 (73.2)	728 (63.25)	23.5	<.001
No	256 (26.8)	423 (36.75)		
Main partner in the past 3 months				
Yes	399 (41.8)	413 (35.88)	7.8	.01
No	555 (58.2)	738 (64.12)		
Number of sexual partner(s) in the past 3 months				
0-1	637(66.8)	840 (72.98)	9.6	.01
Multiple	317 (33.2)	311 (27.02)		
Consistent condom use in the past 3 months				
Yes	329 (55.0)	314 (49.68)	3.5	.06
No	269 (45.0)	318 (50.32)		
Past HIV testing before the recent 3 months				
Yes	277 (29.0)	351 (30.50)	0.5	.47
No	677 (71.0)	800 (69.50)		
Tested for HIV in the past 3 months				
Yes	386 (40.5)	301 (26.15)	48.6	<.001
No	568 (59.5)	850 (73.85)		

[a]Others refers to heterosexual and bisexual.

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Table 4. Correlations between HIV testing–related social media use and HIV-related behaviors among men who have sex with men in 8 Chinese cities, 2016 (N=2105).

HIV-related behaviors	Recent HIV testing–related social media use
	Adjusted odds ratio (95% CI)
Number of sexual partner(s) in the past 3 months	
0-1	Ref
Multiple	1.23[a] (1.01-1.50)
Consistent condom use in the past 3 months	
Yes	1.28[a] (1.01-1.61)
No	Ref
Tested for HIV in the past 3 months	
Yes	2.02[b] (1.63-2.52)
No	Ref

[a]*P*<.05.

[b]*P*<.001.

Multivariable Analyses of Social Media Use and HIV Testing

Multivariable logistic analysis showed that HIV testing–related social media use was significantly associated with the number of sexual partners (adjusted odds ratio [aOR]1.23, 95% CI1.01-1.50) and consistent condom use behaviors (aOR1.27, 95% CI1.01-1.60) in the past 3 months after adjusting for potential confounders. Furthermore, HIV testing–related social media use was also significantly associated with recent HIV testing (aOR2.02, 95% CI 1.63-2.52; Table 4).

Multivariable analysis controlled for age, education, income, marital status, sexual orientation, disclosure status, main partner in the past 3 months, and past HIV testing before the recent 3 months.

There was a platform-linked variation in the relationship between HIV testing–related social media use and HIV testing behaviors in the past 3 months (Table 5). WeChat use was significantly associated with recent HIV testing (aOR2.32, 95% CI 1.66-3.24), but Weibo (aOR 0.88, 95% CI 0.62-1.25), QQ (aOR1.34, 95% CI 0.96-1.86), and gay app (aOR0.80, 95% CI 0.57-1.11) use were not. Table 5 also indicated the relationship between specific HIV testing–related social media use and recent HIV testing behaviors. Contributing on social media was significantly associated with recent HIV testing (aOR2.10, 95% CI 1.40-3.16). Endorsing on social media was significantly correlated with recent HIV testing in bivariate analysis (Crude OR1.46, 95% CI 1.11-1.92) but not in multivariable analysis (aOR1.29, 95% CI0.88-1.90).

Multivariable analysis controlled for age, education, income, marital status, sexual orientation, disclosure status, main partner in the past 3 months, and past HIV testing.

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Table 5. Correlations between specific social media use platforms and HIV testing behaviors in the past 3 months among men who have sex with men in 8 Chinese cities, 2016 (N=954).

Characteristic	Recent HIV testing		
	n (%)	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Social media use platforms			
Weibo use			
Yes	307 (32.2%)	0.98 (0.74-1.29)	0.88 (0.62-1.25)
No	647 (67.8%)		
WeChat use			
Yes	561 (58.8%)	1.94[a] (1.48-2.54)	2.32[a] (1.66-3.24)
No	393 (41.2%)		
QQ use			
Yes	464 (48.6%)	1.33[b] (1.03-1.72)	1.34 (0.96-1.86)
No	490 (51.4%)		
Gay app use			
Yes	561 (58.8%)	0.87 (0.67-1.13)	0.80 (0.57-1.11)
No	393 (41.2%)		
Social media use behaviors			
Observing[c]			
Yes	842 (88.3%)	1.37 (0.91-2.08)	0.66 (0.38-1.15)
No	112 (11.7%)		
Endorsing[c]			
Yes	614 (64.4%)	1.46[d] (1.11-1.92)	1.29 (0.88-1.90)
No	340 (35.6%)		
Contributing[c]			
Yes	664 (69.6%)	2.09[a] (1.56-2.82)	2.10[a] (1.40-3.16)
No	290 (30.4%)		

[a]*P*<.001.

[b]*P*<.05.

[c]Multivariable analysis controlled social media platforms that included Weibo, WeChat, QQ, and gay apps.

[d]*P*<.01.

Discussion

Principal Findings

The rise of social media has created a set of promising tools for HIV prevention [2,12,21].This study examines the relationship between specific social media engagement and HIV testing behavior, providing information necessary to optimize public health efforts on social media. In particular, this study expands the literature by examining associations between social media use and HIV testing, dividing social media use into specific platforms and behaviors, and examining MSM in a middle-income country. Although several previous studies have treated social media as a generic platform [6,42], this study acknowledges the important versatility of social media platforms and specifically focuses on the ways in which social media use is related to HIV testing.

We found that over half of MSM reported HIV testing–related social media use. This is consistent with past studies that have found that MSM commonly use social media to obtain information about HIV testing [23,42-44]. Additionally, ongoing public health interventions use social media to provide information about HIV testing sites, counseling, and self-testing kits [7,45,46]. As health interventions increasingly seek to integrate technology into healthcare services, there would be more chances for MSM to get engaged with HIV testing on social media [47].

HIV testing–related social media use was positively associated with recent HIV testing. This finding supports the positive

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association between Web-based engagement with offline health behaviors [48-50]. It is consistent with the literature from other fields (eg, smoking cessation) showing that social media use is related to offline behaviors [51-53]. Social media has several key advantages, which encourage this link between Web-based engagement and offline behavior. In particular, social media platforms allow public health campaigns to reach more diverse audiences, reduce overall cost, provide opportunities for repeated exposure to messaging, collect real-time feedback, and encourage direct engagement with messaging materials [13]. Men who engage in HIV testing–related social media use may receive detailed information about the testing location, hours of operation, and available services, thus potentially encouraging HIV testing [54].

Certain social media platforms and behaviors are strongly linked to recent HIV testing. WeChat use, in particular, was strongly correlated with recent HIV testing in this study. This is consistent with research showing that instant messaging platforms promote HIV testing in China [55] and the United States [56]. In addition, WeChat's popularity in China and its functional design are particularly conducive to the modes of engagement necessary for impactful public health interventions. On average, an adult in China spends more than 40 min per day on WeChat, and more than half of all users open WeChat more than 10 times per day [57]. The high-frequency use and constant engagement creates many opportunities for target audiences to be exposed to the messaging. Additionally, WeChat's design, which is optimized for mobile phone use and includes services for information, entertainment, and finance within a single app, encourages users to merge their online and offline activities [26,58]. Some community-based organizations have taken advantage of WeChat's interactive functions and now allow HIV test appointment scheduling through the app [59]. An ongoing randomized controlled trial is examining the effectiveness of using WeChat to promote HIV testing [60].

Contributing on social media was strongly correlated with recent HIV testing as compared with observing and endorsing. Among the three specific behaviors, observing represents a type of passive involvement that allows men to encounter information without directly engaging [61]. Although receiving information about HIV testing on social media is commonly reported, previous studies have not found this to be associated with HIV testing [62]. Endorsing represents greater engagement, as individuals must consciously present a position of approval or support to certain persons, information, or actions. However, endorsing can include what is often referred to as "slacktivism," a term indicating actions that are performed online to demonstrate public concern for an issue without requiring significant time or involvement [63]. These public displays of pseudo-engagement may not be conducive to behavioral change, and in fact, may represent detachment from actual behavior by making participants believe that they have already made some significant effort [64]. Compared with observing and endorsing, contributing on social media requires a higher level of cognitive engagement, as individuals need to develop some original perspectives or responses to the issue [65]. Contributing on social media may lead to positive health-related outcomes and influence behavior change [50]. When contributing on social media, men must think through the challenge and cognitively respond to the situation. This contribution process focuses participants' attention and increases overall comprehension of HIV testing issues, encouraging the translation of Web-based activity to actual behavior [66]. This finding is consistent with the theory that social, participatory, and interactive aspects of social media can promote healthy behavior change [11,67].

This study is particularly relevant for policymakers and researchers who seek to use social media to promote behavior change. Although additional randomized controlled studies are needed to further examine the relationship between social media engagement and offline behavior, this study supports the integration of multifunctional platforms, such as WeChat, into public health interventions. Additionally, researchers and policymakers should encourage authentic input from MSM when designing social media interventions. The active engagement of MSM on social media is preferable to top-down, one-sided health communication [68]. Interactive activities, such as community crowdsourcing contests [69] that encourage higher levels of participation, can be organized in part through social media [70].

Limitations

This study also has limitations. First, men were recruited from a gay-specific social media platform, likely resulting in overestimation of the rate of social media use. Second, it is a cross-sectional survey, so causal relationships were not established. Response rates and completion rate were not calculated for this Web-based survey. Third, only 8 cities in China were selected; although cities of various sizes were included, the results are not necessarily applicable for rural areas. Given the variation in HIV infection and HIV testing rates between urban and rural areas of China [71], as well as the varying usage of social media as sources of health information [72], future studies are needed to test the feasibility of social media intervention in rural places. Finally, whereas social media platforms share similar characteristics, the landscape of social media tools and functions varies across nations. Further evaluation is needed to understand the feasibility and effectiveness of specific social media use in international contexts.

Conclusions

Social media interventions have been increasingly incorporated into public health programs [4,12]. This study suggests that Web-based engagement with HIV testing content may spur offline HIV testing behaviors, supporting the role of social media in public health campaigns. Our research suggests that future social media interventions can consider moving beyond merely using social media as a way to disseminate information and should instead leverage the interactive capabilities of various platforms to encourage participation.

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This work was supported by the National Institutes of Health (National Institute of Allergy and Infectious Diseases 1R01AI114310); UNC-South China STD Research Training Centre (Fogarty International Centre 1D43TW009532); UNC Center for AIDS Research (National Institute of Allergy and Infectious Diseases 5P30AI050410)]; University of California San Francisco Center for AIDS Research (National Institute of Allergy and Infectious Diseases P30 AI027763); and the Bill & Melinda Gates Foundation to the MeSH Consortium (BMGF-OPP1120138). This publication was also supported by Grant Number UL1TR001111 from the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health. We thank Dr Lisa B Hightow-Weidman, Dr Kathryn E Muessig, Dr Hongyun Fu, Dr Jason Ong, and anonymous reviewers for helpful comments. We also thank all the team members of the UNC project — China, and the participants who contributed to this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Full survey questionnaire.

[PDF File (Adobe PDF File), 137KB - jmir_v19i7e251_app1.pdf]

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Abbreviations

AGFI: adjusted goodness of fit index
aOR: adjusted odds ratio
CFI: comparative fit index
CFA: confirmatory factor analysis
CMIN/DF: chi-squared test of minimum discrepancy divided by degrees of freedom
GFI: goodness of fit index
MSM: men who have sex with men
NFI: normed fit index
RMSEA: root mean square error of approximation

Edited by G Eysenbach; submitted 03.01.17; peer-reviewed by J Jiang, H Zhao; comments to author 30.03.17; revised version received 25.04.17; accepted 02.06.17; published 19.07.17.

Please cite as:
Cao B, Liu C, Durvasula M, Tang W, Pan S, Saffer AJ, Wei C, Tucker JD
Social Media Engagement and HIV Testing Among Men Who Have Sex With Men in China: A Nationwide Cross-Sectional Survey
J Med Internet Res 2017;19(7):e251
URL: http://www.jmir.org/2017/7/e251/
doi:10.2196/jmir.7251
PMID:28724510

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Original Paper

Ontology-Based Approach to Social Data Sentiment Analysis: Detection of Adolescent Depression Signals

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Abstract

Background: Social networking services (SNSs) contain abundant information about the feelings, thoughts, interests, and patterns of behavior of adolescents that can be obtained by analyzing SNS postings. An ontology that expresses the shared concepts and their relationships in a specific field could be used as a semantic framework for social media data analytics.

Objective: The aim of this study was to refine an adolescent depression ontology and terminology as a framework for analyzing social media data and to evaluate description logics between classes and the applicability of this ontology to sentiment analysis.

Methods: The domain and scope of the ontology were defined using competency questions. The concepts constituting the ontology and terminology were collected from clinical practice guidelines, the literature, and social media postings on adolescent depression. Class concepts, their hierarchy, and the relationships among class concepts were defined. An internal structure of the ontology was designed using the entity-attribute-value (EAV) triplet data model, and superclasses of the ontology were aligned with the upper ontology. Description logics between classes were evaluated by mapping concepts extracted from the answers to frequently asked questions (FAQs) onto the ontology concepts derived from description logic queries. The applicability of the ontology was validated by examining the representability of 1358 sentiment phrases using the ontology EAV model and conducting sentiment analyses of social media data using ontology class concepts.

Results: We developed an adolescent depression ontology that comprised 443 classes and 60 relationships among the classes; the terminology comprised 1682 synonyms of the 443 classes. In the description logics test, no error in relationships between classes was found, and about 89% (55/62) of the concepts cited in the answers to FAQs mapped onto the ontology class. Regarding applicability, the EAV triplet models of the ontology class represented about 91.4% of the sentiment phrases included in the sentiment dictionary. In the sentiment analyses, “academic stresses” and “suicide” contributed negatively to the sentiment of adolescent depression.

Conclusions: The ontology and terminology developed in this study provide a semantic foundation for analyzing social media data on adolescent depression. To be useful in social media data analysis, the ontology, especially the terminology, needs to be updated constantly to reflect rapidly changing terms used by adolescents in social media postings. In addition, more attributes and value sets reflecting depression-related sentiments should be added to the ontology.

(J Med Internet Res 2017;19(7):e259) doi:10.2196/jmir.7452

KEYWORDS

ontology; adolescent; depression; data mining; social media data

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Introduction

Suicide was one of the major causes of death among young people aged 15 to 29 years worldwide in 2012 [1], and in South Korea, it was the single largest cause of adolescent deaths [2]. A large number of the adolescents (40-80%) who commit suicide have a strong link with depression at the time of their death [3], indicating that adolescent depression is one of the main factors contributing to suicidal events.

Adolescent depression affects not only individuals but also their families, the community, and the country as a whole. Moreover, this impact lasts for a long time and has wide-ranging effects. Adolescent depression is a chronic disease with a high risk of relapse. It hinders the normal development and growth of adolescents and contributes to increases in community crimes such as substance misuse and risky sexual behaviors [4]. Furthermore, adolescent depression leads to decreases in productivity [5], which will ultimately lead to an increased burden on the economy [6]. It is thus important to detect adolescent depression and provide interventions at an early stage.

Social networking services (SNSs) are now the most popular Web-based community platforms among adolescents worldwide [7]. Most South Korean adolescents (77.1%) have SNS accounts, and 53% of them interact with more than 100 individuals via these accounts [8]. More than 73% of adolescents in the European Union aged between 13 and 16 years have an SNS account [9]. Moreover, 51% of adolescents aged between 13 and 18 years access their SNS account at least once per day [7].

These SNSs contain abundant information about the feelings, thoughts, interests, and patterns of behavior of adolescents that can be obtained by analyzing SNS postings. In particular, topics such as interactions with friends and cyberbullying can be examined more accurately and with less bias by using SNSs [7], which should thus be considered a valuable source of data for exploring depression-related problems in adolescents [10].

To date, a few studies have examined the mental health status of users by analyzing SNS data. Researchers have explored the correlations between Google Trends (Google Inc, CA) data on mental health (eg, regarding suicide, depression, bipolar disorder, and nonsuicidal self-injury) and public statistics or other gold standards [11-16]. They investigated the potential for utilizing search volumes on specific terms that researchers had defined as representative mental health terms to monitor and prevent mental health problems. Several studies have analyzed the sentiments and content of SNS postings by depressed users. Park et al [17] found that depressed users tended to use negative sentiment words and express anger as compared with nondepressed users in their tweets. Additionally, depressed users had recorded their personal information, such as treatment history of depression, on Twitter. De Choudhury et al confirmed the possibility of using SNS data for understanding depression in individuals [18] and populations [19]. They collected data on depression from Twitter and identified the different characteristics (eg, language, sentiment, social activity) of depressed users versus nondepressed users. These studies focused on determining the sentiment of postings according to the frequency of words conveying sentiment to measure or predict depression. Although De Choudhury et al developed a lexicon of terms representing depression to analyze the content of depression that people talk about on Twitter, the topics of the lexicon were limited to the symptoms of depression and antidepressants only. To analyze the public's feelings, thoughts, and behavior regarding mental health (as expressed on SNSs) thoroughly, we need a model of related concepts and terms that the public use as an analytical framework.

Text mining, a representative tool that analyzes social media data, does not express relationships among terms, which is why additional information is required to understand these relationships [20]. To overcome these limitations, a systematic framework with a taxonomic hierarchy and relationships between terms and terminology is needed. An ontology that expresses "the shared concepts and their relationships in a specific field" [21] could be used as an analysis framework for social media data.

An ontology can suggest effective ways of improving the quality of data analysis by expressing knowledge in a specific domain systematically and helping to understand the data [22]. Konovalov et al [23] used natural language processing (NLP) to analyze military social media postings by employing an ontology relevant to combat exposure as an analytical framework. However, Konovalov et al did not develop a terminology including various natural language terms, and this made text mining more difficult. A terminology includes synonyms of concepts and can help to integrate various forms of natural language. Particularly, since adolescents use newly coined words or expressions, abbreviations, and slang words, we need a terminology in which these terms are aligned with ontology concepts.

Previously, we developed and evaluated a preliminary ontology and terminology as a framework for analyzing social media data on adolescent depression [24]. However, the classes were not defined in detail, and no linkage with an upper ontology was made. Therefore, it is important to develop that ontology further by defining entity-attribute-value (EAV) models of the classes and by linking to the basic formal ontology (BFO). Additionally, description logics of the ontology and its applicability need to be tested.

Thus, the aims of the study were (1) to refine an ontology and terminology for analyzing social media data on adolescent depression, (2) to evaluate the formal description of classes and relationships among classes in the ontology, and (3) to validate the applicability of the ontology and terminology in sentiment analyses.

Methods

Ontology and Terminology Development

The ontology was designed based on the Ontology Development 101 [25] methodology. It was then refined by applying the EAV triplet model to the internal structures of the ontology and by aligning superclasses with an upper ontology.

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Determining the Ontology Domain and Scope

The scope and domain of the ontology were defined by compiling a list of competency questions that the ontology should respond to. These questions were used to evaluate description logics of the ontology. The first author extracted frequently asked questions (FAQs) on adolescent depression from the American Academy of Child and Adolescent Psychiatry, Black Dog Institute, and clinical-depression.co.uk websites to compile a list of competency questions. The second author and corresponding author drew up a list of more detailed competency questions based on the FAQs.

Defining the Classes and Synonyms of the Class As a Terminology

Terms describing the classes were extracted from clinical practice guidelines (CPGs) such as those of the National Institute for Health and Care Excellence (NICE), the US Preventive Services Task Force (USPSTF), beyondblue, and the Korean Clinical Research Center For Depression, as well as related literature (eg, research papers on risk factors, interventions, and screening/diagnostic tools for adolescent depression) and websites (eg, news articles on news sites and expert columns in blogs).

We first defined concepts using terms that were grouped by meaning and then determined classes as concepts with an independent existence and designed a hierarchy between the classes. We also compiled a list of synonyms for each class as a terminology. The synonyms comprised terms extracted not only from CPGs, literature, and dictionaries but also from social media to reflect the real language used by adolescents.

Defining the Properties of Classes and Values Applying the EAV Data Model

We defined the properties of classes, the value of the properties, and the value type using the EAV data model. In this study, entities refer to the core concepts discussed on SNSs regarding adolescent depression, attributes are concepts describing entities in more detail, and value sets are the set of values that an attribute can have. For example, attributes such as “reason for self-harm,” “method of self-harm,” and “frequency of urge to self-harm” describe the “self-harm” (entity) more precisely. Therefore, we can analyze the details of the phenomena related to adolescent depression (eg, self-harm) expressed on SNSs using the EAV triplet model.

Concepts for attributes and values were defined for terms extracted from the sources used in the previous stage but not classified as classes. The questionnaires used for the Korean National Surveys on domestic violence, school violence, and media use, and a survey of the actual conditions in the adolescent crisis in the city of Seoul were also analyzed during this stage.

Aligning the Superclasses With the BFO

Many ontologies have been aligned with upper ontologies such as BFO, Descriptive Ontology for Linguistic and Cognitive Engineering, and Cyc as a means of sharing and integrating heterogeneous knowledge derived from different sources. Therefore, adolescent depression ontology linked to an upper ontology can be combined with other mental health and disease ontologies and applied to other domains.

We aligned superclasses with the BFO that has been used as a foundation for combining ontologies and creating high quality shared ontologies, principally in biomedical research areas. The adolescent depression ontology was aligned with the BFO using the Protégé software version 5.0 beta (Stanford Center for Biomedical Informatics Research, CA).

Ontology and Terminology Evaluation

The resulting ontology was evaluated in terms of description logics and applicability. Description logics are logics for the formal description of classes and the relationships between classes. The applicability refers to the utility of the ontology and terminology in sentiment analyses of social media data.

Evaluation of the Ontology’s Description Logics

The formal description of classes and relationships among classes within the ontology were evaluated using the description logics tab in Protégé. Description logic queries were expressed as combinations between a type of relationship and a core class, that is, depression in our study. For example, to obtain results for “What are the signs and symptoms of adolescent depression?” from the ontology, we entered a competency question in a query input format, that is, “IsSignsAndSymptomsOf some depression.” Since the depression class (domain) was related to the subclasses of signs and symptoms (range) through the “hasSignsAndSymptoms” relationship, and as subclasses (eg, emotional, cognitive, behavioral, and physical changes) of signs and symptoms were related to the signs and symptoms class through “is-a relationship,” we could obtain the results of the query.

We compared a list of classes derived from the ontology with core concepts of answers to the FAQs that were used while compiling the list of competency questions. Three experts in psychiatric nursing, one of whom had experience in ontology development, extracted core concepts from the answers to the FAQs and mapped them onto the ontology classes manually. During the mapping process, terminology provided synonyms for the ontology class concepts. The mapping rate was quantified as the extent to which the classes matched.

Evaluation of the Ontology’s Applicability

The applicability of the ontology was evaluated in two steps. First, we examined the usability of the EAV data model in defining the sentiment phrases for sentiment analyses. We randomly selected about 10% of the sentiment phrases (1358 out of 13,352 total phrases) in the sentiment dictionary for depression [26]. We also examined the extent to which these 1358 sentiment phrases were represented using the EAV triplet of the ontology class concepts.

Second, we identified factors in the signs and symptoms superclass affecting the sentiment of adolescent depression. Adolescent depression–related texts posted on Twitter and 214 social media channels (199 news sites, four blogs, two Web-based communities, and nine discussion boards) in South Korea from January 1, 2012, through December 31, 2014, were extracted using a crawler. The search keywords were

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"depression" and "depressed." Out of 3,703,135 texts, this study analyzed 161,581 texts on "students under 19 years" or "elementary/middle/high school students." Each text was coded as 1 (=positive), 2 (=neutral), or 3 (=negative) according to their sentiment. The total number of texts with any sentiment was 86,957. We then coded the text based on the presence of 31 signs and symptoms classes as 0 (=no) or 1 (=yes). Multiple nominal logistic regression, decision tree (chi-square automatic interaction detection, CHAID), and association rules were conducted to identify factors affecting the sentiments of adolescent depression. Multiple nominal logistic regression was used to determine the degree to which changes in sign and symptom classes affect sentiments toward adolescent depression. A decision tree was used to identify the sentiments of adolescent depression, given the values of several sign and symptom classes were represented by the path from the root to the leaf. The association rules was used for discovering relations between two or more classes present in a Web-based document or post [27]. Regarding the directional association rule (X→Y), we focused on the "lift" indicator, which refers to the ratio between the count of class Y in the presence versus absence of X [27].

Results

Ontology and Terminology Development

The first author collected 35 FAQs on adolescent depression from the American Academy of Child and Adolescent Psychiatry, Black Dog Institute, and clinical-depression.co.uk websites. The second author and corresponding author drew up a list of 53 competency questions based on the FAQs. We identified five domains of adolescent depression from the competency questions. These five domains were risk factors, signs and symptoms, diagnostics, subtype, and interventions.

Table 1 presents nine of the 35 FAQs, the competency questions derived from the nine FAQs, and the identified ontology domains.

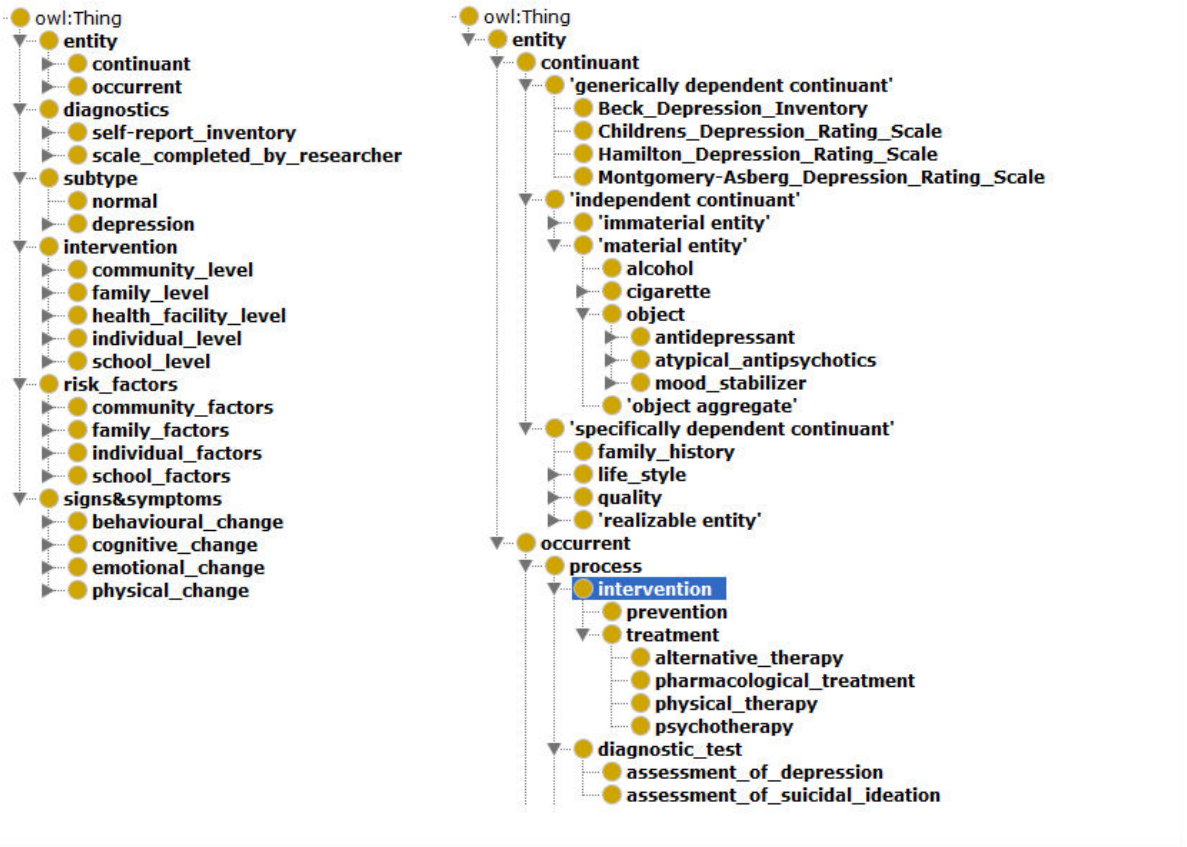
Table 1. Nine frequently asked questions (FAQs), related competency questions, and identified ontology domains.

FAQs	Competency question	Ontology domain
What causes depression in adolescents?	What are the risk factors for adolescent depression?	Risk factors
Can the way I think lead to clinical depression?	What kind of personality is adolescent depression related to?	Risk factors
What are the signs of depression?	What are the signs and symptoms of adolescent depression?	Signs and symptoms
What are the physical effects of depression?	What are the physical symptoms of adolescent depression?	Signs and symptoms
What kinds of self-tests are available for screening depression in teenagers?	What are the diagnostics of adolescent depression?	Diagnostics
What are the different types of depression?	What are the subtypes of adolescent depression?	Subtype
What should treatment consist of?	What methods are used to treat adolescent depression?	Intervention
What kinds of antidepressants are used to treat?	What medications are used to treat adolescent depression?	Intervention
Are medications safe? Do they increase the risk of suicide?	What are the possible side effects and complications of SSRIs[a]?	Intervention

[a]SSRIs: Selective serotonin reuptake inhibitors.

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Figure 1. Superclasses in an adolescent depression ontology alongside the basic formal ontology (BFO, left) and example classes in the BFO positions (right).



These classes had three or four levels of hierarchy, with 443 classes and 60 relationships, including *Is-A* and *Has-A* relationships. Furthermore, the terminology consisted of 1682 synonyms of class concepts. The risk factors superclass was classified into individual, family, school, and community domains [24], whereas the intervention superclass comprised individual, family, school, community, and health facility classes to include the content of prevention and treatment for adolescent depression. On the basis of the criteria of beyondblue's CPG, the signs and symptoms superclass was categorized into emotional, cognitive, behavioral, and physical changes. The superclasses of the ontology along with the BFO class types are shown in Figure 1. Table 2 presents an example of a data model in the ontology.

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Table 2. Example of entity-attribute-value (EAV) data model in the ontology.

Entity	Attribute	Values
Self-harm		
	History of self-harm	Yes
		No
	Reason for self-harm	Academic stresses
		To rebel against parents' values
		Being bullied by peers
		Psychiatric problems
		Chronic poverty
		Traumatic events
	Method of self-harm	Cutting
		Piercing
		Burning
		Carving
		Hitting or punching
		Pulling out hair
		Severe scratching
	Frequency of urge to self-harm	<1 hour
		1-3 hours
		3-6 hours
		6-12 hours
		12-24 hours
		>1 day

Ontology and Terminology Evaluation

Evaluation of the Ontology's Description Logics

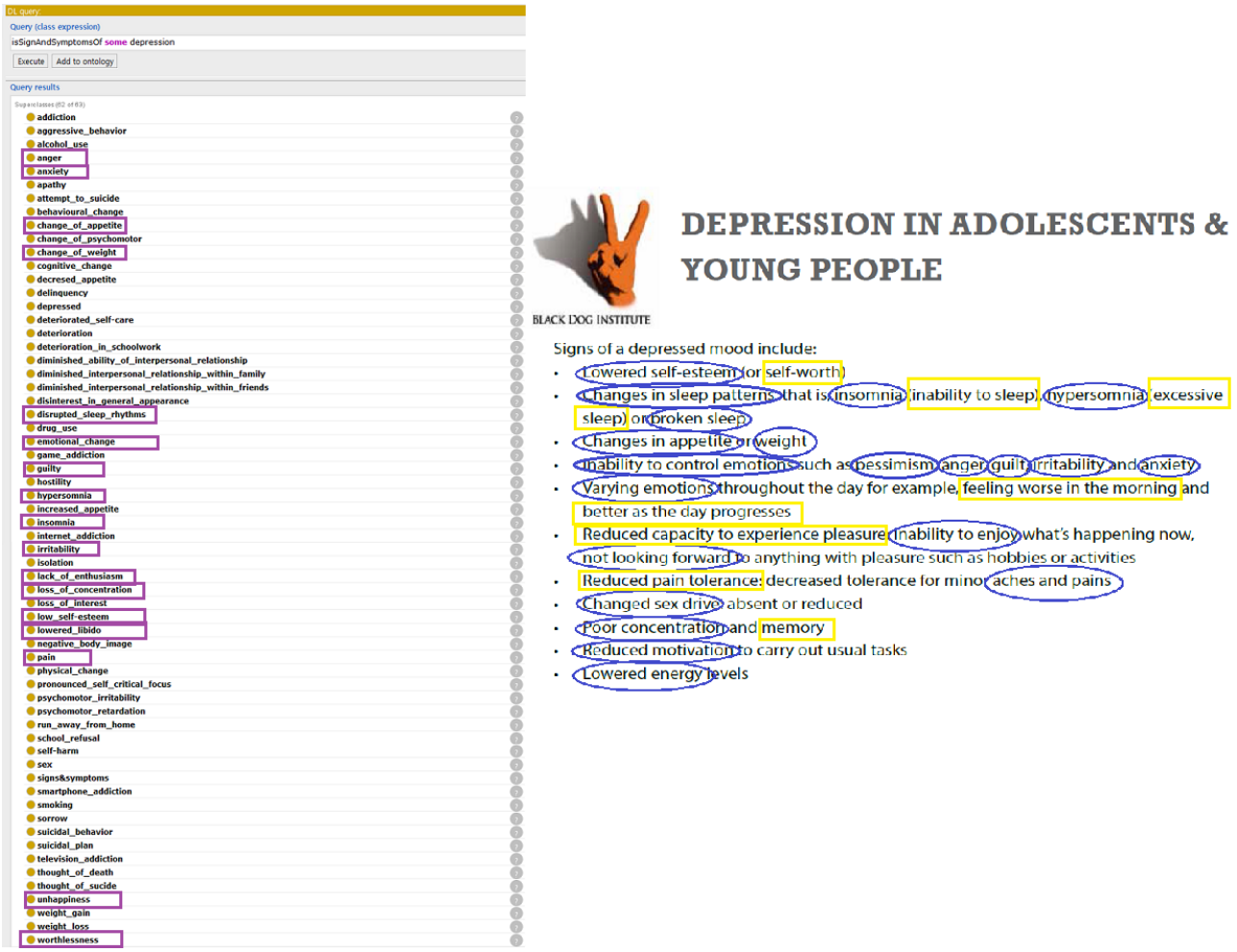
The description logics of the ontology was tested using the mapping rate, that is, the extent to which core concepts extracted from the answers to five FAQs mapped onto ontology concepts. The core concepts extracted from the answers to the FAQs were identical to the results of the mapping of the concepts onto the ontology concepts (conducted by three domain experts).

The overall rate of mapping onto the ontology was 88.7%. For the "What are the risk factors for adolescent depression?" FAQ, 22 out of 22 concepts (100%) extracted from the answers to the FAQ were represented in the ontology. For the "What are the diagnostics of adolescent depression?" FAQ, 3 out of 4 concepts (75.0%) were found in the ontology. For the "What are the subtypes of depression?" FAQ, 5 out of 6 concepts (83.3%) were represented in the ontology. For the "What methods are used to treat adolescent depression?" FAQ, 8 out of 9 concepts (88.9%) mapped onto the ontology concepts. For the "What are the signs and symptoms of adolescent depression?" FAQ, 17 out of 21 concepts (81%) mapped onto the concepts in the ontology.

Figure 2 shows the query results inferred from the ontology (left) and core concepts and their synonyms for answers to the FAQ (right) to the query "What are the signs and symptoms of adolescent depression?." The core concepts of signs and symptoms of a depressed mood in adolescents, derived from the FAQ, are marked with blue circles on the right side of Figure 2. The synonyms of the signs and symptoms class concepts are marked with yellow rectangles.

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Figure 2. Query results inferred from the ontology (left) and core concepts and their synonyms derived from answers to the frequently asked question regarding signs and symptoms of adolescent depression (right).



Evaluation of the Ontology's Applicability

Of 1358 sentiment phrases, 1241 (91.4%) were represented by the EAV triplet of the ontology class concepts. Regarding positive sentiment phrases, 506 out of 559 phrases (90.5%) were defined using the EAV triplet of the ontology. For negative sentiment phrases, 735 out of 799 sentiment phrases (92.0%) were represented by the EAV triplet of the ontology class concepts.

Table 3 presents 10 sentiment phrases represented by the ontology's EAV triplet. For example, the negative-sentiment phrases, "I am bullied," "I have been victim of school violence," and "there is serious bullying" could be represented by combining the entity "bullying" in the risk-factors superclass, with "victim," " experience," and "degree" as attributes and "myself," "yes," and "severe" being the values. "School violence" was included in the terminology as a synonym of bullying.

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Table 3. Sentiment phrases represented by the entity-attribute-value (EAV) triplet ontology.

Polarity	Sentiment phrase	Entity	Attribute	Values
Negative				
	"I am bullied"	Bullying	Experience	Yes
	"I have been victim of school violence"			No
	"There is serious bullying"			
			Degree	Mild
				Moderate
				Severe
			Assailant	Myself
				Classmates or friends
				Seniors
				Juniors
			Victim	Myself
				Classmate or friends
				Seniors
				Juniors
	"Stress is severe"	Stress	Presence	Yes
	"There are many stresses"			No
			Degree	Mild
				Moderate
				Severe
			Cause	Interpersonal relation
				Academic stress
				Disturbed home environment
	"Personality is timid"	Personality	Type	Dependent
				Compulsive
				Introvert
				Negative
				Irritable
	"I am suffering from a severe case of insomnia"	Insomnia	Presence	Yes
				No
			Type	Hard to fall asleep
				A light sleep
			Degree	Mild
				Moderate
				Severe
Positive				
	"My family is harmonious"	Family concord	Presence	Yes
				No
			Parent-child relationship	Harmonious
				Moderate
				Dysfunctional
			Parental relationship	Harmonious
				Moderate
				Dysfunctional
	"I have taken antidepressants regularly"	Antidepressant	Taking drug	Yes
				No

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Polarity	Sentiment phrase	Entity	Attribute	Values
			Cycle of medication	Regularly
				Irregularly
			Route of administration	Oral
				Intravenous
				Subcutaneous
				Intramuscular
				Rectal
			Side effect	Yes
				No
	"I am good at expressing a sentiment"	Expression of emotion	Type	Adept
				Moderate
				Hesitant

The results of multiple nominal logistic regression showed that "fear," "restless," "impulse," "lethargy," "guilty," "sad," "hostility," "academic stresses," and "suicide" contributed negatively to the sentiment on adolescent depression. Additionally, the main factor, also called the root node, affecting the sentiment of adolescent depression was "academic stresses" by the decision tree analysis. The second factors/nodes were "pain" and "anxiety," and the third factors/nodes were "guilty" and "suicide." Among documents with "academic stress" at baseline, those with "pain" and "suicide" increased the probability of having negative sentiment regarding adolescent depression by as much as 2.19 times compared with baseline. In association rules, when a posting expressed "loneliness," "indifference," "sleep," "loss," and "suicide" together, the probability of having negative sentiment on adolescent depression was increased by 2.92 times. For the logistic regression, the predictive validity was .750 for precision and .742 for accuracy. For the decision tree, the validity indicators were .761 for precision and .750 for accuracy.

Discussion

Principal Findings

The objectives of this study were to refine an adolescent depression ontology and terminology as a semantic framework for analyzing social media data and to evaluate them in terms of description logics and applicability. The ontology developed in this study differs significantly from the depression ontologies designed previously [28,29]. First, the ontology developed herein included unique factors of adolescent depression that existing depression ontologies had not identified. For example, adolescent depression is affected not only by individual characteristics but also by environmental factors such as the family, school, and community surrounding the adolescent [30]. Existing depression ontologies have defined environmental factors as the physical environment (eg, climate, noise, and pollution), social environment (eg, conflict, abuse, and discrimination), and financial environment (eg, income) broadly. Although these socioenvironmental factors vary according to the family, school, and community, existing ontologies did not reflect these various types of environmental factors accurately. In this study, we have broken down socioenvironmental factors into family, school, and community levels to describe risk factors of, and interventions for, adolescent depression in more detail. For example, abuse, one of the socioenvironmental factors, was subdivided into "abuse by parents," "abuse by teacher," and "abuse by friend." We also included unique symptoms of adolescent depression such as poor school performance, delinquency, and truancy in the ontology.

Second, the ontology developed in this study integrated the comprehensive scope of adolescent depression, from risk factors, signs and symptoms, diagnostics, and subtypes, to interventions for prevention or treatment because it was created to analyze SNS postings containing wide domains and offering a broad scope of adolescent depression. However, the existing ontologies cover only restricted domains and a limited scope of knowledge for treatments by subtypes [28], depression-related signs and symptoms [29], or pathological processes of depression [31].

Third, the ontology developed in this study has terminology with synonyms of the ontology classes such as slang, fad words, and neologisms. This makes the ontology particularly suitable for analyzing social media data generated by adolescents. However, the existing ontologies use medical jargon or scientific terms to represent concepts describing diagnosis and treatment of depression.

With the description logics test, we were able to not only evaluate errors in the relationships between classes but also the content coverage of the ontology. For example, for risk factors, the ontology included all of the core concepts (22/22, 100%) identified in the answers to the FAQs. For diagnostics, the ontology included 75.0% of the core concepts identified in the answers to the FAQs. Since the ontology covered only screening tools for adolescent depression, "blood test" included among the answers to the FAQs was not mapped onto the ontology. Nevertheless, the ontology was able to answer the competency questions on risk factors, signs and symptoms, diagnostics, subtypes, and interventions for adolescent depression with no error in the description logics.

The ontology developed in this study was used for sentiment analyses. This was possible because each class was modeled as the EAV triplet. Value sets of attributes representing status or degree (eg, "presence" or "severity") of entities contained words

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or phrases describing positive or negative opinions on adolescent depression. Sentiment phrases such as “satisfaction with the curative effect,” “willingness to overcome a problem,” and “likes or dislikes regarding a condition” in the sentiment dictionary for depression were not represented by the EAV triplet of the ontology. Thus, it is important for the ontology to have attributes with value sets that well-represent sentiment phrases pertaining to depression. Nevertheless, since sentiment phrases can be represented using an adolescent depression ontology with domain-specific knowledge, errors in assigning sentiment will be reduced. To identify factors affecting sentiments of adolescent depression, 31 signs and symptoms classes were used as independent variables in logistic regression and data mining such as decision tree and association rules. Terminology played a crucial role in identifying synonyms of signs and symptoms classes appearing in the postings. It was found that academic stresses and suicide were significant factors contributing to negative sentiment in adolescent depression postings. Thus, the presence of academic stress or suicide in postings could be a signal of adolescent depression.

This study improved the interoperability and reusability of an adolescent depression ontology by linking it to an upper ontology, BFO. An adolescent depression ontology could contain general concepts through semantic connections with the BFO. This would augment the applicability of the ontology in other domains.

This ontology can be reused in other studies related to the various competency questions proposed in this study. For example , this ontology can be used as a basis for a meaningful health care decision-making system for depression management in adolescents. The ontology-based adolescent depression management system can identify the symptoms an adolescent has, determine the depression subtypes and diagnostics, and recommend treatment options. Additionally, because classes of the ontology are represented with the EAV triplet, it is possible for health care providers to collect and document data on adolescent depression in more detail using the ontology.

For the ontology to be useful in social media data analysis, it is important that the ontology, especially the terminology, is updated to reflect the rapidly changing terms used by adolescents in social media postings.

Conclusions

In this study, we developed an adolescent depression ontology comprising 443 classes and 60 relationships; the terminology comprised 1682 synonyms among the 443 classes. A terminology with extensive synonyms played a very important role in an analytical framework for SNS data, since this study analyzed natural language texts posted by adolescents and featuring slang and abbreviations. Each class in the ontology was modeled according to the EAV triplet structure, so the ontology can be used for adolescent depression–related sentiment analysis. Description logics between classes were evaluated by mapping concepts extracted from the answers to the FAQs onto ontology concepts derived from description logics queries. The applicability of the ontology was evaluated by sentiment phrases represented by EAV triplets and by sentiment analyses of social media data conducted using the classes in the ontology. The ontology provides an analytical framework for the analysis of SNS data and thereby could improve the accuracy of interpretations of phenomena uncovered by SNS data analysis. However, it is important for the terminology to be updated regularly to reflect the rapidly changing terms used by adolescents in social media postings.

Acknowledgments

This work was supported by a grant from the National Research Foundation of Korea (NRF) funded by the Korea government (NRF-2015R1A2A2A01008207) and Seoul National University Big Data Institute through the Data Science Research Project 2016.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Adolescent depression ontology (detailed).

[PPTX File, 478KB - jmir_v19i7e259_app1.pptx]

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Abbreviations

BFO: basic formal ontology
CHAID: chi-square automatic interaction detection
CPGs: clinical practice guidelines
EAV: entity-attribute-value
FAQ: frequently asked question
NLP: natural language processing
NICE: National Institute for Health and Care Excellence
SNSs: social networking services
USPSTF: US Preventive Services Task Force

Edited by J Torous; submitted 06.02.17; peer-reviewed by M Focsa, J Du, N Bragazzi; comments to author 21.04.17; revised version received 26.05.17; accepted 29.05.17; published 24.07.17.

Please cite as:
Jung H, Park HA, Song TM
Ontology-Based Approach to Social Data Sentiment Analysis: Detection of Adolescent Depression Signals
J Med Internet Res 2017;19(7):e259
URL: http://www.jmir.org/2017/7/e259/
doi:10.2196/jmir.7452
PMID:28739560

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Original Paper

Dental Blogs, Podcasts, and Associated Social Media: Descriptive Mapping and Analysis

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Abstract

Background: Studies of social media in both medicine and dentistry have largely focused on the value of social media for marketing to and communicating with patients and for clinical education. There is limited evidence of how dental clinicians contribute to and use social media to disseminate and access information relevant to clinical care.

Objective: The purpose of this study was to inventory and assess the entry, growth, sources, and content of clinically relevant social media in dentistry.

Methods: We developed an inventory of blogs, podcasts, videos, and associated social media disseminating clinical information to dentists. We assessed hosts' media activity in terms of their combinations of modalities, entry and exit dates, frequency of posting, types of content posted, and size of audience.

Results: Our study showed that clinically relevant information is posted by dentists and hygienists on social media. Clinically relevant information was provided in 89 blogs and podcasts, and topic analysis showed motives for blogging by host type: 55% (49 hosts) were practicing dentists or hygienists, followed by consultants (27 hosts, 30%), media including publishers and discussion board hosts (8 hosts, 9%), and professional organizations and corporations.

Conclusions: We demonstrated the participation of and potential for practicing dentists and hygienists to use social media to share clinical and other information with practicing colleagues. There is a clear audience for these social media sites, suggesting a changing mode of information diffusion in dentistry. This study was a first effort to fill the gap in understanding the nature and potential role of social media in clinical dentistry.

(J Med Internet Res 2017;19(7):e269) doi:10.2196/jmir.7868

KEYWORDS

social media; blogs; podcasts; clinical information; dentistry

Introduction

Internet technology is changing the way clinical information is available to dental practitioners. Similar to the medical community, dental professionals rely, at least in part, on online resources to seek information relevant to their practice needs [1-6]. The notion of continual learning that facilitates knowledge currency is potentially enabled by broad and accelerated electronic access to information [7]. More recently, the adoption of interactive social media, such as blogs and discussion boards, has been shifting the way clinical professionals acquire and interact with relevant practice information [8].

Studies of social media in both medicine and dentistry have largely focused on the value of social media for marketing to and communicating with patients and for clinical education [1,3,5,6,8,9]. While these articles suggest that the use of social media is changing the environment of health communication [10,11], there is still much to be learned about the use of social

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media for communication between health care professionals [12]. Studies in medicine have begun to explore the application and importance of social media for increasing the rapidity and reach of clinical information to physicians, emergency medical personnel, and nurses [1,6,12-14]. We found only 1 such study in dentistry, of the Internet Dental Forum [15]. The aim of our study was to document the entry, growth, and content of blogs, podcasts, and associated social media sources disseminating clinical information to dentists and hygienists. We developed an inventory of blogs and podcasts (Multimedia Appendix 1) and categorized their content to assess the ways that the dental professional community initiates and uses social media to disseminate information for their peers and colleagues.

Methods

Blogs and podcasts are forms of media, accessible to anyone, that provide a vehicle for extended discussion of a topic, such as would be required to convey useful information about advances in dental research to practicing dentists. Therefore, we constructed an inventory of blogs and podcasts aimed at dentists and hygienists. These sources all constitute public domain data available online, and therefore are exempt from institutional review board oversight. We did not include sources that may be clinically relevant but are membership platforms, such as Dentaltown, since they are not public domain data. Nor did we include blogs mounted on the Dentaltown platform.

Blogs and podcasts were inventoried through a combination of online Google Boolean searches ("dentist" OR "dental" OR dentistry" for dentist blogs and podcasts; "hygienist" OR "dental hygiene" for hygienist blogs and podcasts) and iterative searches of discovered sites, accompanying links, and existing curated lists of social media resources. This "snowball" search process [16] was conducted by a team of 3 researchers until the redundancy in sources led to saturation—that is, no new sources were being identified to add to the core population of social media aimed at dental practitioners. Each source was coded by 3 researchers for general content and language, with results checked for consistency. Inconsistent codes were rechecked by 2 additional team researchers to resolve any differences and were recoded accordingly. Our purpose in this exploratory work was to create general coding categories that would allow us to broadly distinguish content aimed at dental practitioners as a first step in assessing social media resources for dental clinicians. Therefore, content was coded as "patient oriented" if the communication was aimed to inform current and potential patients about the practice or clinical procedures; "clinically relevant" if it included any treatment or clinical information relevant to dental clinicians; or "management/profession" if it had no clinically relevant information and was limited to financial, marketing, or other aspects of the dental profession (Textbox 1). Using this inventory as a foundation, we searched for YouTube video channels, Facebook pages, and Twitter handles associated with the blog and podcast hosts. We excluded accounts if they were personal sites or appeared to communicate with patients only.

To verify that we had an unduplicated list of unique sources, we identified the host (individual's name or names), their organizational affiliation, active practicing status, degree, and host type (practicing dentists and hygienists; consultants; companies, such as distributors or manufacturers; professional associations; or media). We eliminated duplicates to arrive at our final inventory of 89 hosts of 264 social media sources (51 blogs, 46 podcasts, 69 Twitter, 56 Facebook, and 42 YouTube). We then examined descriptive statistics on the range of modalities used (by host) and variation across the different groups of interest (by host type, audience, and content). Table 1 provides a description of the measures.

Of the social media resources in our inventory, blogs are most amenable to content coding due to their easily extractable text. Thus, as an additional step in our exploratory work, we extracted the raw text from the blog sites and used topic modeling to gauge and organize content. Our purpose was to explore the patterns and content of clinically relevant information disseminated to dental practitioners through social media. This technique identifies clusters of words that occur together, that is, in the same paragraph, relatively often. We gathered the raw text of 18,991 posts from the 24 blogs we had broadly categorized as clinically relevant into a database and performed text analysis using Wordstat 7 software (Provalis Research). First, we removed common words and reduced inflected or derived forms to a common root. Topics were identified in the text using a 2-stage factor analysis of a word-by-paragraph matrix in which words with a factor loading of 0.50 were retained. In the first stage, all blogs were analyzed, and the pattern of co-occurrence of topics in blogs was used to assign blogs to 1 of 2 groups based on topic similarity; 7 blogs did not cluster with others and were analyzed independently in the second stage. To identify the topics characterizing the posts of each group of blogs, a second factor analysis of the paragraph-by-word matrix was performed for each group separately. The results were lists of topics represented by words that frequently occurred together in paragraphs in blog posts.

Textbox 1. Content coding categories for content aimed at dental practitioners in blogs and podcasts.

Clinically relevant

- Includes at least one post, episode, or video about clinically relevant topics, including patient care, dental procedures, dental materials, clinical technology, and use of dental or dental hygiene products.

Dental management/profession

- Discusses topics relevant to dental practice management or the dental or dental hygiene profession, practice management technology or software for office management exclusive of patient care, and does not include any reference to patient care or clinical issues.

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Table 1. Dental social media modality measures.

Type	Measures	Description
Blog		
	Duration	Length of time between first post and most recent post
	Count	Number of blog entries
Podcast		
	Duration	Length of time between first episode and most recent episode
	Count	Number of podcast episodes
Twitter		
	Duration	Length of time between joining and most recent tweet
	Count	Number of tweets
	Followers	Number of Twitter followers
Facebook		
	Duration	Length of time between start of the Facebook page and most recent post
	Likes	Number of times the specific Facebook page has been “liked”
YouTube		
	Duration	Length of time between first uploaded video and most recent uploaded video on channel
	Uploads	Number of videos uploaded to the channel
	Subscribers	Number of individual subscriptions to the channel
	Views	Sum of the number of views of all uploaded videos on the channel

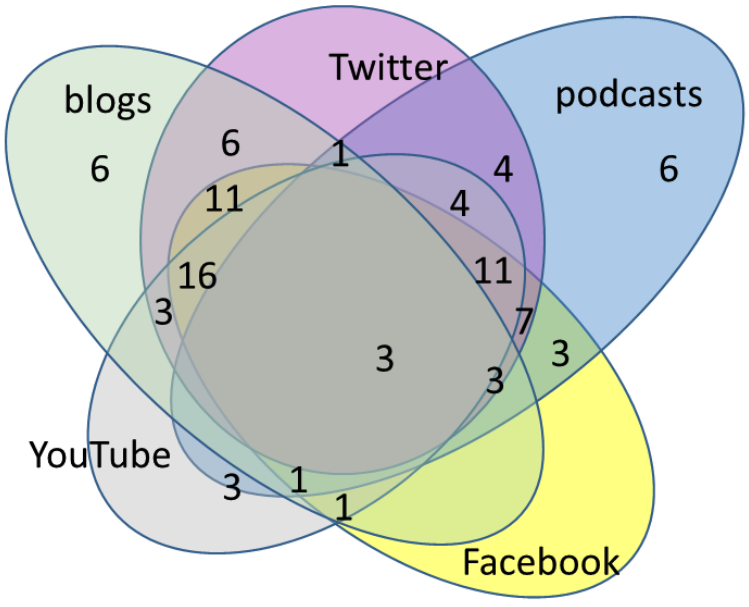
Results

Social Media Hosts and Modalities

Of the 264 social media accounts across all modalities aimed at the dissemination of clinical information to dentists, we found 89 unique social media hosts maintaining an average of 3 modalities (eg, a blog, Twitter account, and Facebook account). The largest group of hosts (49 hosts, 55%) were practicing dentists or hygienists, followed by consultants (27 hosts, 30%), media including publishers and discussion board hosts (8 hosts, 9%), and professional organizations and corporations, including Patterson Dental and DentalEZ (5 hosts, 6%).

Blog and podcast hosts were relatively distinct, with only 8 hosts having both a blog and a podcast. Only 12 of the 89 hosts maintained just 1 platform, and 3 hosts used all 5 types of social media. The 5-way Venn diagram in Figure 1 shows how hosts used multiple modalities and how they overlapped.

Figure 1. Social media modality combinations, by 89 hosts.



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Table 2. Number of social media sites targeted at dental clinicians, by host type and content.

Host type	Number	No. of which engaged in other social media			Share of accounts with clinically relevant content (all modalities) n (%)
		Facebook	Twitter	YouTube	
Practicing dentists and hygienists					
Blog	20	9	13	6	38 (79)
Podcast	24	12	17	8	28 (46)
Both	1	1	1	0	0
Consultants					
Blog	9	7	9	5	1 (3)
Podcast	13	8	8	9	5 (13)
Both	5	4	4	2	3 (15)
Media					
Blog	5	5	5	2	16 (94)
Podcast	0	0	0	0	0
Both	1	1	1	1	4 (100)
Professional associations					
Blog	3	3	3	3	7 (58)
Podcast	0	0	0	0	0
Both	1	1	1	1	3 (75)
High-volume social media dentists					
Blog	4	2	4	3	7 (54)
Podcast	0	0	0	0	0
Both	0	0	0	0	0
Companies					
Blog	2	2	2	2	8 (100)
Podcast	1	1	1	1	1 (25)
Both	0	0	0	0	0
Totals by modality					
Blog	43	28	36	21	69 (57.5)
Podcast	38	21	26	18	33 (33)
Both	8	7	7	4	10 (32)
Grand total					
Blog and podcast	97	56	69	43	112 (44.8)

Table 2 provides the number of hosts using each of the modalities. The table shows that practicing dentists and hygienists were much more likely than the others to just blog or podcast, but not engage in the other social media. In contrast, for consultants, media, associations, high-volume bloggers, and companies, blogging and podcasting seemed to be part of an overarching social media effort that more often than not included also Facebook, Twitter, or YouTube. The media and dental equipment companies were most engaged in providing clinical information. In contrast, consultants blogged and podcast about practice management for the most part. Practicing dentists tended to blog about clinical information, but their podcasts could be either clinically or management focused. Of the 4 high-volume dentists, 3 blogged and tweeted about clinically relevant information, but they used Facebook and YouTube for more management-oriented information.

Social Media Duration and Presence in Dentistry

Social media emerged between 1999 and 2006: Facebook was launched in 2004, YouTube in 2005, and Twitter in 2006. Practicing dentists and consultants began to use these platforms within 2 years of their creation. While widespread podcast availability began in 2004 [17], the first dental podcast began in 2008. The first adopters of social media for communication with clinicians were practicing dentists, hygienists, and consultants, followed by industry and institutions, and, later,

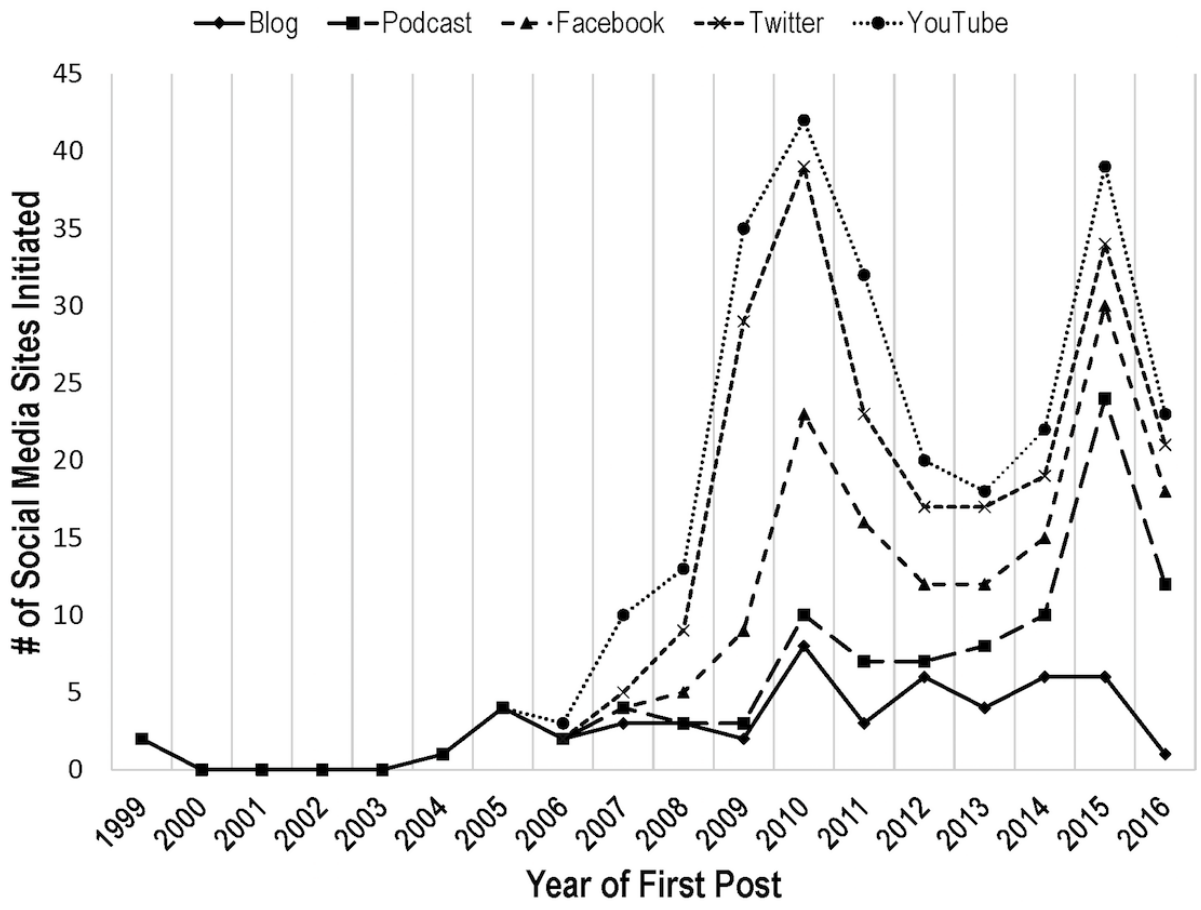
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media organizations. While 2 consultants to the dental industry were active since 1999, most blogs in our dataset began around 2004-2005. Figure 2 provides a summary of the number of social media sites initiated by year in our dental inventory. Multimedia Appendix 2 provides a detailed timeline for all sites included in our analysis.

Hosting a social media site does not, however, indicate active use. We were limited to observing media that were active at or near the time we collected our data because discontinued blogs and other social media disappear (although some maintained their site without having posted for some time). Keeping in mind this caveat, Facebook was the least likely to disappear and YouTube the most. We found that 40% of YouTube sites (17/42 hosts), 71% of blogs (36/51 hosts), 72% of podcasts (33/46 hosts) and Twitter feeds (50/69 hosts), and 86% of Facebook pages (48/56 hosts) that we cataloged had posted within 2 months of our data collection in July 2016. About one-third of the discontinued offerings had been active for less than 11 months, and 16 of those for less than 1 month, suggesting experimentation with social media publishing. Both practicing dentists and consultants experimented. On the other hand, media outlets did not experiment but were also the latest to enter blogging or podcasting, starting 3 years later than practicing dentists on average. Every media blog and podcast we identified was still active at the time of this analysis.

Hosts also varied in how regularly they posted. Practicing dentists, not surprisingly, posted considerably less often than companies, media, and consultants. As Table 3 shows, practicing dentists averaged fewer than 10 blog posts per month, while the companies, media, and consultants posted well into double digits every month. This was not surprising, given the business development rationale for high visibility in the latter 3 groups. The 4 practicing dentists identified as high-volume posters stood out for posting up to 300 blog posts per month. They relied heavily on posting press releases or abstracts of journal articles to achieve this. These dentists are well-recognized speakers, so they may also have similar motivations to the other business-oriented groups. Notably, there was less variation in posting volume across the host types in low-effort Twitter posting. Conversely, practicing dentists were relatively active in posting videos and podcasts at about 5 per month, while high-volume social media dentists did not podcast. Howard Farran of Dentaltown was the most determined podcaster, averaging 26 posts per month. A total of 2 sites were initiated with a 1-time posting of a large amount of material on a single day, suggesting the use of social media as a type of repository.

Figure 2. Year of initial social media post, by modality, for all hosts and modalities.



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Table 3. Social media presence: number and duration of postings.

Host type	Number	No. of months active	Posts per month, mean (SD)	Minimum	Maximum
Blog					
Practicing dentist or hygienist	21	70	9.7 (19.9)	0.3	86.9
Consultant	14	82	1.7 (1.4)	0.0	4.2
Media	6	33	21.9 (31.4)	0.0	82.2
Association	4	68	8.7 (5.8)	0.5	12.9
High-volume social media dentist	4	101	92.4 (143.4)	16.3	307.5
Company	2	35	58.6 (64.4)	13.0	104.1
Twitter					
Practicing dentist or hygienist	31	52	26.3 (69.8)	0.3	371.4
Consultant	21	69	71.7 (219.0)	0.0	1020.6
Media	6	63	32.7 (16.6)	10.2	48.6
Association	4	74	35.7 (17.0)	17.4	52.8
High-volume social media dentist	4	102	47.3 (38.0)	3.5	95.1
Company	3	87	45.9 (23.4)	27.4	72.3
YouTube					
Practicing dentist or hygienist	14	41	4.5 (7.3)	0.0	27.4
Consultant	16	54	1.7 (3.3)	0.1	13.5
Media	2	24	7.6 (7.9)	2.0	13.2
Association	4	104	1.5 (0.8)	0.9	2.6
High-volume social media dentist	3	112	0.2 (0.2)	0.0	0.3
Company	3	68	0.8 (0.4)	0.4	1.1
Podcast					
Practicing dentist or hygienist	25	11	5.1 (7.7)	0.5	41.0
Consultant	18	21	3.6 (N/A)	0.4	14.0
Media	1	11	26.4 (N/A[a])	26.4	26.4
Association	1	55	0.3 (N/A)	0.3	0.3
High-volume social media dentist	0	N/A	N/A (N/A)	N/A	N/A
Company	1	15	1.2 (N/A)	1.2	1.2

[a]N/A: not applicable.

Social Media Content

Hosts varied in the extent to which they provided clinical or practice-specific content. Looking across our 89 hosts, the 49 practicing dentists and hygienists and the 5 industry or association sites provided a balanced mix of clinical, professional, and management information across the platforms. In contrast, the 27 consultants were primarily focused on aspects of business practice, and the media outlets tended to prioritize clinical information. Only 2 of the 49 social media content sites published by practicing dentists or hygienists were exclusively clinical.

To probe the content of blogs in more detail, we topic modeled blogs containing at least some clinical content. Topics are lists of words that relatively frequently occurred in the same blog. In a topic model, each blog post can be a mix of topics, and each topic can be found in more than 1 blog post. The topics associated with each group of blogs were unique, but the sets of words overlapped. Following Ramage et al [18], we took advantage of this overlap to classify the topics into categories. Table 4 lists the categories, the number of topics associated with each category, and sample words drawn from topics in that category. Table 5 shows the number of topics in each category for each group of blogs or blog. Multimedia Appendix 3 displays the full list of topics

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Table 4. Categories of topics with samples.

Categories	No. of associated topics	Sample words
Leading topic		
Status/social	5	talk; thing; stuff; weekend
Product announcement	2	visit; product; announce
Dental care		
Clinical	37	odontogenic; nasal; sinusitis
Materials or equipment	12	mill; impression; scanner
Oral health	5	oral, health, bleach
Dental practice related		
Company or organization	12	caesy; patterson
Internet related	12	google; search; website; site
Computers and imaging	9	drive; storage; backup; gb; hard
Fees and payment	7	fee; provider; medicare; scholarship
Management and employees	5	manager, team
Conferences	3	booth; meeting; exhibit
Other		
School	6	school, class
Child	4	child; smile; kid; health
Academic papers	4	study; publish; article; outcome
Miscellaneous other	53	food, video, glide, marketing
Total	176	

In 4 of the cases, the strongest topic we labeled “status/social.” Many blogs shared a concern with the life side of work-life balance, and this is visible in the prominence of this topic. In the main group of 13 blogs, 73% (3414 posts) of posts contain at least one of the following words: guy, kid, talk, thing, stuff, weekend, kind, or couple. High-volume bloggers, in contrast, posted a lot of press releases, such as “announcements of products from industry leaders”—all words that appeared in their leading topic. Interestingly, the high-volume bloggers’ version of the status/social topic (their second strongest), instead of words referring to other people, contained “I’m” and “I’ve,” suggesting a focus on self as the authors perhaps sought to build themselves into brands. The DentalEZ blog’s lead topic differed, suggesting many announcements inviting readers to “stop” in at an upcoming “meeting” where they will have a “booth” on the “exhibit floor.”

While nonclinical content was a unifying factor across the blogs, clinical topics distinguished blogs from each other. The clinical words were so specialized and varied that blogs with a clinical focus did not cluster together. For example, Jablow, a high-volume poster with a lot of clinical content, separated from the other high-volume bloggers. Jablow, Lee Ann Brady, NYC Dentist, and Endo Blog each had at least 8 clinically relevant topics, and they remained singletons, not clustering with each other.

Issues associated with managing a practice were broadly discussed by many blogs. These issues include money (ie, fees, payment, and scholarships for students); teams and employees; websites and social media; brand names; conferences; and computer equipment (a favorite of high-volume bloggers). The topics were rounded out with a sprinkling of discussion of dental school, of children, of academic papers in blogs that posted abstracts of journal articles such as Jablow, and miscellaneous weak single-word topics.

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Table 5. Number of topics in each category by blog.

Categories	Main group	High volume	Jablow	DentalEZ	New Dentist Now	Lee Ann Brady	NYC Dentist	Endo blog	Voice of Dental Ed	Total
Blogs	13	4	1	1	1	1	1	1	1	24
Posts	4677	9122	3007	658	522	478	318	193	16	18,991
Leading topic										
Status/social	1	1	0	0	1	1	0	0	1	5
Product announcement	0	1	1	0	0	0	0	0	0	2
Dental care										
Clinical	1	1	7	1	0	11	6	10	0	37
Materials or equipment	1	2	5	2	0	0	0	2	0	12
Oral health	1	0	1	0	0	1	2	0	0	5
Dental practice related										
Company or organization	1	2	5	3	1	0	0	0	0	12
Internet related	3	3	1	1	2	1	1	0	0	12
Computers and imaging	0	8	0	0	0	0	1	0	0	9
Fees and payment	1	0	0	0	3	0	1	2	0	7
Management and employees	2	1	0	1	1	0	0	0	0	5
Conferences	0	0	0	2	1	0	0	0	0	3
Other										
School	1	0	1	1	0	0	1	0	2	6
Child	1	0	1	1	1	0	0	0	0	4
Academic papers	0	0	2	1	0	0	0	1	0	4
Miscellaneous other	6	4		8	1	4	9	8	13	53
Total	13	19	24	13	10	14	12	15	3	176

Social Media Audience and Engagement

Ultimately, the question of whether practicing dentists and hygienists access these social media sites was central to understanding their impact. Our ability to ascertain the audience, or potential dental practitioner users, of the clinically relevant information provided through social media was, however, limited. Detailed access ("visits"), click, and download data for blogs and podcasts are typically available only to the host. However, using publicly available statistics, we were able to roughly estimate the potential reach of Facebook, Twitter, and YouTube. From these statistics, we found that the number of Facebook page likes was the largest, followed by Twitter followers, and then YouTube subscribers. Comparing across host types, practicing dentists and hygienists collectively had an audience size for YouTube that was about average for typical users of that modality, but a below-average audience size for Twitter and Facebook (Table 6). The average audience on Twitter was larger for dental management/profession topics, while the audience on Facebook was larger for clinically relevant topics.

As a caveat, these numbers demonstrate observable audience, but nothing more. Likes and followers can be bought, and we assumed that institutions with concerns for their business model and brand image might be more likely to invest in robot followers or likes. Comparing audiences directly across social media modalities was not reasonable, as subscription and followership behavior is different across these platforms. Further, liking and subscribing is a 1-click action and we could not assume continued active engagement going forward. Nor did we know who that audience was, which posts were viewed, or which posts were shared or forwarded.

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Table 6. Average audience size by host type and content.

Host type	Type of content	Facebook page likes	Twitter followers	YouTube subscribers
Company				
	Clinically relevant	3703	11,207	149
	Dental management/profession	0	2346	34
Consultant				
	Clinically relevant	640	30	47
	Dental management/profession	1768	2711	138
High-volume social media dentist				
	Clinically relevant	0	2923	11
	Dental management/profession	4995	19,491	8
Media				
	Clinically relevant	25,685	7103	2808
	Dental management/profession	0	0	9
Practicing dentist or hygienist				
	Clinically relevant	15,528	398	775
	Dental management/profession	684	3292	102
Professional association				
	Clinically relevant	84,541	3195	2178
	Dental management/profession	0	21,703	1012

Discussion

Our study showed that clinically relevant information is posted by dentists and hygienists on social media. To our knowledge, this study provided the first inventory and descriptive analysis of dental social media hosts and platforms. In the dental profession, dentist-to-dentist information distribution has always taken place formally at professional meetings and in study groups, and informally among colleagues. However, social media provide an opportunity for willing clinicians to share their tacit and earned wisdom across geography and time, suggesting a fundamental shift in the way information can be acquired by dental professionals. While clinical evidence will no doubt continue to be sourced from peer-reviewed research, how clinicians access and interact with that information—from others via online trusted sources rather than the pages of a journal—may be changing. Social media researchers note that "traditional media drove reach, while social media created intimacy and engagement" [19]. The familiarity or intimacy of social media hosts helps to build learning communities within the profession, extending collegial support systems (such as study groups) to the online format. Our topic analysis suggested that part of the power of the medium, in comparison with more formal channels, is the discussion of the full context of professional work (personal and professional). This is consistent with Burnett's "information neighborhoods," where professionals will wander around familiar and comfortable places (blogs, Twitter feeds, etc) and "bump into" useful information for which they were not explicitly looking or did not know they needed [20]. For dental practitioners, we showed that these neighborhoods include clinical information, but also a range of other resources relevant to practice management and the profession. So, a search for a treatment approach or solution may also lead to the discovery of something related to practice management or professional development.

With the growth of online access and resources, researchers have studied how, where, and why clinicians access both traditional and electronic resources [1,5,9,20-24]. These studies have laid the groundwork for understanding the relative attraction and use of online sources. The fact that most of the social media platforms are less than a decade old, and that the dental community has been active on these platforms for even fewer years, suggests that use of these resources will continue to evolve. Thus, published studies in recent years may not have captured the shift in interest in online resources, particularly among younger dentists and hygienists [2,4,21,23-32].

As social media continue to evolve, and a younger generation of dental clinicians move into practice, use of social media can be expected to increase. Spallek and colleagues [33] argued that the issue is not whether clinicians will use social media for professional use (because this is certain), but rather *how* social media information transmission benefits can be maximized. Perhaps the most striking finding of our research is the phenomenon of clinicians as information providers for other clinicians on social media. Clinician-to-clinician information dissemination likely fills a gap that many clinicians feel between dental research and the day-to-day context of practice [34]. Like Landry [35], we do not expect these social media resources to substitute for other traditional sources, but rather to supplement them. The professional trust and familiarity that develops in social media-enabled networks can create an identifiable source

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for rapidly disseminated, reliable information among professionals, which may be creating an important change in the information landscape [36,37].

Our study has limitations, but also presents opportunities for future work. In terms of limitations, social media are dynamic and there may be relevant blogs or podcasts that we have inadvertently excluded. The findings of this study present several questions relevant for future inquiry. Methodologically, our exploratory categorization and topic modeling illustrates the complexity of studying clinically specific information diffusion. Terms vary, and in these modalities are intertwined with other nonclinical content. Future research may include the development of topic dictionaries that allow for finer coding and categorization of clinical content in dentistry. For example, natural language processing has been helpful in other studies and may have application here as well [38]. In terms of scope, our study did not address how dental clinicians locate, select, or make use of information that is available on these blogs, podcasts, and other social media. Nor do we know how the social media hosts selected the information to be provided, the quality of the information provided, or its relevance to clinical practice. We do not understand the cumulative effects on the perceived value or quality of the information based on the overall visibility and involvement of dental social media hosts in the dental community. However, our work has developed a foundation to address the important implementation and clinical translation of science to practice issues relevant to social media in dentistry.

Our study demonstrated the participation of practicing dentists and hygienists in the social media environment as a way to share clinical and other information with practicing colleagues. We identified the use of different multimedia and text-based social media platforms for reaching dental practitioners. While this study was exploratory, we hope that it may provide an early indication of the potential that social media may have to develop and strengthen learning communities in dentistry and advance the uptake of current clinical information by practitioners. For dentists, it provides insight into the availability and providers of clinically relevant information in social media.

Acknowledgments

This work was partially supported by US National Institutes of Health (NIH) grant U19-DE-22516. Opinions and assertions contained herein are those of the authors and are not to be construed as necessarily representing the views of the respective organizations or the NIH. Thank you to Nathanael Pate and Joshua Bowling for research assistance.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Blog and podcast inventory.

[PDF File (Adobe PDF File), 41KB - jmir_v19i7e269_app1.pdf]

Multimedia Appendix 2

Timeline of dental social media.

[PDF File (Adobe PDF File), 727KB - jmir_v19i7e269_app2.pdf]

Multimedia Appendix 3

Topic model of dental blogs.

[PDF File (Adobe PDF File), 191KB - jmir_v19i7e269_app3.pdf]

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Edited by G Eysenbach; submitted 15.04.17; peer-reviewed by H Spallek, T Chan, A Keepanasseril; comments to author 10.05.17; revised version received 09.06.17; accepted 12.06.17; published 26.07.17.

Please cite as:
Melkers J, Hicks D, Rosenblum S, Isett KR, Elliott J
Dental Blogs, Podcasts, and Associated Social Media: Descriptive Mapping and Analysis
J Med Internet Res 2017;19(7):e269
URL: http://www.jmir.org/2017/7/e269/
doi:10.2196/jmir.7868
PMID:28747291

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Original Paper

Patterns of Twitter Behavior Among Networks of Cannabis Dispensaries in California

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Abstract

Background: Twitter represents a social media platform through which medical cannabis dispensaries can rapidly promote and advertise a multitude of retail products. Yet, to date, no studies have systematically evaluated Twitter behavior among dispensaries and how these behaviors influence the formation of social networks.

Objectives: This study sought to characterize common cyberbehaviors and shared follower networks among dispensaries operating in two large cannabis markets in California.

Methods: From a targeted sample of 119 dispensaries in the San Francisco Bay Area and Greater Los Angeles, we collected metadata from the dispensary accounts using the Twitter API. For each city, we characterized the network structure of dispensaries based upon shared followers, then empirically derived communities with the Louvain modularity algorithm. Principal components factor analysis was employed to reduce 12 Twitter measures into a more parsimonious set of cyberbehavioral dimensions. Finally, quadratic discriminant analysis was implemented to verify the ability of the extracted dimensions to classify dispensaries into their derived communities.

Results: The modularity algorithm yielded three communities in each city with distinct network structures. The principal components factor analysis reduced the 12 cyberbehaviors into five dimensions that encompassed account age, posting frequency, referencing, hyperlinks, and user engagement among the dispensary accounts. In the quadratic discriminant analysis, the dimensions correctly classified 75% (46/61) of the communities in the San Francisco Bay Area and 71% (41/58) in Greater Los Angeles.

Conclusions: The most centralized and strongly connected dispensaries in both cities had newer accounts, higher daily activity, more frequent user engagement, and increased usage of embedded media, keywords, and hyperlinks. Measures derived from both network structure and cyberbehavioral dimensions can serve as key contextual indicators for the online surveillance of cannabis dispensaries and consumer markets over time.

(J Med Internet Res 2017;19(7):e236) doi:10.2196/jmir.7137

KEYWORDS

cannabis; marijuana; social networking; social media; Internet

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Introduction

Dramatic population-based shifts in cannabis use have occurred over the past 15 years in the United States [1]. As of July 2017, 29 states and Washington DC have enacted laws that permit medical cannabis use. Much research has helped to understand individuals who use cannabis for medical purposes [2], ranging from their consumption patterns and motivations for use to service satisfaction and clinical preferences [3-6]. Similar efforts have explored how state laws differentially impact operation and enforcement of cannabis businesses, health centers, and cultivation practices [7,8]. Nevertheless, significant public debate remains about the medicinal value of cannabis given the large body of clinical and population-based studies showing increased risk of many adverse outcomes [8], especially with regard to the effects of high potency strains and concentrated products like edibles [9,10].

Notably, these debates coincide with the growing availability of medical and recreational cannabis products at dispensaries across the United States. In California, the world's largest legal market for cannabis, medical cannabis patients report that they vary their purchasing behaviors based upon product pricing and availability at dispensaries as well as the specific conditions for which they received a physician recommendation [11]. Patients also report that experiences and interactions with dispensary staff like budtenders greatly influence their purchasing behaviors, including their willingness to try new products [12]. Because dispensaries serve as the purveyors of cannabis products and strongly influence population-based consumption [11,12], many advertise their products and services through a wide variety of platforms, including social network platforms like Twitter.

While it is estimated that 1 in 2000 tweets pertain to cannabis [13], there are currently no studies that specifically focus on how dispensaries use Twitter to engage with medical cannabis patients and their larger follower base. This gap is particularly salient as content analyses of influential Twitter users show that cannabis-related tweets tend to elicit positive sentiments towards cannabis, including heavy and frequent use behaviors [13]. A recent study found that WeedTweets (@stillblazingtho), a Twitter account with over 1 million followers, posts an average of 10 tweets per day and that these tweets tend to normalize regular cannabis use, especially among youth and certain minority populations [14]. In addition, other studies have detected higher frequencies of tweets related to cannabis concentrates (eg, edibles, dabs, and oils) in states that allow medical and recreational consumption [15,16], which may be partially attributable to increasingly permissive and accepting attitudes toward cannabis.

Considering the well-documented impacts of social networks on consumer preferences and behaviors [17-19], an explicit focus on the exchange of cannabis-related information may provide valuable insights into how networks of cannabis consumers form around dispensaries on Twitter. For instance, some dispensaries regularly use Twitter to share their menus, inform their followers about new products, offer coupons and promotions, promote retail services, post industry trends and events, and mention findings from scientific studies. Other dispensaries, however, may engage in these practices less frequently or have more sporadic Twitter usage, which could influence their ability to form strong and sustained networks of followers.

More importantly, systematic investigation of dispensaries on Twitter can provide insights into how dispensaries behave on the Internet and how these behaviors influence the formation of shared follower communities. This comparative study therefore examines a set of 12 Twitter cyberbehaviors among two samples of cannabis dispensaries from the San Francisco Bay Area (SFBA) and Greater Los Angeles (GLA). For each metropolitan area, we visualize overall network structure and community formation based upon shared followers, then reduce the cyberbehaviors into a more parsimonious set of dimensions with principal components factor analysis. Finally, we utilize quadratic discriminant analysis to investigate whether the extracted dimensions of cyberbehavior significantly differentiate between dispensary communities in California.

Methods

Study Sample

We adapted aspects of targeted sampling methods to select cannabis dispensaries in SFBA and GLA. Traditionally, these methods have been used in social science and public health studies to access "hidden" populations (eg, medical cannabis patients or people who inject drugs) outside of community or medical settings [20]. Targeted sampling integrates components of street ethnography, theoretical sampling, stratified survey sampling, quota sampling, and respondent-driven sampling [21-24]. As it improves upon convenience samples through a purposive and rigorous process, a growing body of studies has used targeted sampling to recruit representative samples that are comparable to those achieved through random sampling techniques [25-28].

In the context of cannabis dispensaries in California, we included licensed, registered, and commercially zoned dispensaries from the Medical Dispensary Program in San Francisco, the Cannabis Regulatory Commission in Oakland, the Medical Cannabis Commission in Berkeley, and the Medical Marijuana ID Program in Los Angeles. We then cross-referenced the initial database with Leafly, WeedMaps, and THCFinder, three popular cannabis sites that allow users to geolocate dispensaries throughout the United States, including California. These sites include streamlined platforms with comprehensive information about social network profiles, which allowed us to expand our initial database and create a larger catchment of dispensary accounts on Twitter. With this final sample of dispensary accounts, we collected the account IDs of followers and the last 3200 tweets available as of February 16, 2016. Finally, a set of 12 cyberbehaviors were derived with metadata from the accounts and fell into three broad categories: account age, posting frequency, and tweet composition (Table 1).

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Table 1. Definitions for Twitter cyberbehaviors.

Cyberbehaviors	Definition
Account age	
Overall age	Number of days a Twitter account has existed
Total days tweeting	Number of days at least one tweet was sent from an account
Posting frequency	
Tweets collected	Total number of tweets collected from an account timeline
Percentage of days tweeting	Percentage of days since an account was created that there has been a tweet
Max. tweets per day	Maximum number of times an account has posted a tweet in a single day
Average tweets per day	Mean number of times an account tweets per day[a]
Median absolute deviation	Median absolute deviation (MAD) of tweets per day
Tweet composition	
Hashtag (#)	Percentage of tweets collected that contained a hashtag
Mention (@)	Percentage of tweets collected that mentioned another user directly
Retweet (RT)	Percentage of tweets collected that were retweets
Media	Percentage of tweets collected that contained embedded media[b]
Hyperlink (http://)	Percentage of tweets collected that contained a hyperlink

[a]Excludes days on which an account did not tweet.

[b]Images, videos, and documents.

Network Structure and Community Detection

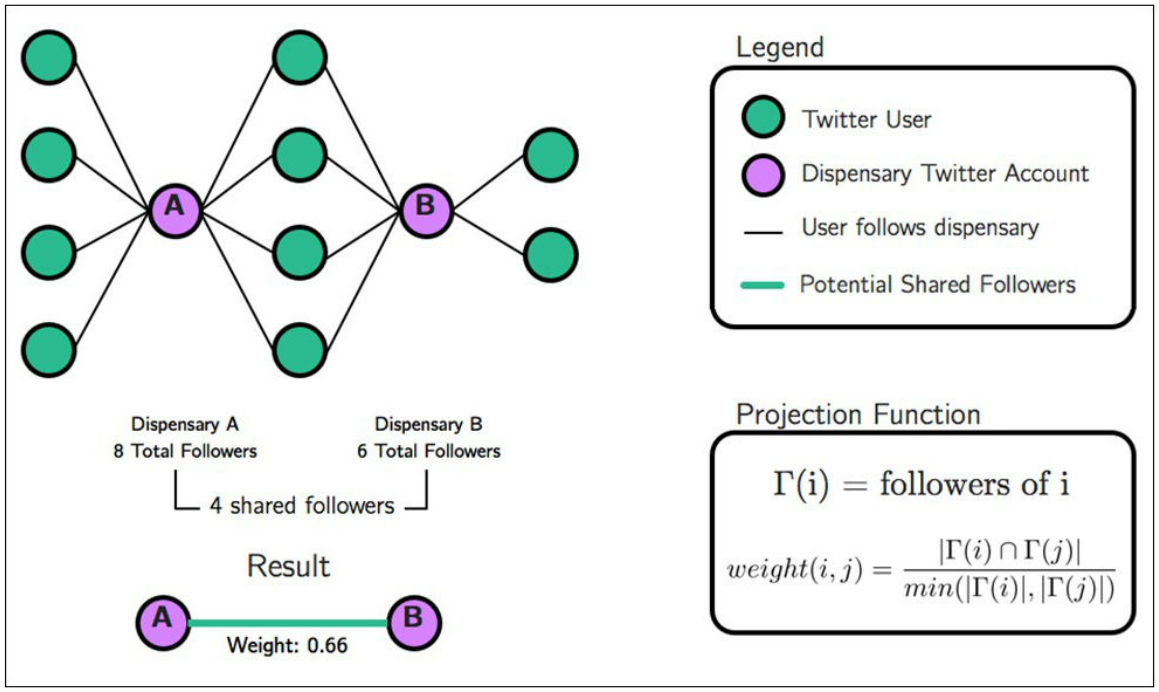
With the account information for each dispensary and their followers, we created a projection from the dispensary networks with edge weights representing shared followership [29]. Because the sampled dispensary accounts had a highly right-skewed distribution of followers, we normalized follower counts between two dispensaries by calculating the ratio of shared followers to potential shared followers, where *potential shared followers* was the minimum of the follower counts of the two dispensaries. With similarities to the Jaccard index, this measurement computed a projection function that determined the shared potential followers between dispensaries [30,31]. As depicted in Figure 1, two hypothetical dispensaries share four followers out of a total of six potential shared followers, yielding a projection function of 66%.

The Louvain Method [32] was then utilized to detect dispensary communities in SFBA and GLA. This unsupervised algorithm finds communities of large networks and provides a hierarchical structure for the network through an iterative, two-stage process that maximizes modularity. The method first began by selecting a random dispensary (ie, node) and assigning that dispensary to a community of one of its neighboring dispensaries, until all existing dispensaries in the network were assigned to a community. In the second phase, each dispensary represented a community from phase one, while edges between dispensaries represented the sum of the weights of the previous connections between dispensaries in those two communities. These two phases of optimizing modularity and constructing a meta-network in each city were repeated until a network with the maximum value of modularity was found.

After creating the network data and calculating communities, we visualized each city's network with a force-directed graph drawing algorithm. This network visualization algorithm places nodes with more shared follower potential closer to each other and repulses nodes with limited or no potential. For the purposes of this study, dispensaries from the same community were visualized using colored nodes.

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Figure 1. Hypothetical shared follower network.



Cyberbehavioral Dimensions and Community Classification

For the 12 cyberbehaviors, descriptive statistics were computed to characterize each city's set of communities. Wilcoxon rank-sum and Kruskal-Wallis tests were also performed to explore any statistically significant differences between cities and communities for the 12 cyberbehaviors. We then conducted principal components factor analysis (PCA) with a 12x12 correlation matrix of the cyberbehaviors to extract empirically meaningful dimensions. PCA provided a method with which to address multicollinearity among the cyberbehaviors and arrive at a more parsimonious set of dimensions that account for the data variability. Lastly, we performed quadratic discriminant analysis (QDA) to determine the classification accuracy of the extracted cyberbehaviors [33]. For the purpose of this study, QDA produced classification tables for each city, which allowed for distinguishing between modularity classes with the extracted cyberbehavioral dimensions from the PCA.

Results

Descriptive Statistics

Overall, a total of 119 dispensary accounts were examined, with 61 in SFBA and 58 in GLA. The mean values for each cyberbehavior are shown for the two cities in Table 2. Each account in SFBA and GLA was approximately three years old on average. The cyberbehaviors for posting frequency and tweet frequency were highly comparable between the two cities. Although dispensary accounts in SFBA spent a higher number of days tweeting and sent more tweets than accounts in GLA, no significant differences were found.

Network Structure and Community Formation

Figure 2 visualizes the two shared follower networks of dispensaries in SFBA and GLA. The size of the nodes corresponds to the total number of followers, the thickness of the edges indicates the shared follower potential, and the color of the nodes refers to the community classifications from the Louvain method. Overall, the distribution of shared followers between each pair of accounts differed between SFBA and GLA. The range of shared followers was .2% to 71% in SFBA compared with 3% to 46% in GLA.

Among the SFBA networks, 21% (n=13, marked in green) of dispensaries were in a weakly connected community with all members having a modest number of Twitter followers. Another 38% (n=23, marked in orange) were in a fairly centralized community of dispensaries with strong interconnections between smaller accounts. The largest community accounted for 41% of the sample (n=25, marked in purple) and had strong interconnections through the most popularly followed dispensary. In GLA, a community accounting for 38% (n=22, marked in orange) of the network had the two dispensaries with the most followers, although its members were weakly connected. A small and weakly connected network accounted for 17% of the network (n=10, marked in green), with only two that had a relatively large group of followers. Despite only a modest number of followers on Twitter, the remaining 45% of the network (n=26, marked in purple) formed the largest and most strongly connected community, indicating a substantial portion of shared followers between any given pair of members.

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Table 2. Descriptive statistics for Twitter cyberbehaviors.

Cyberbehaviors	SFBA[a] (n=61)	GLA[b] (n=58)	*P* value[c]
	Mean	Mean	
Account Age, Days (Years)	1107.8 (3.0)	1006.2 (2.8)	.49
Total Days Tweeting	285.5	202.6	.14
Tweets Collected	965.4	590.3	.21
Max. Tweets Per Day	15.1	16.4	.87
Average Tweets Per Day	3.0	2.9	.72
MAD[d] Tweets Per Day	0.8	0.8	.92
Percentage of Days Tweeting	25.9	24.1	.34
Percentage of Tweets with Media	20.4	21.0	.98
Percentage of Tweets with #[e]	40.4	40.4	.92
Percentage of Tweets with @[f]	26.1	27.6	.54
Percentage of Tweets with RT[g]	10.2	10.5	.63
Percentage of Tweets with Hyperlink	55.9	51.8	.47

[a]SFBA: San Francisco Bay Area.

[b]GLA: Greater Los Angeles.

[c]The *P* values were calculated with the Wilcoxon rank-sum tests to accommodate for the nonparametric nature of the cyberbehaviors.

[d]MAD: median absolute deviation.

[e]#=hashtag.

[f]@=user mention.

[g]RT: Retweet.

In the subgraphs (Figure 3), we recalibrated the tie-strength and considered an edge to be present when the proportion of shared followers of a given pair of dispensaries was above the 95th percentile of shared follower potential between any given pair of dispensaries in each of the two cities. We tested various thresholds of shared follower potential: the median, the third quartile (75th percentile), 90th percentile and 95th percentile. As highly consistent network graphs were found, the 95th percentile was used as the final threshold to produce the subgraphs with the strongest tie-strength in the social networks with the best visual clarity.

As Figure 3 illustrates, one dispensary is particularly popular in SFBA, where it not only attracts substantially more followers than its counterparts, but also has stronger connections to the followers. In contrast, large dispensaries in GLA are not as strongly connected and centralized as those in SFBA, given that they do not share many followers (Figure 3). Although four of them seem to be very popular with a large group of followers, they occupy different network positions and attract different groups of Twitter users through a smaller but highly centralized and interconnected dispensary. Additionally, there was a cluster of well-connected dispensaries with a group of small, but mostly shared followers.

Cyberbehavioral Dimensions

The mean values for the cyberbehaviors are summarized for the extracted communities in Multimedia Appendix 1. In SFBA, the weakly connected orange community had lower rates of maximum tweets per day, average tweets per day, hashtags, and user mentions, despite having the highest number and percentage of days where a tweet was sent. In comparison, the moderately connected green and strongly connected purple communities had higher frequencies of tweets as well as more user engagement (eg, mention and retweet), hashtag usage, embedded media, and hyperlinks. Significant differences between SFBA communities were found for account age, total days tweeting, average tweets per day, and percentage of tweets with media. For the GLA dispensaries, the highly connected purple community had the highest percent of days tweeting, embedded media, hashtag usage, and hyperlinks. The weakly connected green and orange communities tended to have higher account ages, total tweet days, and total tweets. The only significant differences between GLA communities were found for account age.

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Figure 2. Shared follower networks in the San Francisco Bay Area and Greater Los Angeles.

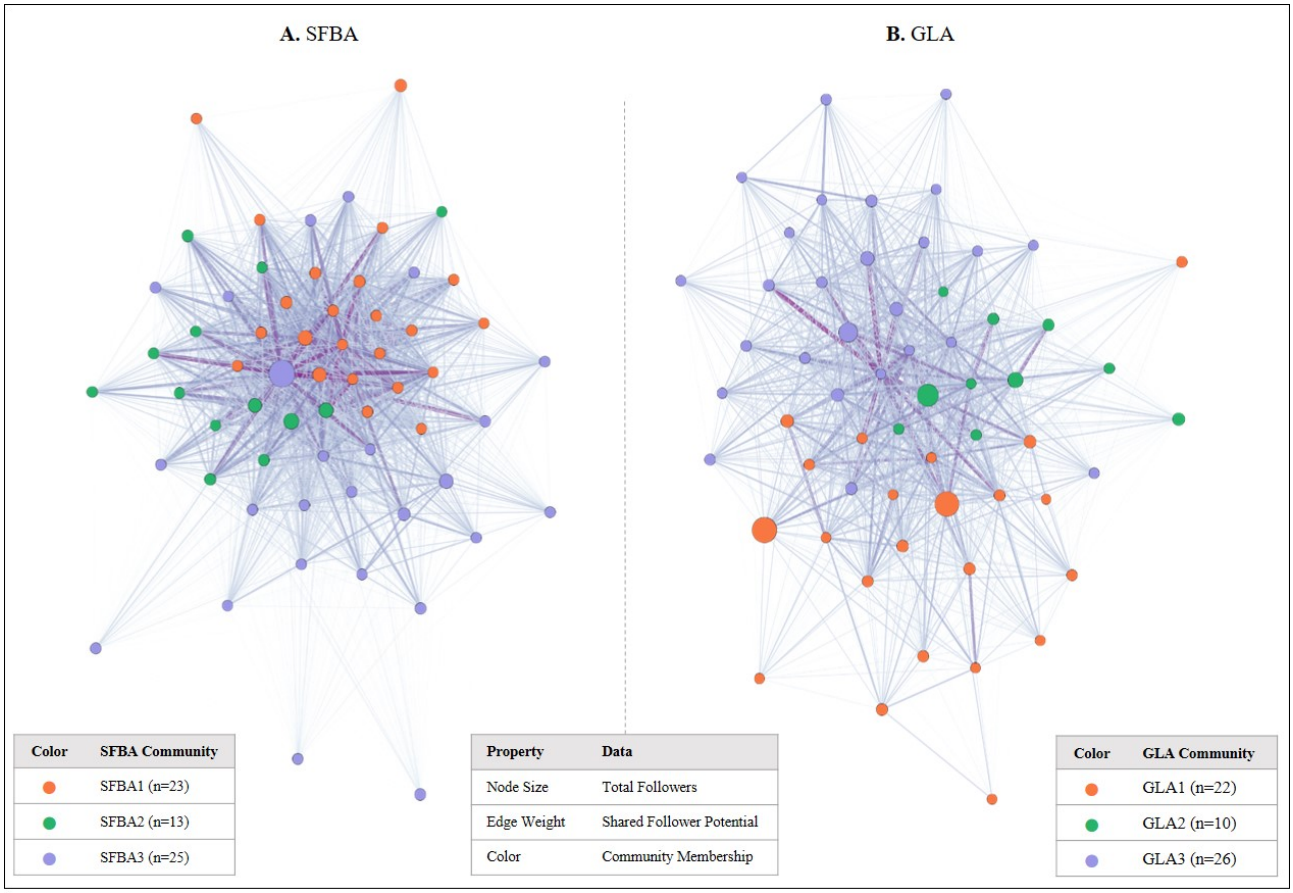
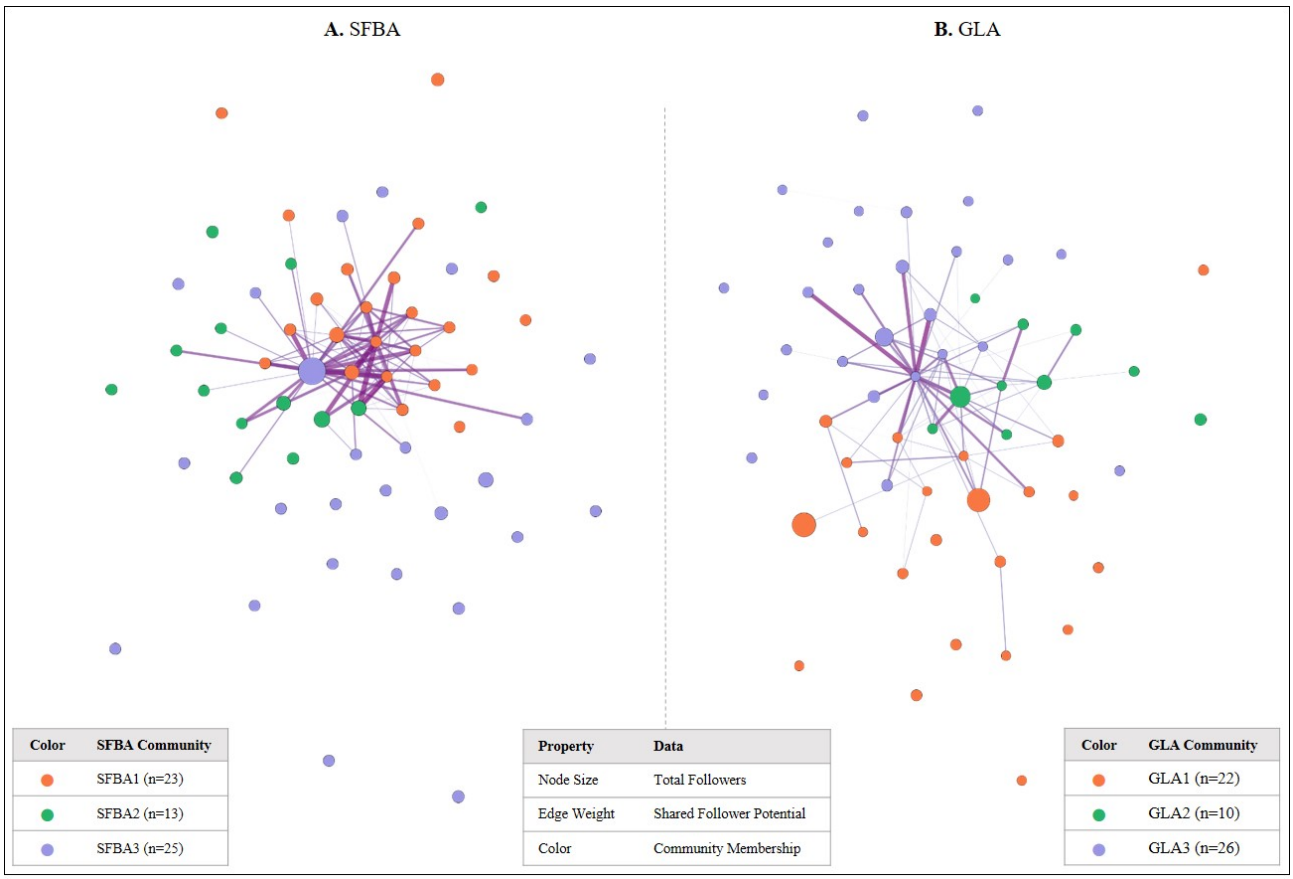


Figure 3. Shared follower network subgraphs in the San Francisco Bay Area and Greater Los Angeles.



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The principal components factor analysis yielded five relevant factors (eigenvalues>1.0) that describe the Twitter behaviors of dispensaries in SFBA (Table 3). The first factor for SFBA was classified as *activity* (eigenvalue=4.3) and included three behaviors indicating the daily message frequency of users: maximum tweets per day, average tweets per day, and median absolute deviation of tweets per day. The second factor, *age* (eigenvalue=3.2), included two items: account age and percentage of tweets with media like images and videos, suggesting a specific Twitter usage pattern among SFBA dispensaries with older accounts that were less likely to include media in their tweets.

We categorized the third factor for SFBA dispensaries as *longevity* (eigenvalue=1.4) with both total days tweeting and percentage of days tweeting loading on to this dimension, followed by *engagement* (eigenvalue=1.2) with both percentage of tweets that were retweets (ie, tweets being forwarded or shared with others by users who read the original tweet) and mentions (ie, including another user account in the tweet) being loaded on this factor. The engagement dimension captures how users interact with each other on Twitter. Lastly, *referencing* (eigenvalue=1.0) included two items that link the tweet to additional information sources: percentage of tweets with hashtags (#) and hyperlinks (http://).

Table 3. Results from principal components factor analysis of the 12 cyberbehaviors in the San Francisco Bay Area.

Cyberbehaviors	Activity	Age	Longevity	Engagement	Referencing
Eigenvalues[a,b]	4.3	2.2	1.4	1.2	1.0
Account Age	0.02	**0.60**	−0.02	0.01	−0.18
Total Days Tweeting	−0.06	0.29	**0.54**	−0.05	−0.13
Percentage of Days Tweeting	−0.04	−0.20	**0.74**	0.06	0.12
Tweets Collected	0.28	0.19	0.32	−0.11	−0.03
Max. Tweets Per Day	**0.46**	0.03	0.07	0.10	−0.01
Average Tweets Per Day	**0.64**	−0.03	−0.15	−0.06	0.02
MAD[c] Tweets Per Day	**0.53**	−0.05	0.05	0.06	0.02
Percentage of Tweets with Media	0.05	− **0.64**	0.14	−0.07	−0.29
Percentage of Tweets with #[d]	−0.03	−0.21	−0.06	0.16	**0.55**
Percentage of Tweets with @[e]	0.01	−0.01	0.02	**0.68**	−0.10
Percentage of Tweets with RT[f]	−0.01	0.07	0.02	**0.68**	0.05
Percentage of Tweets with Hyperlinks	0.03	0.14	0.10	-0.11	**0.73**

[a]The presence of dimensionality was supported when eigenvalues were 1.0 or greater. Values for each cyberbehavior are expressed as varimax-rotated factor loadings.

[b]Bold factor loadings denote values greater than or equal to .40.

[c]MAD: median absolute deviation.

[d]#=hashtag.

[e]@=user mention.

[f]RT: Retweet.

We found highly similar cyberbehavioral dimensions among the GLA dispensaries (Table 4). The factor that explained the most variance was *activity* (eigenvalue=3.0), including average tweets per day and median absolute deviation of tweets per day with the largest loadings. We classified the second factor as *longevity* (eigenvalue=2.4), given that account age, total days tweeting, and total number of tweets collected significantly loaded on to this dimension. The third factor found from the GLA data was *engagement* (eigenvalue=1.8), with the same two behavioral items being loaded on to this dimension. A similar *referencing* dimension was found (eigenvalue=1.3) in GLA, although hashtags were accompanied with a significant loading for percent tweets with multimedia content when compared with hyperlinks in SFBA. For GLA, a significant loading for *hyperlinks* formed its own dimension (eigenvalue=1.3).

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Table 4. Results from principal components factor analysis of the 12 cyberbehaviors in Greater Los Angeles.

Cyberbehaviors	Activity	Longevity	Engagement	Referencing	Hyperlinks
Eigenvalues[a,b]	3.0	2.4	1.8	1.3	1.2
Account Age	0.14	**0.48**	0.05	0.26	0.29
Total Days Tweeting	0.10	**0.66**	0.01	0.08	0.08
Percentage of Days Tweeting	0.16	0.20	0.25	0.39	0.29
Tweets Collected	0.22	**0.54**	0.00	0.02	0.01
Max. Tweets Per Day	0.33	0.05	0.14	0.26	0.32
Average Tweets Per Day	**0.64**	0.03	0.02	0.06	0.12
MAD[c] Tweets Per Day	**0.59**	0.03	0.05	0.08	0.09
Percentage of Tweets with Media	0.11	0.01	0.01	**0.62**	0.21
Percentage of Tweets with #[d]	0.08	0.00	0.19	**0.54**	0.09
Percentage of Tweets with @[e]	0.01	0.00	**0.66**	0.13	0.01
Percentage of Tweets with RT[f]	0.00	0.03	**0.66**	0.07	0.01
Percentage of Tweets with Hyperlinks	0.11	0.00	0.01	0.04	**0.80**

[a]The presence of dimensionality was supported when eigenvalues were 1.0 or greater. Values for each cyberbehavior are expressed as varimax-rotated factor loadings.

[b]Bold factor loadings denote values greater than or equal to .40.

[c]MAD: median absolute deviation.

[d]#=hashtag.

[e]@=user mention.

[f]RT: Retweet.

Classification Accuracy of Cyberbehavioral Dimensions

Table 5 illustrates how the communities classified by the cyberbehavioral dimensions (ie, columns) corresponded to the true communities identified through the Louvain Method (ie, rows). As depicted by the bolded diagonals, the dimensions correctly classified 75% (46/61) of the dispensary communities in SFBA. The orange community had the best classification precision, followed by the green and purple communities.

In GLA, the dimensions correctly classified 71% (41/58) of the dispensary communities, with high classification precision among the orange and purple communities (Table 6). Only 20% of the green community was correctly classified, most likely due to limited sample size. Additional loading statistics for the dimensions in the QDA may be found for each city in Multimedia Appendix 2 and interpreted like the factor loadings from the PCA.

Table 5. Classification table for the communities of dispensaries in the San Francisco Bay Area.

San Francisco Bay Area (N=61)	Classified community		
True community	Orange	Green	Purple
Orange (n=23)	**20 (87%)**[a]	0 (0%)	3 (13%)
Green (n=13)	2 (15%)	**9 (69%)**	2 (15%)
Purple (n=25)	3 (12%)	5 (20%)	**17 (68%)**

[a]Bold diagonals illustrate correctly classified communities.

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Table 6. Classification tables from the quadratic discriminant analysis of dispensaries in Greater Los Angeles.

Greater Los Angeles (N=58)	Classified community		
True community	Orange	Green	Purple
Orange (n=22)	**18 (82%)**[a]	0 (0%)	4 (18%)
Green (n=10)	3 (30%)	**2 (20%)**	5 (50%)
Purple (n=26)	4 (15%)	1 (4%)	**21 (81%)**

[a]Bold diagonals illustrate correctly classified communities.

Discussion

Principal Findings

As a popular social network platform that enables rapid information exchange about controversial social phenomena, Twitter represents an unregulated domain where cannabis dispensaries can form communities through regular communication and engagement with large audiences. In this study, the networks in SFBA and GLA both included sets of highly influential dispensaries with large groups of shared followers. However, the network structure of SFBA was more strongly connected and centralized than that of GLA, which had four large dispensaries that occupied relatively separate network spaces. The most strongly connected dispensaries in both cities had newer accounts, higher daily activity, more frequent user engagement, and increased usage of embedded media, keywords, and hyperlinks. As such, both network structure and cyberbehaviors significantly distinguished between the communities in each city, which provides evidence for contextual indicators that can be utilized for the surveillance of information exchange among dispensaries on Twitter.

Cyberbehaviors and Distinguishable Communities

Among the large and interconnected dispensary communities, the cyberbehaviors indicated regular tweets to shared followers that may include patient, consumer, and cannabis industry populations with strong mutual interests. The younger age of these highly active dispensaries may also demonstrate the emergence of new marketing strategies that streamline product promotions, share information, and develop brand loyalty within a larger sharing economy on Twitter [34]. In addition, these communities exhibited comparatively higher user engagement and referencing, two dimensions that may reciprocate collective consumption of cannabis through Twitter-mediated interactions and cooperative cyberbehaviors that rapidly disseminate cannabis-related information [35]. Together, the structural and dimensional characteristics of these communities indicate that influential dispensaries may use Twitter to boost social traffic to their websites and grow their social networks [18,36-41].

In contrast, the dispensaries on the network periphery had lower shared follower potential and exhibited more generic cyberbehaviors (eg, text-only tweets) that do not provide followers with engaging content or links to additional resources. As populations with greater socioeconomic status are significantly more likely to send and receive hyperlinks [42-45], these dispensaries may lack the resources to engage in cyberbehaviors that place them in more densely connected network spaces characterized by regular communications and strategic engagements with larger populations of shared followers. The *referencing* and *hyperlink* dimensions found in this study may therefore serve as key contextual measures of social capital among cannabis markets in California. Indeed, several large dispensaries were able to occupy their own network spaces outside of the center cores in both cities through increased *referencing* and *hyperlinks*, which may help attract shared followers with regional preferences, motivations, and norms related to cannabis consumption [46]. As several California studies have found that dispensaries are more likely to cluster in communities with higher levels of cannabis demand, consumption, and morbidity [47-50], follow-up analyses that incorporate geospatial data will be better suited to determine how network position corresponds to the geographic distribution of dispensary communities in California and other states [51].

With regard to community formation among dispensaries, we conceptualized shared followers as a form of affinity that signals mutual interest and affiliation with dispensaries they choose to jointly follow. By incorporating this feature into a social network to understand interconnections between dispensaries, shared followers represent a potential resource that may flow between dispensaries and help form communities in response to unique patterns of cyberbehavior among dispensaries [52-54]. In the larger context of public health surveillance, the social networks constructed in SFBA and GLA may serve as the foundation for more rigorous studies to evaluate how new social policies and regulations disrupt or facilitate community formation and cyberbehavior. Moreover, the rapidly growing presence of dispensaries on the Internet suggests that the cyberbehaviors identified in this study may be useful measures to capture the frequency and types of communication that occur on Twitter [55,56]. Coordinated efforts to engage with researchers, policymakers, and stakeholders will be necessary to better understand the utility of these measures and develop scalable strategies to monitor large-scale industry practices on Twitter and other social media platforms [57,58].

Limitations

Although this study utilized shared follower potential to understand network structure and community formation among dispensaries, we acknowledge the multiple ways in which social networks may be represented. Instead of shared follower

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networks, a strict flow network using shared or liked tweets among dispensaries may demonstrate different dynamics of social interaction and information propagation [59]. Indeed, exploratory analyses revealed very low levels of message diffusion among dispensaries in SFBA and GLA, which suggests that shared followers typically do not exchange or directly engage with dispensary tweets. Considering the referencing dimension, the content from dispensary tweets may also be constructed as a semantic network that not only illustrates conceptual connections between phrases, keywords, and hashtags, but also classifies how cannabis products are priced and promoted [60,61]. While such analyses were beyond the scope of this paper, rigorous content analyses will provide the framework with which to create a classification system that can be systematically trained to identify direct-to-consumer advertising of cannabis products and other specific types of tweets, such as health claims, industry events, scientific studies, and sentiment towards state and federal policies [61-63].

Similarly, the ability of the cyberbehavioral dimensions to distinguish between communities suggests that metadata can provide additional insights into dispensary and consumer behaviors on Twitter. Larger studies that leverage these dimensions with metadata like dispensary type (eg, nonprofit, delivery, and health services), provisions for state and local laws, and geospatial characteristics may improve the detection of dispensary communities [64]. For example, computational methods like stochastic block modeling can improve the accuracy of community detection with metadata without *a priori* assumptions about their correlations [65]. In other words, these methods can learn (eg, unsupervised and semi-supervised) whether important correlations exist and subsequently use or ignore metadata depending on whether they provide useful information to network structure and community formation [65]. Finally, integrative techniques like exploratory graph analysis, latent network modeling, and residual network modeling represent new and exciting approaches that can help derive more parsimonious cyberbehavioral dimensions when compared with PCA and other latent variable modeling approaches [66,67].

Conclusions

The findings from this study indicate that network structure and multiple dimensions of dispensary behavior on Twitter shape two of California's largest cannabis markets. As California successfully passed Proposition 64 on the November 2016 ballot, the legalization of recreational cannabis use for adults aged 21 years and older further stresses the need to determine the policy implications of online cannabis marketing and monitor community activity through contextual measures of cyberbehavior that may influence population-based consumption. In addition, the emergence of online marketplaces and mobile apps demonstrates how the digitization of dispensaries has started to shift consumers away from storefronts to high-tech collaborative consumption platforms that personalize product choices and automate purchases. With Twitter as a key part of this digital paradigm shift, the scalable methodology used in this study will serve as the basis for more rigorous designs that longitudinally track community formation and patterns of cyberbehavior among dispensaries.

Acknowledgments

This study was supported by an Independent Research and Development (IR&D) Grant and Strategic Investment Fund (SIF) at RTI International. An earlier version of this paper was presented at the 2016 International Conference on Computational Social Science.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Descriptive statistics for cyberbehaviors among communities of dispensaries.

[PDF File (Adobe PDF File), 173KB - jmir_v19i7e236_app1.pdf]

Multimedia Appendix 2

Canonical loadings for Twitter cyberbehaviors among communities of dispensaries.

[PDF File (Adobe PDF File), 559KB - jmir_v19i7e236_app2.pdf]

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Abbreviations

GLA: Greater Los Angeles
PCA: Principal components factor analysis
QDA: Quadratic discriminant analysis
SFBA: San Francisco Bay Area

Edited by I Weber; submitted 09.12.16; peer-reviewed by A Kurti, M Meacham; comments to author 22.01.17; revised version received 06.03.17; accepted 07.04.17; published 04.07.17.

Please cite as:
Peiper NC, Baumgartner PM, Chew RF, Hsieh YP, Bieler GS, Bobashev GV, Siege C, Zarkin GA
Patterns of Twitter Behavior Among Networks of Cannabis Dispensaries in California
J Med Internet Res 2017;19(7):e236
URL: http://www.jmir.org/2017/7/e236/
doi:10.2196/jmir.7137
PMID:28676471

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Original Paper

Assessing Suicide Risk and Emotional Distress in Chinese Social Media: A Text Mining and Machine Learning Study

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Abstract

Background: Early identification and intervention are imperative for suicide prevention. However, at-risk people often neither seek help nor take professional assessment. A tool to automatically assess their risk levels in natural settings can increase the opportunity for early intervention.

Objective: The aim of this study was to explore whether computerized language analysis methods can be utilized to assess one's suicide risk and emotional distress in Chinese social media.

Methods: A Web-based survey of Chinese social media (ie, Weibo) users was conducted to measure their suicide risk factors including suicide probability, Weibo suicide communication (WSC), depression, anxiety, and stress levels. Participants' Weibo posts published in the public domain were also downloaded with their consent. The Weibo posts were parsed and fitted into Simplified Chinese-Linguistic Inquiry and Word Count (SC-LIWC) categories. The associations between SC-LIWC features and the 5 suicide risk factors were examined by logistic regression. Furthermore, the support vector machine (SVM) model was applied based on the language features to automatically classify whether a Weibo user exhibited any of the 5 risk factors.

Results: A total of 974 Weibo users participated in the survey. Those with high suicide probability were marked by a higher usage of pronoun (odds ratio, OR=1.18, *P*=.001), prepend words (OR=1.49, *P*=.02), multifunction words (OR=1.12, *P*=.04), a lower usage of verb (OR=0.78, *P*<.001), and a greater total word count (OR=1.007, *P*=.008). Second-person plural was positively associated with severe depression (OR=8.36, *P*=.01) and stress (OR=11, *P*=.005), whereas work-related words were negatively associated with WSC (OR=0.71, *P*=.008), severe depression (OR=0.56, *P*=.005), and anxiety (OR=0.77, *P*=.02). Inconsistently, third-person plural was found to be negatively associated with WSC (OR=0.02, *P*=.047) but positively with severe stress (OR=41.3, *P*=.04). Achievement-related words were positively associated with depression (OR=1.68, *P*=.003), whereas health- (OR=2.36, *P*=.004) and death-related (OR=2.60, *P*=.01) words positively associated with stress. The machine classifiers did not achieve satisfying performance in the full sample set but could classify high suicide probability (area under the curve, AUC=0.61, *P*=.04) and severe anxiety (AUC=0.75, *P*<.001) among those who have exhibited WSC.

Conclusions: SC-LIWC is useful to examine language markers of suicide risk and emotional distress in Chinese social media and can identify characteristics different from previous findings in the English literature. Some findings are leading to new hypotheses for future verification. Machine classifiers based on SC-LIWC features are promising but still require further optimization for application in real life.

(J Med Internet Res 2017;19(7):e243) doi:10.2196/jmir.7276

KEYWORDS

suicide; psychological stress; social media; Chinese; natural language; machine learning

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Introduction

Background

Suicide is the second leading cause of death in 15-29-year-olds globally and the first for this age group in China [1,2]. In addition to suicide as the most extreme action, more young people are suffering from emotional distress, which not only reduces their quality of life but also becomes a risk factor for severe mental disorder and suicide [3,4]. Therefore, early identification and intervention in emotional distress and suicidal thoughts are imperative for preventing suicide deaths.

To assess suicide risk and emotional distress, many tools have been developed and validated. Some examples of such tools include Adult Suicide Ideation Questionnaire [5], Suicide Probability Scale (SPS) [6], Depression Anxiety Stress Scales-21 (DASS-21) [7,8], and the recently developed Suicidal Affect-Behavior-Cognition Scale [9]. These tools often require respondents to either fill in a questionnaire or participate in a professional interview. However, distressed or suicidal people often have low motivation to seek help from professionals [10-12]. In addition, a recent study found that taking a suicide assessment may lead to negative affect changes on individuals with depressive symptoms [13]. From the suicide prevention point of view, a tool that can assess one's suicide risk and emotional distress in a natural setting without costing his or her efforts and attention is preferable and can increase the opportunities for early identification and intervention.

Previous Work

The wide use of Web-based social media has provided a natural setting where interpersonal communications can be well documented for studying suicide and mental health issues [14]. Cases of social media being used by individuals to express suicidal thoughts, look for suicide methods, or even live broadcast suicidal behaviors have been reported and studied in different countries [15-17] including China [18,19]. With Twitter and Facebook blocked in China, Sina Weibo (referred to as Weibo hereafter; Sina is a company name and Weibo literally means Microblog) is one of the most popular social media platforms among the Chinese population. According to China Internet Watch, Weibo had more than 313 million of monthly active users by the end of 2016 [20], which is close to the number of worldwide monthly active users of Twitter [21]. A recent study empirically demonstrated that Weibo users who have suicidal ideation or distressed mental states are very likely to tell others about their suicidal thoughts on Weibo [22]. This is in line with psycho-linguistic studies that see words or language as a meaningful marker to convey or predict different aspects of our minds [23].

Previous studies have demonstrated the potential to use social media data to assess suicide risk or depression in English [16,24-26]. There are relatively few studies on the same topic in Chinese, and only a handful of studies have explored the topic using Weibo data. These studies had several major limitations. First, some studies validated their machine learning models against human annotated suicide risk level [27,28]. The human annotators were often graduate students who were not systematically trained in suicide prevention. The validity of their annotation requires empirical examination [29]. Empirically validated assessment tools are a more rigorous way to validate machine classifier's performance [24].

Second, most of the previous studies have artificially boosted the percentage of suicidal or depression cases in their total sample [30,31] or their classifiers were trained to distinguish extremely high suicidal cases from extremely low suicidal ones but excluding those in the middle [32]. Such study designs have difficulty being applied to real life scenarios, where people with different levels of risk are mixed, and suicidal people often count for a small proportion of the total population.

Last but not the least, previous Chinese studies have utilized a locally developed dictionary, namely, simplified Chinese micro-blog word count dictionary [33], for analyzing Weibo posts [32,34]. The advantage of the locally developed dictionary is that it might have a higher coverage of Chinese Web-based language. However, the disadvantage is that the results can hardly be compared with other countries' studies that often use the standardized linguistic inquiry and word count (LIWC) dictionary [35]. More importantly, when previous work used the local dictionary to classify a Weibo user's suicide risk, the classifiers' performance showed a large space for improvement [32] or remained unclear [31]. In this case, it is worthy of empirical examination to find out whether using standardized LIWC dictionary can achieve comparable or even better performance than using a locally developed dictionary.

Aim of the Study

This study aimed to explore whether computerized language analysis methods can be utilized to assess Chinese individuals' suicide risk and emotional distress based on their Weibo posts. Specifically, we not only analyzed what Simplified Chinese-Linguistic Inquiry and Word Count (SC-LIWC) categories were associated with suicide risk or emotional distress but also applied machine learning method to automatically classify whether a social media user was having suicide risk or emotional distress. We examined the computerized markers' performance against conventional self-assessment tools to evaluate their utility.

Methods

Data Collection

A Web-based survey of Weibo users was conducted to assess the respondents' suicide risk and emotional distress (ie, depression, anxiety, and stress). The invitation letter to participate in this survey was widely sent out to general Weibo users by various promotion activities. For a Weibo user to be eligible for the study, she or he had to be 18 years or older (by self-report). A 30 Renminbi incentive for each complete survey was provided to boost the respond rate. With the respondents' consent, their Weibo posts that were posted in the public domain during the 12 months before the survey were downloaded by calling Weibo API. The survey fulfilled the *Checklist* for Reporting Results of Internet E-Surveys (CHERRIES) checklist and details of the procedure have been reported in previous publications [22,32]. In addition, when multiple survey feedback were submitted from the same Internet protocol addresses, only

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the first submission was used to avoid duplicate participation. In contrast to a previous study [32], this study excluded those who posted nothing throughout the 12 months but not those who posted fewer than 100 posts. Eventually, data provided by 974 respondents remained for further analyses.

The study has obtained ethical approvals from the Human Research Ethical Review Committee at the University of Hong Kong and the Institute Review Board of the Institute of Psychology at the Chinese Academy of Sciences.

The survey measured respondents' suicide probability score, depression, anxiety, stress, and Weibo suicide communication (WSC) as the outcome variables. In addition, the respondents' Weibo posts language features were extracted as independent variables or features for machine learning. The details of how those data were obtained are elaborated in the following subsections.

Suicide Probability

The Chinese version of the SPS was adopted to assess the respondents' suicide probability. The SPS was originally developed in the United States and then translated and validated in China [36,37]. The Cronbach alpha coefficient of the scale in our study was .749.

Depression, Anxiety, and Stress

The Chinese version of the DASS-21 was used to measure the respondents' emotional distress, which has been validated in China and has shown good construct validity and criterion-related validity [7,8,38]. The scale includes 3 subscales to measure depression, anxiety, and stress, respectively. In our study, the Cronbach alpha coefficient was .859 for the depression subscale, .767 for the anxiety subscale, and .821 for the stress subscale.

Weibo Suicide Communication (WSC)

WSC was measured by a single-item question on whether or not the respondent had told others via Weibo in the past 12 months that he or she wanted to kill himself or herself. Given Weibo's multiple functions, WSC can be delivered by publishing Weibo posts, sending private messages to others, or expressing suicidal thoughts in a group chat. For this question, the respondent was not limited to any particular type of Weibo communication.

Language Features

Weibo posts were segmented using the Stanford word segmenter [39] that resulted in 349,374 words and phrases. Thereafter, the SC-LIWC [33] dictionary was applied to count the appearance of each category of words in every respondents' Weibo posts. The SC-LIWC dictionary includes 7450 words that are grouped into 71 categories, including 7 main linguistic or psychological categories and 64 subcategories. In addition, the total number of words or phrases that each respondent published in the 12 months was counted as the 72nd category. Scores of the SC-LIWC categories were counted as percentages of the total number of words.

Data Analysis

Simplified Chinese-Linguistic Inquiry and Word Count (SC-LIWC) Categories as Markers

Five rounds of logistic regression analysis were applied by including the 5 suicide risk factors (SPS, depression, anxiety, stress, and WSC) as dependent variables, respectively. Binary classifications of the 5 risk factors were used in the logistic regression analyses. We followed previous studies to use the total score of 80 as the cut-off for the SPS [6,36,40], 10 for severe depression, 7 for severe anxiety, and 12 for severe stress [7,8,38] to categorize the respondents to "at-risk" and "others" groups, respectively. As for WSC, the "at-risk" group is defined as exhibiting WSC, whereas the "others" group as not exhibiting WSC in the past 12 months. For each suicide risk factor, all 72 linguistic features of SC-LIWC were entered as independent variables to a stepwise regression for feature selection at a significance level of .05.

Automatic Machine Classifiers as Markers

The support vector machine (SVM), a supervised machine learning model, was employed to build algorithms for automatically classifying whether a Weibo user is having suicide risk or emotional distress. SVM is a well-known and highly effective approach yielding high accuracy in affect and sentiment analysis in computer science [41]. The scores of the SC-LIWC categories were included as the features for SVM classification.

SVM classification also requested the outcome variable to be binary, which was consistent with the logistic regression analysis. R version 3.0.0 (The R Project for Statistical Computing) with package "e1071" was used to conduct SVM training [42].

Furthermore, since our previous examination found that exhibiting WSC can be explained by suicidal ideation and negative affectivity [22], we further used the WSC variable as a filter. Specifically, we only included those respondents who reported having WSC in the survey and then ran the SVM training solely on those respondents. It was expected that this screening method could further improve the performance of the SVM model. All the classification results were generated with leave-one-out cross validation that was found to be able to provide an almost unbiased estimator of the generalization properties of statistical models [43,44].

Receiver operating characteristic (ROC) curve analysis was operated for analyzing and comparing the diagnostic accuracy of the SVM classifications for the 5 risk factors. The primary outcomes of the study were the area under the ROC curves, sensitivities, and specificities of the SVM classifiers.

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Table 1. Logistic regression on total respondents (N=976).

Dependent variable	SC-LIWC[a] category	Examples in Chinese with English translation[b]	Estimate	Standard error	Odds ratio	*P* value
Suicide probability scale						
	Personal pronoun	你 (you [as singular])、她们 (they [as females])	0.17	0.05	1.18	.001
	Verb	分享 (share)、开车 (drive)、听 (listen)	−0.24	0.06	0.78	<.001
	Prepend[b]	之中 (among)、以上 (above)、为止 (until)	0.40	0.16	1.49	.02
	Multifunction[c]	的 (of or target or possessive or adjectival suffix)、有 (have or own or possess or exist)、是 (yes or indeed or right or to be or demonstrative pronoun or this or that)	0.12	0.06	1.12	.04
	Total length (every 1000 words)		0.007	0.003	1.007	.008
Weibo suicide communication						
	Personal pronoun	他 (he)、大家 (all)、你们 (you [as plural])	0.14	0.05	1.15	.004
	Third-person plural	她们 (they [as females])、他们 (they [as males])	−3.88	1.95	0.02	.047
	Work	工厂 (factory)、面试 (interview)、薪水 (salary)	−0.34	0.13	0.71	.008
Depression						
	Second-person plural[b]	你们 (you [as plural])、汝等 (you [as plural])	2.12	0.82	8.36	.01
	Work-related	工厂 (factory)、面试 (interview)、薪水 (salary)	−0.58	0.20	0.56	.005
	Achieve-related	擅长 (good at)、尽责 (responsible)、高手 (master)	0.52	0.18	1.68	.003
Anxiety						
	Work-related	工厂 (factory)、面试 (interview)、薪水 (salary)	−0.26	0.11	0.77	.02
Stress						
	Third-person plural	她们 (they [as females])、他们 (they [as males])	3.72	1.81	41.33	.04
	Second-person plural[b]	你们 (you [as plural])、汝等 (you [as plural])	2.40	0.85	11.00	.005
	Health-related	失眠 (insomnia)、医生 (doctor)、运动 (exercise)	0.86	0.30	2.36	.004
	Death-related	亡故 (die)、自杀(suicide)、遗嘱 (will)	0.96	0.38	2.60	.01

[a]SC-LIWC: Simplified Chinese-Linguistic Inquiry and Word Count.

[b]The translations were adopted from ZDIC [45].

[c]The category only applies to Chinese but not English.

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Results

SC-LIWC Categories as Markers

Table 1 presents the SC-LIWC categories that showed independent effects on differentiating those at-risk ones from the other respondents in the final regression model after stepwise selection. *P*<.05 was adopted as the cut-off for statistical significance. For example, as shown in Table 1, a 1% increase in usage of any pronoun would increase the risk of having high level of SPS by 18% (odds ratio, OR=1.18, *P*=.001). By contrast, more frequent use of verb was associated with lower risk (OR=0.78, *P*<.001). In short, Weibo users with high suicide probability were marked by a higher usage of pronoun, prepend and multifunction words, a lower usage of verb, and a greater total word count. The markers of the other 4 risk factors showed more commonalities. For example, second-person plural was positively associated with severe depression and stress, whereas work-related words were negatively associated with WSC, severe depression, and anxiety. Meanwhile, some special characteristics were associated with the different risk factors. Third-person plural was found to be negatively associated with WSC but positively with severe stress. Achievement-related words were positively associated with depression, whereas health- and death-related words were positively associated with stress.

Automatic Machine Classifiers as Markers

Table 2 demonstrates the AUCs, sensitivities, and specificities of the SVM classifiers for whether a Weibo user was at one of the five types of risk. There were no significant AUCs for the SVM classifiers of the total respondents for the 5 risk factors. However, when we filtered out those non-WSC respondents, SVM classification significantly identified those with high suicide probability or severe anxiety. The classification for severe stress was marginally significant, whereas the one for severe depression was still not significant. The performance characteristics of the 3 significant and marginally significant SVM classifiers are shown in Figure 1 as summarized by ROC curves.

Table 2. Receiver operating characteristic (ROC) curve analyses on supportive vector machine (SVM) classifiers of Weibo users' suicide probability and emotional distress.

Outcome Variables	n (%)	AUC[a] (95% CI)	*P* value	Sensitivity[b] (%)	Specificity (%)
For all respondents (N=976)					
Had Weibo suicide communication	117 (12)	0.56 (0.50-0.61)	.06	61	49
High suicide risk (SPS≥80)	190 (19)	0.48 (0.44-0.53)	.43	64	32
Severe depression (DASS[c]-Depression score>10)	49 (5)	0.47 (0.38-0.55)	.41	63	33
Severe anxiety (DASS-Anxiety score>7)	140 (14)	0.45 (0.40-0.50)	.06	58	32
Severe stress (DASS - Stress score > 12)	45 (5)	0.47 (0.39-0.56)	.52	64	33
For respondents who had Weibo suicide communication (N=117)					
High suicide risk (SPS[d]≥80)	51 (44)	0.61 (0.51-0.72)	.04	65	58
Severe depression (DASS-Depression score>10)	23 (20)	0.57 (0.42-0.72)	.31	65	50
Severe anxiety (DASS-Anxiety score>7)	43 (37)	0.75 (0.65-0.84)	<.001	70	66
Severe stress (DASS-Stress score>12)	20 (17)	0.64 (0.52-0.76)	.05	65	57

[a]AUC: area under the curve.

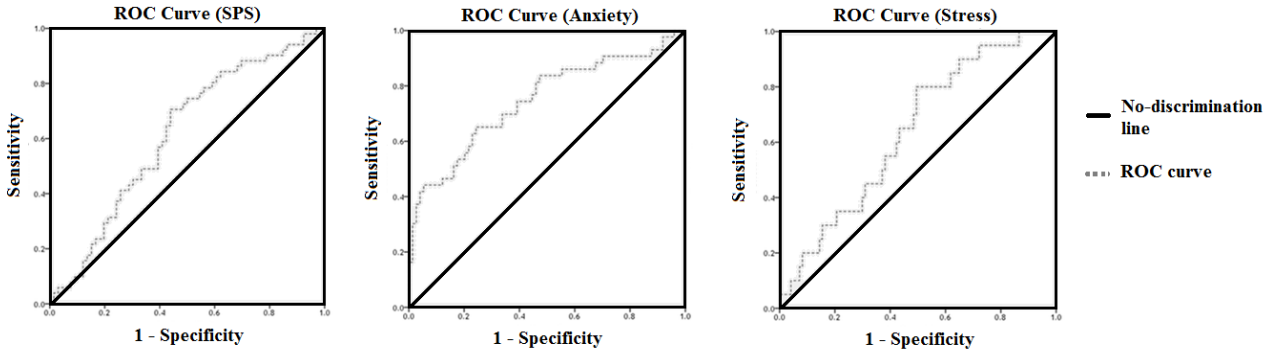
[b]Sensitivity and specificity at the optimal cut-off were reported.

[c]DASS: Depression Anxiety Stress Scales.

[d]SPS: Suicide Probability Scale.

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Figure 1. Receiver operating characteristic (ROC) curves of the supportive vector machine (SVM) classification for high suicide risk, severe anxiety, and stress among participants who had Weibo suicide communication.



Discussion

Principal Findings

The study demonstrates the utility of natural language processing (NLP) methods to assess suicide risk and emotional distress in Chinese social media. Significant associations between certain SC-LIWC categories and suicide risk or emotional distress were identified. In addition, automatic machine classifiers achieved satisfying accuracy when classifying suicide probability and anxiety level among those who had expressed suicidal thoughts to others via Weibo. However, the classifiers' performance on classifying depression and stress levels needs to be improved at large. The study sheds light on the potentials and challenges of developing automatic computerized program to assess mental risk based on natural language processing in Chinese. Although the study design is data-driven rather than hypothesis-driven, we will further discuss some key results by relating them to existing theories and previous research findings.

SC-LIWC Categories as Markers

It is noteworthy that this study did not find a significant association between first person singular pronouns (ie, I, me, and my) and suicide risk or emotional distress, which is inconsistent with a number of previous studies [46-48]. The phenomenon might be related to the fact that first person singular in Chinese conveys an ambiguous meaning, which not merely refers to the addresser as himself or herself but also shows a tendency toward putting him or her in a whole community that the addresser belongs to, thus bringing the addresser a sense of empathy and friendly interpersonal relationship [49]. In this case, the use of first person singular in Chinese not necessarily indicates a self-focus mind and may not be able to mark suicide risk or emotional distress like in English. In addition, it is of note that a recent study examining linguistic characteristics of suicide related Tweets found that the first person pronouns can differentiate strongly-concerned Tweets from safe-to-ignore Tweets [48]. However, they have excluded possibly concerning Tweets from their original dataset that made their results not directly comparable with ours.

In addition, those Chinese social media users with greater levels of depression and anxiety were more likely to write more of second person plural pronouns in their public posts. This suggests that they preferred referring or talking to a group of others directly in their posts, which was potentially inviting a direct communication with others. Suicide prevention professionals may make best of this opportunity to proactively engage with at-risk ones and offer help and support. The findings on third person plural's association with the outcome variables were not consistent. While being negatively associated with WSC, it showed positive association with stress. No previous literature reported similar findings. Nevertheless, the inconsistency suggests that those having severe stress might be different from those having WSC in terms of how they relate themselves with third parties.

Death-related words were associated with severe stress but not suicide probability. This finding is different from previous findings in English that suicidal poems talked about death-related more often [47], as well as a Japanese study that showed tweeting "want to commit suicide" could predict suicidal ideation and attempt [16]. The divergence might be related with the different study design: our study compares people with greater suicide risk to those with lower risk, whereas the previous studies did comparisons either between those suicides deceased and alive nonsuicidal ones, or between those with history of suicide attempts with those without. Furthermore, our findings suggest that the Chinese Weibo users at high suicide probability might express their suicidal thoughts implicitly, rather than using words of death and suicide, in the public domain. By contrast, those with severe stress but not necessarily planning to kill themselves were more likely to disclose their emotional distress by using words relating to death and suicide.

The usage of achievement-related words was positively associated with depression. This is in line with previous studies that found achievement-oriented to be often confounded with depressive symptoms [50-53]. However, a previous machine learning study based on Twitter users in the United States found that the greater usage of achievement-related words in Tweets was associated with being nonsuicidal [24]. Although the US study did not examine depression, the differences between our findings with theirs warrant more studies on the cross-cultural differences regarding the relationship between achievement and suicide or emotional distress.

The use of work-related words was negatively associated with depression, anxiety, and WSC. The phenomenon might be interpreted from two different angles. First, it suggests that those distressed individuals were likely unemployed, which is known

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to be a risk factor for suicide and emotional distress. The alternative interpretation is that those who were more motivated by their work would demonstrate more positive mental states.

Automatic Machine Classifiers

The results of the machine learning analysis demonstrated the challenges of automatically assessing one's suicide probability or emotional distress by NLP. This is related to the fact that prevalence of the outcome variables among the general population is somewhat low. However, by adding a filter of WSC, our machine classifiers' performance has been improved, especially that of suicide probability and anxiety. This is because WSC was found to be highly correlated with the outcome variables [22], which helps to boost the prevalence of the outcome variables among the filtered population. As discussed in the Introduction section, previous studies often artificially boosted the percentage of suicidal or depression cases in their total sample [30,31] or purposely excluded those with medium level of risk from the sample [32]. Different from those studies, the filter of WSC used in this study indicated real behaviors of expressing one's suicidal thoughts via Weibo to others. In real life scenarios, it is feasible to encourage those who have read or received Weibo posts or messages about suicidal thoughts to refer those posts to our algorithms for further assessment.

There is certainly room to further optimize the machine classifiers' sensitivity and specificity. Braithwaite and colleagues' recent study using Twitter data in the United States adopted a similar study design as the presented study but their classifiers outperformed ours in terms of accuracy [24]. Braithwaite and colleagues used different scales to measure suicide risk and different machine learning model to develop their classifiers. It is worthy of our future efforts to find out whether following their approaches can improve the classification performance in the Chinese settings as well. Nonetheless, the performance of the suicide probability classifier and anxiety classifier with filter is promising. It is important that applying the classifiers to review and assessing the posts is much more efficient, convenient, and less costly compared with doing it manually or inviting those Weibo users to conduct questionnaire survey.

Limitations

A few limitations of the study should be noted. The machine classifiers developed by this study need to be further optimized, especially the classifiers of depression and stress. More replicative studies are still needed to examine the transferable validity of our research findings.

The Web-based survey adopted a random sampling approach. However, the respondents may have been self-selected because of their interest in psychological research. Nonetheless, we have compared the basic demographic characteristics (ie, age and gender) of the survey respondents with the general Weibo users and found no significant differences [32].

Last but not the least, the study was conducted in a data-driven manner that led to the results being less structured and some results difficult to interpret. In fact, the study has brought up more questions and new hypotheses for future studies rather than verifying or confirming existing theories.

Implications and Future Research

To apply the language markers and automatic classifiers in real life, we would suggest Weibo users to be more cautious when reading a post or message about suicide. When suspecting someone might be at risk, they can refer the person's Weibo account to our classifiers that will automatically screen that person's public posts and further assess his or her conditions. It will be beneficial if a longitudinal study can be carried out to apply the algorithms developed by this study to screen and assess Weibo posts continuously and provide the results to suicide prevention professionals for double check and follow-up. In turn, the experts' feedback and follow-up results should be fed back to the model's developers for optimization [54].

Some social media platforms, such as Facebook and Instagram, have developed "report" functions to allow users to flag those that are expressing suicidal thoughts. The report will be manually reviewed by in-house reviewers to decide whether the flagged person is indeed at risk. If automatic classifiers such as the ones developed by this study can be integrated into such kind of Web-based report function, it will improve review efficiency and better empower social media platforms and users to contribute to suicide prevention. As social media are rapidly penetrating into our daily life, the opportunities for detecting and engaging distressed individuals via social media should not be missed.

Conclusions

This study demonstrates that natural language in social media can be utilized as markers to differentiate those at-risk individuals from the general population and that the language markers are culturally sensitive. The automatic computer program shows potential for aiding human watchers to assess suicide probability and anxiety by improving the assessment efficiency but not compromising significant accuracy.

Acknowledgments

The study was supported by the HKU Seed Fund for Basic Research (201601159010) and General Research Fund (17628916).

Conflicts of Interest

None declared.

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Abbreviations

AUC: area under the curve
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
DASS-21: Depression Anxiety Stress Scales-21
LIWC: Linguistic Inquiry and Word Count
ROC: receiver operating characteristic
SC-LIWC: Simplified Chinese Linguistic Inquiry and Word Count
SPS: Suicide Probability Scale
SVM: supportive vector machine
WSC: Weibo suicide communication

Edited by G Eysenbach; submitted 09.01.17; peer-reviewed by M Zhang, P Thompson, H Sueki, M Larsen, TR Soron; comments to author 02.03.17; revised version received 07.04.17; accepted 24.04.17; published 10.07.17.

Please cite as:
Cheng Q, Li TMH, Kwok CL, Zhu T, Yip PSF
Assessing Suicide Risk and Emotional Distress in Chinese Social Media: A Text Mining and Machine Learning Study
J Med Internet Res 2017;19(7):e243
URL: http://www.jmir.org/2017/7/e243/
doi:10.2196/jmir.7276
PMID:28694239

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Original Paper

Internet Hospitals in China: Cross-Sectional Survey

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Abstract

Background: The Internet hospital, an innovative approach to providing health care, is rapidly developing in China because it has the potential to provide widely accessible outpatient service delivery via Internet technologies. To date, China's Internet hospitals have not been systematically investigated.

Objective: The aim of this study was to describe the characteristics of China's Internet hospitals, and to assess their health service capacity.

Methods: We searched Baidu, the popular Chinese search engine, to identify Internet hospitals, using search terms such as "Internet hospital," "web hospital," or "cloud hospital." All Internet hospitals in mainland China were eligible for inclusion if they were officially registered. Our search was carried out until March 31, 2017.

Results: We identified 68 Internet hospitals, of which 43 have been put into use and 25 were under construction. Of the 43 established Internet hospitals, 13 (30%) were in the hospital informatization stage, 24 (56%) were in the Web ward stage, and 6 (14%) were in full Internet hospital stage. Patients accessed outpatient service delivery via website (74%, 32/43), app (42%, 18/43), or offline medical consultation facility (37%, 16/43) from the Internet hospital. Furthermore, 25 (58%) of the Internet hospitals asked doctors to deliver health services at a specific Web clinic, whereas 18 (42%) did not. The consulting methods included video chat (60%, 26/43), telephone (19%, 8/43), and graphic message (28%, 12/43); 13 (30%) Internet hospitals cannot be consulted online any more. Only 6 Internet hospitals were included in the coverage of health insurance. The median number of doctors available online was zero (interquartile range [IQR] 0 to 5; max 16,492). The median consultation fee per time was ¥20 (approximately US $2.90, IQR ¥0 to ¥200).

Conclusions: Internet hospitals provide convenient outpatient service delivery. However, many of the Internet hospitals are not yet mature and are faced with various issues such as online doctor scarcity and the unavailability of health insurance coverage. China's Internet hospitals are heading in the right direction to improve provision of health services, but much more remains to be done.

(J Med Internet Res 2017;19(7):e239) doi:10.2196/jmir.7854

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KEYWORDS

eHealth; Internet; health care; medical informatics; China

Introduction

The Internet hospital, a new approach to outpatient health care, is the provision of health services via Internet technologies. Patients can now be at home or go to a local clinic. They can use a website or a smartphone app, and consult with a doctor based in a top-level hospital in a tier-one city [1]. The Internet hospital has become an emerging trend in China in recent years because it has the potential to provide widely accessible outpatient service delivery [1,2]. To date, China's Internet hospitals have not been systematically investigated.

The rapid growth of the Internet and the increasing use of the Internet and mobile devices have contributed to a flourishing Internet medical services industry in China. The market for Chinese Internet medical services was 11.4 billion yuan (US $1.7 billion) in 2014 and 15.7 billion yuan in 2015, with an increase of 37.7% [3]. The population of Internet medical services users was 194.8 million in 2016, accounting for 26.6% of all Internet users [4].

In China, patients often have difficulty gaining access to appropriate health care [5]. In big-city top-flight hospitals, patients often queue overnight just to get a consultation lasting a few minutes [6]. The Internet hospital overcomes geographical obstacles and shatters time barriers, and as a result it has the capacity to address the difficulty of wait times by providing Chinese patients online access to skilled doctors.

The objective of this study was to provide an overview of the Internet hospitals in China as of March, 2017. We therefore conducted a cross-sectional study to describe the characteristics of China's Internet hospitals, and to assess their health service capacity.

Methods

Selection of Internet Hospitals

We searched Baidu, the popular Chinese search engine, to identify Internet hospitals, using search terms such as "Internet hospital," "web hospital," or "cloud hospital." The Internet hospitals mentioned in related news and reports were searched (up until March 31, 2017) using specific Internet hospital names. All Internet hospitals in mainland China were eligible for inclusion if they were officially registered. The inclusion criteria were as follows: simplified Chinese language of the Web page or app, service tailored toward mainland China (excluding Taiwan, Hong Kong, and Macau regions), and signed contracts with the local government or local hospital, officially acquiring the designations of Internet hospitals. We cross-referenced search results against a published list [7] and added any Internet hospitals that met the inclusion criteria. Two investigators (XX and LL) identified the Internet hospitals independently.

Data Collection

After identifying the Internet hospital list, each Internet hospital was reviewed using information from the Internet hospital's website and app (if available). An Excel (Microsoft) spreadsheet was used to record standard information of each Internet hospital. The data collected from each Internet hospital included the construction date; location; investor; consultation characteristics such as service object (provided service to patient or hospital), access method, consulting method (video chat, telephone, and graphic message; graphic message is a message with both text and graph), number of doctors available online (can deliver instant medical service), health insurance coverage, and consultation fee per time; and processes and stages.

We assessed the consultation characteristics of an Internet hospital by the official description, website, and smartphone app. The number of doctors available online for each Internet hospital was calculated as the median online doctors in 2 weeks. The consultation fee per time was the median fee of online doctors in one Internet hospital. If the Internet hospital had more than 100 doctors online simultaneously, we calculated the median of the top 100 doctors on the page.

Internet hospital processes included access to medical service, medical qualification, doctor source, medical service level, and medical service range. Access to medical services included online (defined as access to medical services via website or app) and offline (defined as access to medical services via local medical institutions) access. Medical qualification is an evaluation of whether the Internet hospital had or did not have a licensed medical qualification. Doctor sources included local hospitals, medical unions, district and nationwide. Medical service level was based on information (defined as appointment making, diagnosis or checkup report getting, and payment online); consultation (defined as remote diagnosis, electronic medical prescription, and health care management); and big data (defined as collection, analysis, and use of large amount of health care-related data and sharing data among hospitals).

Internet hospitals were divided into three stages (phases of development), including hospital informatization, Web ward, and full Internet hospital [7]. Those in the hospital informatization stage provide online appointments, getting reports, and paid services, and the doctors are from local hospitals or medical unions. Those in the Web ward stage provide purely online medical services, and the doctors are from local hospitals, medical unions, or regional hospitals. Full Internet hospitals provide an integration of online and offline medical services, and the doctors are from across the nation.

At least two of five investigators (XX, WZ, LL, SF, and FL) extracted the data independently. Any disagreements in abstracted data were resolved by discussion.

Data Management and Analysis

Data management and analysis was performed using Microsoft Excel 2013. Nominal and ordinal data are presented using frequencies and percentages, bar charts, Venn diagrams, and statistical map. Skewed distributed continuous data are presented in percentile, median, and interquartile range.

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Results

Internet Hospital Characteristics

We identified 68 Internet hospitals, of which 43 (63%) have been put into use and 25 (37%) were under construction. From inception until March 2017, 1 (1%), 3 (4%), 5 (7%), 39 (57%), and 20 (29%) Internet hospitals were launched in 2013, 2014, 2015, 2016, and 2017, respectively (Figure 1). The five leading provinces (Ningxia, Guangdong, Guizhou, Zhejiang, and Henan) had 44 Internet hospitals, accounting for 65% of all Internet hospitals in China (Figure 2). Most Internet hospitals were launched by Internet companies (72%, 49/68), followed by traditional hospitals (16%, 11/68), information technology (IT) service providers (6%, 4/68), pharmaceutical companies (3%, 2/68), and the government (3%, 2/68).

Consultation

In terms of the consulting characteristics of 43 established Internet hospitals, 3 (7%) of the Internet hospitals provided services to both patient and hospital, 36 (84%) provided services exclusively to patients, and 4 (9%) provided services exclusively to hospitals. Only 25 (58%) of the Internet hospitals asked doctors to deliver health services at a specific Web clinic, whereas 18 (42%) did not. Patients accessed outpatient service delivery via website (74%, 32/43), app (42%, 18/43), or offline medical consultation facility (37%, 16/43) from the Internet hospital. The consulting methods include video chat (60%, 26/43), telephone (19%, 8/43), and graphic message (28%, 12/43); 13 (30.2%) Internet hospitals cannot be consulted online any more (Figure 3). The median number of doctors available online was zero (interquartile [IQR] 0 to 5; max 16492). The median consultation fee per time was ¥20 (approximately US $2.90, IQR ¥0 to ¥200; Table 1).

Figure 1. Construction date of Internet hospital in China.

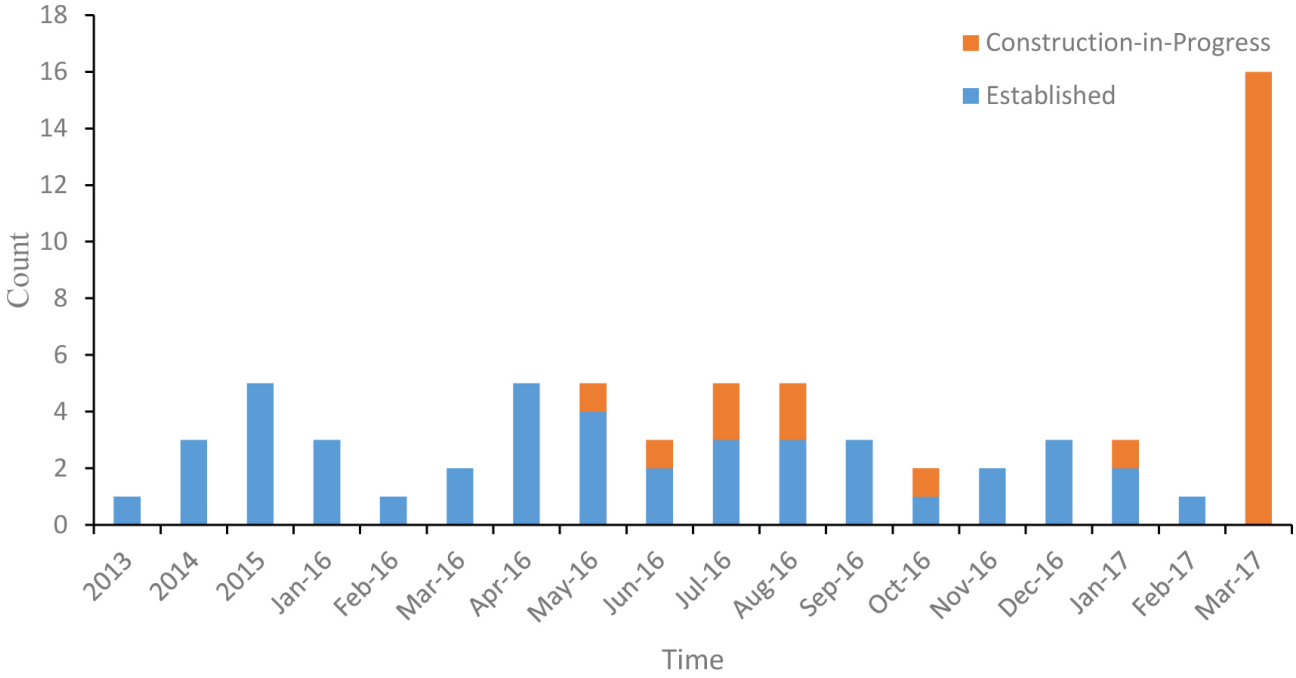


Table 1. Number of doctors and consultation fee of Internet hospitals in China.

Variables	Minimum	P5[a]	P25	P50	P75	P95	Maximum
Number of doctors available online	0	0	0	0	5	224	16492
Consultation fee (yuan/time)	0	0	0	20	200	200	1000

[a]Px: xth percentile.

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Figure 2. Spatial distributions of Internet hospitals in China.

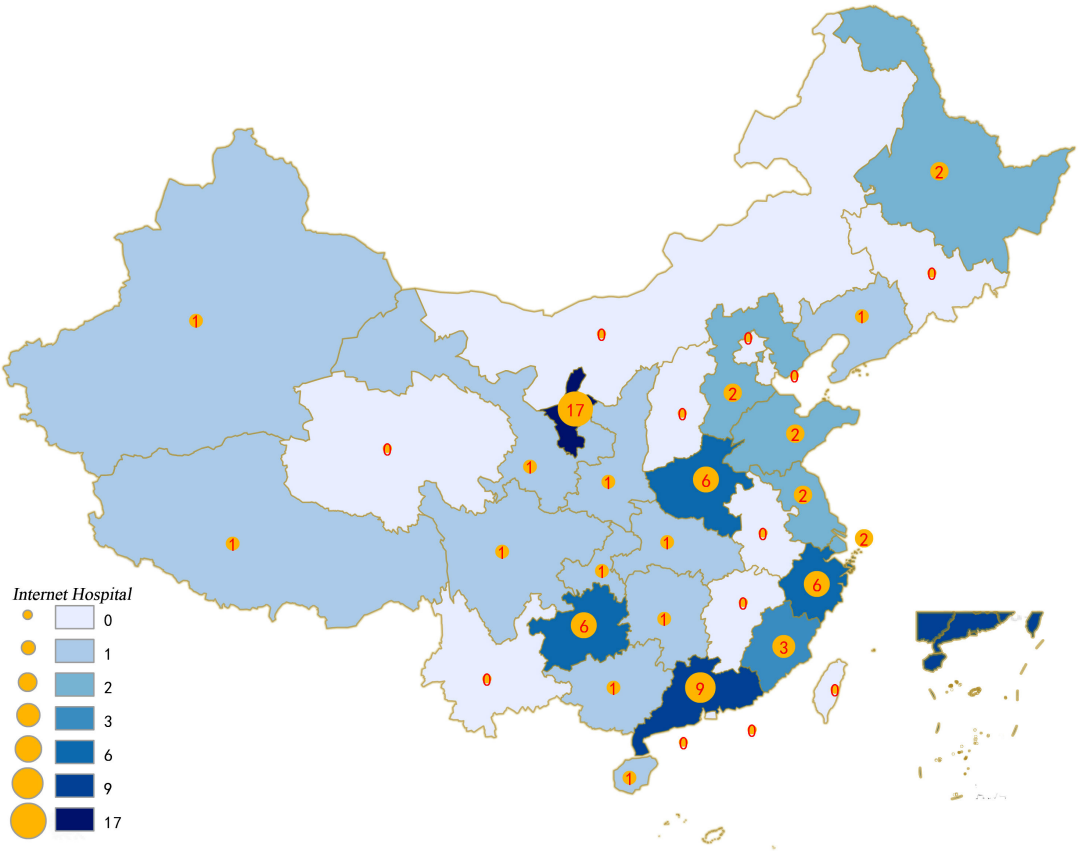
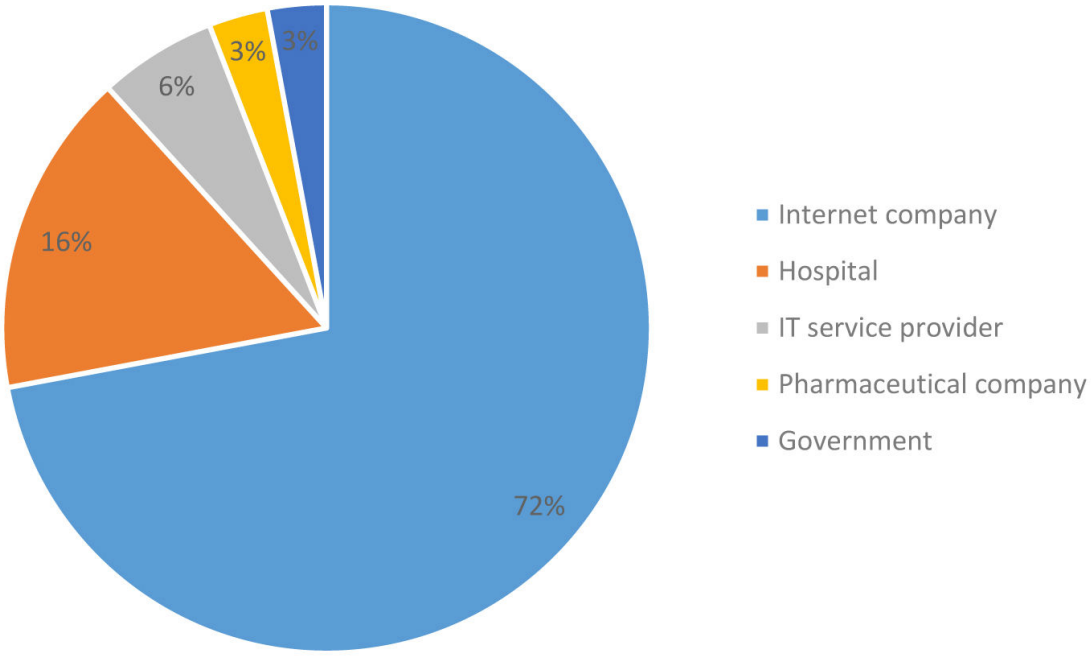


Figure 3. China's Internet hospitals' consultation characteristics.



Processes and Stages

Table 2 shows the processes and stages of the 43 established Internet hospitals. Of these, 13 (30%) were in hospital informatization stage, 24 (56%) were in Web ward stage, and 6 (14%) were in full Internet hospital stage. Additionally, 20 (47%) Internet hospitals could provide access to medical services through both online (website or smartphone app) and offline local medical institutions. Most Internet hospitals (95%, 41/43) had licensed medical qualification. Only 4 (9%) Internet hospitals had doctors from across the nation, 29 (67%) had doctors from local hospitals or medical unions, and 10 (23%) had doctors from regional hospitals. With regard to their medical service level, 5 (12%) Internet hospitals were at

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information-level, meaning, they helped patients register and get their diagnosis or the checkup report online. Furthermore, 34 (79%) Internet hospitals were at consultation-level and provided long-distance diagnosis, electronic medical prescription, and health care management; 4 (9%) Internet hospitals achieved big data-level, which entailed the collection, analysis, use of large amounts of healthcare–related data, and the of sharing of data among hospitals; and 30 (70%) Internet hospitals could distribute drugs to patients' homes through cooperative pharmaceutical companies. Only 6 (14%) Internet hospitals were included in the coverage of health insurance.

Table 2. Processes and stages of Internet hospitals in China (N=43).

Characteristics		n (%)
Stages		
	Hospital informatization	13 (30)
	Web ward	24 (56)
	Full Internet hospital	6 (14)
Access to medical service		
	Online or offline	23 (53)
	Online and offline	20 (47)
Medical qualification		
	No	2 (5)
	Yes	41 (95)
Doctor source		
	Local hospital or medical union	29 (67)
	District	10 (23)
	Nationwide	4 (9)
Medical service level		
	Information	5 (12)
	Consultation	34 (79)
	Big data	4 (9)
Medical service range		
	Health care	13 (30)
	Health care + drug delivery or medical insurance	24 (56)
	Health care + drug delivery + medical insurance	6 (14)

Discussion

Statement of Principal Findings

This cross-sectional study provided an overview of China's Internet hospital in March 2017.

Internet hospitals in China show an emerging trend and are clustered in the city with local policy support. Internet hospitals provide convenient outpatient service delivery through video chat, telephone, and graphic message. However, many of the Internet hospitals are not yet mature and are faced with various issues such as online doctor scarcity and the unavailability of health insurance coverage.

A Surge in 2016

A key insight from our study is that there has been an emerging trend of Internet hospitals in China in recent years. Despite this, the first officially sanctioned Internet hospital in China was founded in October, 2014 [1]; only 9 Internet hospitals were launched by 2015. In 2016, however, a multitude of Internet hospitals were established in China, with approximately 39 newly-built Internet hospitals in the country. Furthermore, 20 Internet hospitals were launched by March 2017.

The emergence of Internet hospitals is partly due to the integration of offline businesses with online commerce, both in line with the current national efforts to promote the classification of treatment policy and the current market ecology [3,8,9]. On the other hand, the traditional medical resources' inability to meet the needs of the public medical services also contributed to the development of Internet hospitals [1,7,10].

Matthew Effect

We found there was a Matthew effect, especially with medical resources concentrated in a few leading Internet hospitals. Our findings show that the leading Internet hospital had about 16,500 doctors available online, but on the other hand, approximately 75% of Internet hospitals had no more than 5 doctors available online. One possibility is that in the leading Internet hospitals,

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which are sponsored by Internet enterprises, the consultation price can be set by the doctors themselves; this is approximately 200 yuan, generally far surpassing the traditional public hospitals' standard rate of 5 to 20 yuan, and thus a major incentive for the doctors [9]. Another possibility is that the leading Internet hospital has a total of 26,000 licensed doctors in more than 2400 hospitals across China, and has branches in 19 cities and provinces including Beijing, Guangdong, Henan, Sichuan, Gansu, Guizhou, and Ningxia [11]. However, most Internet hospitals only have doctors from their own hospital or medical union.

Processes and Stages

Another key finding from our study was that, although Internet hospitals help in improving the quality of medical services, many of the Internet hospitals are not yet mature and are faced with various issues such as online doctor scarcity and not being covered by health insurance. There is a shortage of doctors in China because the demand for medical services in the country has far outstripped supply [12,13]. Furthermore, the shortages are exacerbated by a high turnover of staff caused by heavy workloads, deteriorating doctor-patient relationships, and a resulting increase in work-related stress [12,14,15]. Those systemic issues should be resolved by the government to provide a positive medical environment [13].

The Internet hospital is a medical development model that includes health education, medical information, electronic health records, disease risk assessment, online disease counseling, electronic prescription, telemedicine, and remote treatment and rehabilitation with the Internet as a carrier and technical means [16]. However, most Internet hospitals remain at the hospital informatization stage or Web ward stage. The final stage of an Internet hospital should be a smart hospital, which entails providing big data, artificial intelligence, and precision medicine. China's Internet hospitals are heading in the right direction to improve how health service is effectively provided, but much more remains to be done.

Policy Support

To implement the ambitious strategy that China is now rolling out to improve its health system [17,18], several key challenges need to be met. The challenges are improvement of the quality of care, and enhancement of equity, including addressing disparities among China's diverse regions. The Internet hospital has the potential to resolve part of these challenges [1,5]. The authorities encourage hospitals to offer patients more accessible medical services via the Internet according to a guideline released by the State Council in July 2015 [8].

Internet hospitals are clustered in the city with local policy support, including Internet medical services fees, health insurance, and other issues. Our study found that the five leading provinces had 44 Internet hospitals, accounting for 64.7% of all Internet hospitals in China. China's first Internet hospital base was established on March 19, 2017, in the city of Yinchuan, capital of northwest China's Ningxia Hui Autonomous Region. To make Internet hospitals a reality, Yinchuan city has come out with China's first rules on the management of Internet hospitals and built a complete supervision and management system. Yinchuan city government will go on to link the Internet hospitals with the medical insurance system in 2017. Thus, 17 nationally known Internet medical service institutions signed contracts with the Yinchuan city government to establish Internet hospitals [19]. Other cities or provinces also provide policy support to Internet hospitals [20,21]; this bodes well for the economics of Internet hospitals.

Limitations

A limitation of this study is that we had no related individual doctor or patient data, the use of which would have provided greater detail about health worker characteristics and outpatient service characteristics, allowing us to evaluate the health service capacity, medical resources, and patient satisfaction of Internet hospitals. A further limitation was that this study focused merely on Internet hospitals without traditional hospitals as controls; therefore, we cannot compare the advantages and disadvantages between them. These aspects should be investigated in future studies.

Prospective

China's top-level hospitals have continually invested in upgrading their IT infrastructure, and a lot of Internet companies such as We Doctor, Alibaba, and Tencent are involved in this industry [3,22]. Combined with the surge in use of smartphones, mobile Internet, and big investments in innovation [23], the Internet hospital has a promising future in China.

The Internet system gives patients in rural and remote areas better access to services and helps achieve the integration of online and offline medical services. China's enthusiastic adoption of innovative eHealth systems could encourage the rest of the world to make the Internet an integral part of their medical care. With the Internet increasingly available across the globe, the innovations and experiences of China's Internet hospital will be helpful and influential for any developing country whose medical resources are clustered in their big cities.

Conclusions

The Internet hospital in China is a large and continuously growing market. By March 2017, it was apparent that although the Internet has the potential to overcome some of the challenges due to the rapid changing environment of health care needs, reform, and provision in China, many of the Internet hospitals had not yet matured, and faced various issues, such as online doctor scarcity and the unavailability of health insurance coverage.

Acknowledgments

We thank the assistance from Shui Xu, the funding support from National Key Research and Development Program of China (2016YFC1000102 and 2016YFC1000307), and National Natural Science Foundation of China (81602854).

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Conflicts of Interest

None declared.

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Abbreviations

IT: information technology
IQR: interquartile range

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Edited by G Eysenbach; submitted 12.04.17; peer-reviewed by N Bragazzi, M Larsen; comments to author 24.05.17; accepted 30.05.17; published 04.07.17.

Please cite as:
Xie X, Zhou W, Lin L, Fan S, Lin F, Wang L, Guo T, Ma C, Zhang J, He Y, Chen Y
Internet Hospitals in China: Cross-Sectional Survey
J Med Internet Res 2017;19(7):e239
URL: http://www.jmir.org/2017/7/e239/
doi:10.2196/jmir.7854
PMID:28676472

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Original Paper

Self-Directed Telehealth Parent-Mediated Intervention for Children With Autism Spectrum Disorder: Examination of the Potential Reach and Utilization in Community Settings

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Abstract

Background: There is a significant need for strategies to increase access to evidence-based interventions for children with autism spectrum disorder (ASD). One novel approach is to train parents to use evidence-based interventions for their child with ASD via telehealth. Pilot work examining the efficacy of one such program, ImPACT Online, demonstrated a high rate of parent program engagement, low attrition, and associated gains in parent learning and child social communication.

Objective: The objective of this study was to conduct an open trial of ImPACT Online to better understand its dissemination potential.

Methods: We examined the reach and representativeness of families who registered (n=36) compared to families who were referred (n=139) to the open trial for one referral site. We then compared the demographics of all families who enrolled in the open trial (n=112) to families who enrolled in one of two controlled trials of the same program (n=50). We also examined metrics of program engagement for the open and controlled trials, the relationship between program engagement and changes in parents' intervention knowledge, and program evaluation for the participants in the open trial.

Results: In total, 25.8% (36/139) of the parents who were given information about the program at their child's diagnostic feedback session registered with the program. The parents who enrolled in the open (OT) and controlled trials (CT), respectively, were similar in gender (OT: 84.8% (95/112); CT: 88% (44/50), female), marital status (OT: 80.4% (90/112) ; CT: 69.6% (32/46), married), education (OT: 58.0% (65/112); CT: 54.0% (27/50), college degree or higher), and employment status (OT: 58.0% (65/112); CT: 65.3% (32/49), employed outside the home). The child participants were similar in terms of gender (OT: 83.0% (93/112); CT: 76.0% (38/50), male) and race and ethnicity (OT: 38.4% (43/112); CT: 24.0% (12/50), minority). However, the mean chronological age of the child participants in the open trial group was significantly higher (Mean=60.0 months) than in the controlled trial group (Mean=43.0 months), with t_{160}=5.22, P<.001. Parents in the open trial engaged with the program at a significantly lower rate than the controlled trial, $F_{3,81}$=21.14, P<.001. Program engagement was significantly associated with gains in parent intervention knowledge across both the groups, beta=.41, t=2.43, P=.02. Participants in the open access trial evaluated the program highly, but several barriers were noted.

Conclusions: These data suggest that additional strategies may need to be developed to support families in using telehealth-based parent-mediated intervention in community settings.

(J Med Internet Res 2017;19(7):e248) doi:10.2196/jmir.7484

KEYWORDS

autism; parenting education; telemedicine

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Introduction

Autism spectrum disorder (ASD) is a chronic and pervasive neurodevelopmental disorder characterized by deficits in social communication and the presence of restricted and repetitive behaviors [1]. Individuals with ASD often require intensive and comprehensive intervention across the life span [2]. There has been a dramatic increase in the number of individuals diagnosed with ASD over the last two decades, with prevalence rates reaching 1 in 88 [3]. However, there has not been corresponding growth in the availability of evidence-based services, contributing to high levels of unmet service needs for individuals with ASD and their families [4]. These issues highlight the need for systematic research focused on developing and improving strategies for dissemination and implementation of evidence-based ASD services.

Parent-mediated intervention is one cost-effective and ecologically valid way to increase access to evidence-based ASD intervention. Numerous studies have established that parents can be successfully taught to use evidence-based strategies to improve their child's social-communicative functioning [5]. Additional benefits of parent-mediated intervention include increase in generalization and maintenance of child skill, a reduction in parent stress, and an increase in family leisure time [6,7]. Yet, there continue to be barriers involved with the dissemination of parent-mediated intervention, including a shortage of trained professionals, limited financial resources and transportation, lack of child care, geographic isolation, lengthy waitlists, and extensive time commitments [8]. Thus, it is essential to consider the adaptation of evidence-based, parent-mediated interventions for non-traditional service delivery methods [9]. Telehealth and technology-based applications have the potential to augment or even replace traditional service models to increase access to evidence-based services [10]. Self-directed telehealth programs can provide a cost-effective means for intervention to be accessed from anywhere at any time [10]. They can deliver highly standardized instruction with fidelity, while also supporting individualized learning [11]. The use of self-directed telehealth programs to provide instruction in evidence-based interventions has been explored across health-related disciplines, disorders, and treatment approaches with promising outcomes [12]. Taken together, these data suggest that telehealth applications may serve as a promising alternative service-delivery model to increase the reach of evidence-based ASD practices, including parent-mediated intervention [13].

Although there has been growing interest in using telehealth to deliver parent-mediated intervention for children with ASD, empirical evaluations of such programs are limited. Several recent studies have demonstrated the initial efficacy of evidence-based, parent-mediated autism interventions when delivered by computer or over the internet, with or without therapist assistance [14-17]. One such program, ImPACT Online, is an interactive website that teaches parents to promote their child's social communication within the context of play and daily routines [14,18,19]. The content was modified from Project ImPACT, an evidence-based social communication curriculum for young children with ASD [20]. ImPACT Online can be delivered as a self-directed intervention or with therapist assistance via videoconferencing. A recent pilot randomized controlled efficacy trial comparing the two formats demonstrated positive effects on parent learning and child social communication skills for both groups, although there was an added benefit of therapist assistance on some parent and child outcomes [14,18]. Although engagement with the program website was significantly higher among parents in the therapist-assisted group, parents in the self-directed group engaged with the program at a relatively high rate, with 69% completing the program [19]. There was also a significant positive relationship between program completion and improvements in parent intervention knowledge and fidelity, independent of therapist assistance, suggesting that the use of the self-directed website contributed to parent learning.

Self-directed telehealth interventions do not require a trained professional and can typically be administered at a much reduced cost. Thus, they have a strong dissemination potential [21] and may provide an effective method for increasing access to intervention for underserved families of children with ASD. At the same time, much is unknown regarding the potential impact such interventions may have should they prove efficacious in larger trials. For example, it is currently unclear whether families who participate in controlled trials of telehealth parent-mediated interventions are representative of families who would use these interventions in the community. In addition, little is known about the reach of such programs in the community or the representativeness of the community families who choose to enroll. Research on self-directed telehealth programs for other conditions suggests that they may have a more limited reach than anticipated. For example, only 5% of health plan participants recruited by personal letter enrolled in a treatment trial of a Web-based weight loss program [22]. Further, those who enrolled in a Web-based weight loss program through their workplace were more likely to have higher household incomes, education, and health literacy than those who did not enroll, indicating disparities in access [23].

In addition, it is not clear whether the high rates of program engagement observed in our pilot trial of ImPACT Online would be observed in participants who openly enroll in the program. Attrition rates during open trials of self-directed telehealth interventions are often much higher than those found in controlled trials of the same intervention, in which potential participants are closely screened, monitored, and "pushed" to continue engaging with the program by the research staff [24]. For example, Christensen et al [24] found that less than 1% of individuals who enrolled in an open trial of MoodGym, a self-directed CBT-based telehealth program for depression, completed all five modules, compared with nearly 23% in their controlled trial; this represents a 450-fold increase in attrition among community participants.

Highly efficacious programs that have a limited reach or low quality implementation are not likely to have a significant impact on public health [25]. Therefore, it is important to evaluate these factors, alongside more traditional evaluations of program efficacy, to understand the potential impact that telehealth-based, parent-mediated intervention can have on access to care for underserved families of children with ASD [25]. This

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information will be critical to understanding the likelihood that this type of intervention will be able to reach the families for whom it is designed as well as identifying the required program modifications and supports necessary to facilitate its use and ultimate impact.

This study conducted an open trial of ImPACT Online to better understand the dissemination potential of a self-directed, telehealth-based, parent-mediated intervention for families of children with ASD. Specifically, we examined (1) the reach and representativeness of a subset of families who enrolled in the open trial, (2) the demographics of families who enrolled in the open trial compared to families who enrolled in one of our two controlled trials of the same program, 3) metrics of program engagement for the open and controlled trials, (4) the relationship between program engagement and changes in parents' intervention knowledge, and (5) program evaluation for the open trial.

Methods

Participants

Participants in the open trial group (n=112) were parents of a child with ASD between the ages of 27 and 152 months who self-enrolled through the ImPACT Online website. To be included in the analyses, the participant had to identify as the child's mother, father, or step-parent, live in the United States, be proficient in English, and complete the intake questionnaires. In addition, the child had to score above the cut-off on the Modified Checklist for Autism in Toddlers (M-CHAT; under 36 months) [26] or the Social Communication Questionnaire (SCQ; 36 months or older) [27]. An additional 101 registrants were excluded because they or their child did not meet one or more of these inclusion criteria.

Participants in the controlled trial group (n=50) were parents of a child with ASD between the ages of 19 and 73 months who had enrolled in the pilot (n=27) or full-scale efficacy trial (n=23, recruitment ongoing) of ImPACT Online. To participate, the participant had to identify as the child's mother, father, or step-parent, live within 3 hours of the research lab, and be proficient in English. Inclusion criteria for the child included being between the ages of 18 and 95 months at intake, meeting criteria for ASD on the Autism Diagnostic Observation Schedule-2nd Edition (ADOS-2) [28], and having no known medical cause of ASD. Table 1 presents participant characteristics by group.

Table 1. Participant demographic information.

Characteristics	Group			
	Open trial	Controlled trial	Test statistics	*P* value
Parent characteristics				
Gender: female, n (%)	95 (84.8%)	44 (88.0%)	χ^2_1 (N=162)=0.3	.59
Education level: college degree, n (%)	65 (58.0%)	27 (54.0%)	χ^2_1 (N=162)=0.2	.63
Marital status: married, n (%)	90 (80.4%)	32 (69.6%)	χ^2_1 (N=158)=2.2	.14
Employment status: employed, n (%)	65 (58.0%)	32 (65.3%)	χ^2_1 (N=161)=0.8	.39
Internet literacy, mean (SD)	36.7 (3.5)	37.6 (3.9)	t_{156}=-1.49	.14
Child characteristics				
Gender: male, n (%)	93 (83.0%)	38 (76.0%)	χ^2_1 (N=162)=1.1	.29
Race/Ethnicity: minority, n (%)	43 (38.4%)	12 (24.0%)	χ^2_1 (N=162)=3.2	.07
Chronological age in months, mean (SD)	60.0 (21.1)	43.0 (13.7)	t_{160}=5.22	<.001
Mean intervention in hours / week (SD)	6.9 (9.2)	10.7 (10.1)	t_{97}=-1.95	.05

Study Procedures

Open Trial Group

Information about the open trial was disseminated via flyers given to families by professionals at community organizations serving children with ASD, websites providing information about ASD, and an Internet search. Community organizations who expressed interest were given recruitment materials with a unique site code which participants entered at the time of program registration to track referrals. Recruitment materials provided a link to the ImPACT Online website. The website described the content of the program, system requirements, research requirements, and allowed visitors to view a brief video demonstration of the program. Participants had to indicate their consent to participate in research before registering. After registration, participants were asked to complete several short pre-treatment questionnaires and were then given access to the program. 6 months after registration, participants were sent an email asking them to complete the post-treatment questionnaires. Non-responders were sent a follow-up email one week, and two weeks later, until a total of three emails were sent. Participants received a US $25 gift certificate for the completion of the post-treatment questionnaires. Throughout their participation,

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participants in the open trial received no individual contact with research staff.

Controlled Trial Group

Information about the pilot and subsequent full-scale efficacy trials was disseminated via community providers to families within 3 hours of the research lab. Interested parents were directed to contact the research lab to learn more about the specific study. Consent and intake assessments were conducted in person at the research lab and in the family's home. All participants were provided a computer and high speed internet, if needed.

After intake assessments, pilot study participants were randomly assigned to a self-directed (n=13) or therapist-assisted group (n=14). Participants in the full-scale study were randomly assigned to a self-directed (n=6), therapist-assisted (n=8), or informational control group (n=9). Participants in the self-directed groups for both studies received periodic individual phone and email contact from project staff regarding research-related tasks throughout their participation, but they received no support in learning the intervention. Participants in the therapist-assisted groups for both studies received access to the ImPACT Online website in addition to twice-weekly coaching via videoconferencing to help them learn the intervention. Participants in the informational control group received access to an informational website and monthly support calls. Participants completed post-treatment questionnaires and assessments after roughly 6 months, and again at a 3-month follow-up. Participants received a US $25 gift certificate for the completion of assessments at pre- and post-treatment, and follow-up.

Intervention

ImPACT Online is a secure, password-protected, interactive Web application. The content was adapted from Project ImPACT [20], a naturalistic, developmental behavioral intervention (NDBI) [29] that teaches parents to promote their child's social communication during play and daily routines. The instructional content was presented in 12, self-directed lessons, each of which took approximately 75 minutes to complete. Each lesson contained a narrated slideshow (average length=27.2 minutes), written manual, self-check questions, video-based exercises, homework plan, and reflection questions. Parents were advised to practice the intervention with their child for one week following each lesson. Parents could also access supplemental material outside of the lessons, including a video library that contained longer video examples of the intervention, a moderated forum, and additional program handouts and informational resources. Parents received automated weekly emails that provided tips for implementing the intervention techniques along with a link to the program to encourage program use.

Measures

Program Reach

One community organization, a university-based diagnostic center, tracked the number of referrals made to the program (recruitment flyers distributed during the diagnostic feedback session). The organization also tracked the age of the child in months, the child's gender, and the family's zip code. Zip codes were used to derive a median household income using US Census data for the referral group. This information was then compared with the same data provided by families who enrolled in the program using the referral site's unique access code to calculate the potential reach of the program and the representativeness of the participants.

Participant Demographics

Participants were asked to provide information on their gender, education level, employment status, marital status, and zip code. They were also asked to provide information on their child's gender, age, diagnostic status, the number of hours per week, and the type of intervention their child received.

Internet Fluency

Participants completed a brief, modified version of the Computer-Email-Web Fluency Scale [30] at pre-treatment to assess their level of comfort using the computer and Internet. Items such as (1) how frequently do you conduct a search using an Internet search engine, and (2) how frequently do you send or receive email, were rated on a 5-point scale from never (1) to daily (5). Total scores on the measure could range from 8 to 42, with higher scores indicative of greater comfort with using the Internet.

Program Engagement

Program engagement was measured via ImPACT Online's electronic tracking of user behavior. Four metrics of program engagement were calculated: (1) average number of logins to the site, (2) average number of minutes spent on the site across the intervention period, (3) percent of learning activities visited at least once across the 12 lessons (out of a possible 71), and (4) program completion defined by having visited 75% or more of the learning activities. We also examined the percent of participants completing each lesson to determine whether there was a drop-off in program engagement associated with a particular lesson. Completion was defined as having clicked on 75% or more of the learning activities for a lesson at least once.

Parent Intervention Knowledge

Participants completed the ImPACT Knowledge Quiz, a 20-item, multiple-choice quiz, that assesses comprehension of the key elements of ImPACT at intake and approximately 6 months later to measure changes in their intervention knowledge.

Program Evaluation

Participants in the open trial were asked to complete several measures to evaluate their experience with the program and barriers to program engagement 6 months after registering with the site. The Behavioral Intervention Rating Scale (BIRS) is a well-validated measure that asks individuals to endorse items that assess the acceptability of a treatment's procedures and its perceived effectiveness on a 6-point scale, ranging from 1 (highly disagree) to 3 (neutral) to 6 (highly agree) [31]. The BIRS was modified to better reflect the goals of the current intervention (acquisition of social-communication skills). Cronbach alpha for the BIRS was .97. The Website Usability Scale is a 10-item questionnaire developed for this project [19].

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Participants rate the ease of use of the website and the perceived helpfulness of each program component on a 6-point scale, with higher scores indicating greater usability. Cronbach alpha for the website usability scale was .96. The Barriers to Treatment Participation Scale is a 44-item, well-validated measure of common barriers to participation in child outpatient treatment [32] . Questions are answered on a scale of 1 (“Never a problem”) to 5 (“Very often a problem”), with higher scores indicative of a greater number of perceived barriers. Items were modified to reflect potential barriers associated with the use of a self-directed, telehealth-based parent training intervention (as opposed to clinician-led, clinic-based therapy), resulting in the removal of 17 items assessing therapist- and clinic-related barriers, and the addition of 5 items assessing technology-related barriers. The modified scale contained 32 items and had a Cronbach alpha of .87. Participants were also asked to respond to 3 open-ended questions: (1) Please indicate any benefits of this program, (2) Please indicate any limitations of this program, and (3) Please provide any recommendations for improving this program.

Results

The data were examined for normality by inspecting the skewness coefficient. Number of logins and the amount of time spent on the site were both positively skewed; a square root transformation was used to normalize their distributions. Intervention knowledge at post-treatment was negatively skewed; an arcsine transformation was used to normalize intervention knowledge at pre and post-treatment. All other data were normally distributed.

We first examined the reach of ImPACT Online for one referral site by comparing the number of parents who registered for ImPACT Online with the number of parents who were provided a referral from a professional at the time of diagnosis at that site (n=139). A total of 36 parents (25.8%) who were given information about ImPACT Online at the time of their child’s diagnosis registered with the site. Child gender, age, and median household incomes per year were compared for parents who registered (participant sample) and the referral sample. No significant differences were found between the two groups regarding gender distribution (Referral sample: 73.8% male; Participant sample: 71.4% male), χ^2_1 (N = 161) =.1, P=.78, child age in months (Referral sample: mean=41.8, SD=12.5; Participant sample: mean=41.7, SD=11.6), t_{34}=−.03, P=.98, or median income (Referral sample: mean=$48,379, SD=$13,685; Participant sample: mean=$52,528, SD=$16,730), t_{35}=1.49, P=.15).

Next, we compared the demographics of families who enrolled in the open trial (OT; n=112) with the controlled trial studies (CT; n=50), regardless of whether they had completed the 6-month follow-up period or their group assignment in the lab-based trials. As shown in Table 1, parent participants in both groups were primarily female (OT: 84.8% (95/112); CT: 88% (44/50)), married (OT: 80.4% (90/112); CT: 69.6% (32/46)), slightly over half in each group had a college degree or higher (OT: 58.0% (65/112); CT: 54.0% (27/50)), and were employed full or part time (OT: 58.0% (65/112); CT: 65.3% (32/49)). Scores on the CEWFS ranged from 25 to 42, with average scores toward the upper end of the scale for both groups (OT: mean=36.7, SD=3.5; CT: mean=37.6, SD=3.9). Chi-square analyses and independent sample t tests revealed no significant group differences on any of these parent demographic variables.

The majority of child participants in both groups were male (OT: 83.0% (93/112); CT: 76.0% (38/50)), and rates did not significantly differ between groups. The children’s mean chronological age was significantly higher in the open trial (mean=60.0, SD=21.1) than the controlled trial (mean=43.0, SD=13.7), t_{160}=5.22, P<.001, likely due to the age restriction of the controlled trials. Children in the open trial were marginally more likely to be a racial or ethnic minority than the lab-based trials (OT: 38.4% (43/112); CT: 24.0% (12/50)), χ^2_1, (n=162) =3.2, P=.07, which could reflect the general demographics of the recruitment area for the controlled trials.

Participants in both groups reported that their children received a variety of different intervention services (eg, special education, ABA, speech therapy, occupational therapy, play groups), with intensities ranging from 0 to 41 hours per week. However, children in the open trial (mean=6.9, SD=9.2) received marginally fewer hours per week of intervention than children in the controlled trials (mean=10.7, SD=10.1), t_{97}=−1.95, P=.05.

Next, we examined program engagement metrics for the subset of participants in the open trial who had completed the 6-month follow-up period (n=94). A number of participants who enrolled in the open trial did not access the program after completing the pre-treatment assessments. Thus, we only included data from participants who accessed the first lesson (n=68, 61% of sample). In our previous work, therapist assistance was shown to enhance parent engagement in the program [19]. Thus, in order for the data to be comparable across studies, only the participants in the controlled trials who were assigned to the self-directed group and had completed the follow-up were included (n=17).

We examined group differences on the first three metrics of program engagement using MANOVA (Multivariate analysis of variance). There was a significant effect of trial type on program engagement, $F_{3, 81}$=21.14, P<.001; Wilk’s Λ=.53, =.47. As observed in Table 2, the participants in the open trial engaged significantly less with the program on all of these metrics than the controlled trials. In addition, only 12% of participants in the open trial completed the program compared with 88% of participants the controlled trials, which represents a significant group difference, χ^2_1 (N=85)=40.3, P<.001.

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Table 2. Program engagement.

	Group[a]			
	Open trial	Controlled trial (self-directed)	Test statistic	*P* value
Number of logins, mean (SD)	9.9 (8.5)	29.8 (13.3)	$t_{83}=-6.95$[b]	<.001
Amount of time on site, mean (SD)	188.1 (197.1)	701.3 (371.0)	$t_{83}=-7.09$[b]	<.001
% Learning activities completed, mean (SD)	26.3 (27.2)	88.6 (26.0)	$t_{83}=-8.55$	<.001
% Participants completing program	12%	88%	χ^2_1 (N=85)=40.3	<.001

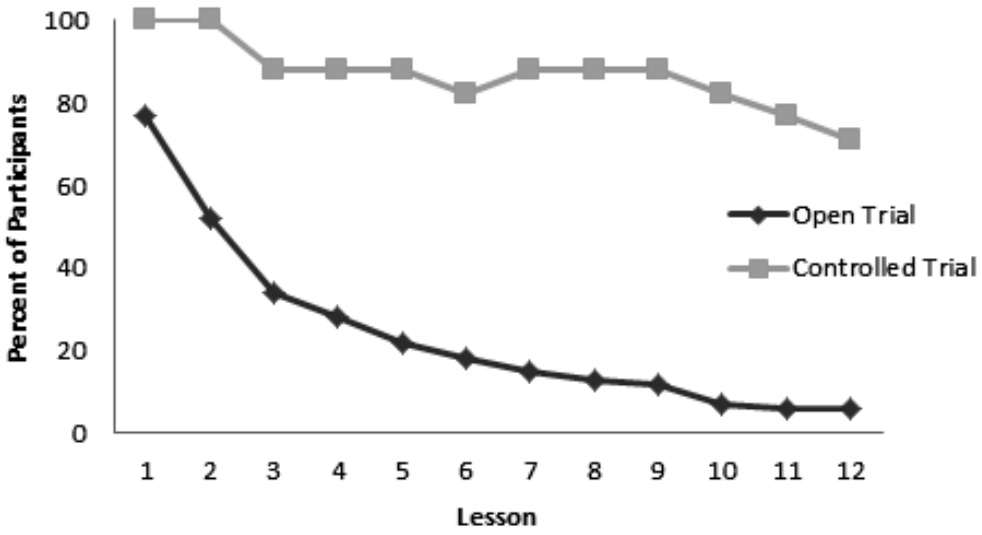
[a]Raw values.

[b]analysis used transformed data.

To better understand the rate of attrition, we examined the percent of participants who completed each lesson for the two groups. As observed in Figure 1, attrition in the open trial group occurred early in the program, with majority of participants discontinuing the program by the second lesson. In contrast, participants in the controlled trials maintained a high rate of engagement across the lessons.

We examined the degree to which program engagement was predictive of gains in parent intervention knowledge. We included those participants in the open trial (n=26, 38%) and the self-directed groups of controlled trials (n=16, 94%) who had completed the post-treatment questionnaire. For this analysis, we used a hierarchical linear regression, with parents' intervention knowledge at the 6-month follow-up as the dependent variable. Parents' pre-treatment intervention knowledge and trial type were entered in the first step. Program engagement, defined as percent of learning activities completed, was entered in the second step. After controlling for pre-treatment intervention knowledge and trial type, program engagement was a significant predictor of post-treatment intervention knowledge, beta=.41, *t*=2.43, *P*=.02, and explained additional variance in post-treatment intervention knowledge (*R2* change=.10, *F*=5.88, *P*=.02). This finding suggests that regardless of the trial type, participants who completed more of the program made greater improvements in their intervention knowledge from pre- to post-treatment.

Figure 1. Percent of participants completing each lesson by group.



Finally, we examined the program evaluation measures for the participants in the open trial (n=26). Participants reported the program as highly acceptability on the BIRS (mean=4.6, SD=1.0) and the website as highly usable (mean=4.9, SD=1.0). Parents also reported low levels of perceived barriers on the modified BTPS (mean=1.9, SD=.5). To understand the most common perceived barriers to using this program better, we examined the means for individual items on the modified BTPS. The three barrier items with the highest means (means ≥2.5) were: (1) "I did not have the time to practice (complete the homework)" (mean=3.0, SD=1.2); (2) "During the course of treatment, I experienced a lot of stress" (mean=2.9, SD=1.4); and (3) "Crises at home made it hard for me to complete the program" (mean=2.8, SD=1.3).

The open-ended responses were analyzed by compiling responses and identifying emergent themes using inductive content analysis. Two authors worked independently to develop

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codes based on the written responses. They then met to discuss initial codes and develop consensus regarding final codes. Any conflicts were discussed until consensus was reached. The most frequent themes identified in response to the program's benefits, limitations, and recommendations are presented in Textbox 1.

Textbox 1. Open-ended response themes.

Program Benefits

- Accessibility of the program
- Ease of learning the intervention
- Acceptability of intervention strategies
- Improvement in child social communication skills

Program Limitations

- Need for therapist support
- Lack of online community support
- Time requirements
- Stress in the home
- Technology barriers

Program Recommendations

- Teleconference support from coach
- Increase online community support
- Simplification of training components
- Make available on other platforms

Discussion

Principal Findings

In this study, we conducted an open trial of the self-directed format of ImPACT Online to understand its dissemination and implementation potential better. Our reach data indicate that only a quarter of parents who were provided information about the program at the time of their child's diagnosis registered with the site. This finding is somewhat sobering given that parents in our pilot study reported that they would have liked to have received information about the program at the time of their child's initial ASD diagnosis [18]. The fact that such a low percentage of families enrolled in the program may suggest that the diagnostic feedback session may not be the optimal time to provide a referral to this type of program. Parents of children with ASD consistently report that the diagnostic process is extremely stressful [33] and, while in retrospect, immediate access to parent-mediated intervention may sound attractive, at the time it may be perceived as too overwhelming. At the same time, the reach of telehealth interventions in general is poorly understood [34] and studies of eHealth interventions for other conditions, such as weight loss, have found much lower reach for their interventions, even among patients at high-risk for negative health outcomes [22]. So perhaps, the enrollment rate that we observed is, in fact, promising; however, without additional research in this area, it is difficult to know.

Our reach data were obtained from a specialty diagnostic clinic that provided a referral to the program at the time of diagnosis. It is unclear what the reach of this program would be in other communities or means of dissemination, such as advertisements, web-links, personal invitation via mail or email, or personal recommendation provided by an intervention provider. Different methods of dissemination may be expected to lead to different levels of enrollment as well as ongoing engagement with the program. Additional research that can examine differences in referral methods and the optimal times to refer parents to such programs would be helpful.

Although the data we were able to collect about families before they enrolled in the open trial were very limited, what we did collect suggested that those families who enrolled in the program were not significantly different from the referral sample in terms of median household income, child gender, or age. Although limited by sample size, this finding provides some indication that the families who enrolled in the open trial were fairly representative of the referral group. In addition, our demographic information suggests that, for the most part, participants who enrolled in our controlled trials were very similar to families who enrolled in the open trial. Although these data are, again, limited due to sample size constraints, they provide some confidence that the data being generated from our ongoing efficacy study may well generalize to community users. At the same time, there were few families with very low socioeconomic status in any of our samples, and thus, participation was not representative of the full range of families who could potentially benefit from this type of intervention. Therefore, future research should focus on increasing enrollment of parents from low socioeconomic status backgrounds into both open and controlled trials of telehealth-based, parent-mediated intervention.

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Our program engagement data suggested much lower rates of engagement among our open trial participants than the participants in our controlled trials. This finding is not surprising given the previous research on telehealth-based interventions for other conditions. Participants in our controlled trials received a significant amount of personal contact with the research team throughout their participation, which may have affected their motivation to engage with the program. Although program engagement was much lower among participants in the open trial than the controlled trial, it was still higher than many open trials of similar interventions [35-37]. This may suggest a higher level of motivation among parents of children with ASD than individuals who are pursuing health promotion or mental health services for themselves.

It has been proposed that program completion may not be necessary to achieve significant improvements, in part because some individuals who discontinue eHealth interventions do so because they improve [38]. Inspection of the percent of participants completing each lesson suggests that there was an early decline in lesson completion among participants in the open trial. This is particularly problematic given that the first three lessons are focused on background information and the primary intervention content is not presented until lesson four, at which point fewer than 30% of participants completed the lesson. Thus, it appears unlikely that early attrition is due to improvements in this case. Although our data were limited due to a high percent of participants lost to follow-up (dropout attrition), we also found an association between the amount of program content accessed and increase in parent intervention knowledge, suggesting that that program engagement is an important factor in learning. This finding suggests a possible need to retool the content of the program to introduce intervention content earlier or for the use of additional strategies, particularly during the first few lessons, to boost engagement in real world contexts.

Our program evaluation data for the open trial participants suggested high levels of the treatment acceptability and website usability and low levels of perceived barriers. Our qualitative data complemented these findings, suggesting that parents identified a number of benefits of the program, including the accessibility of the program, and the ease of learning the intervention, the acceptability of the intervention strategies, and improvement in their child's social communication skills. These themes have also been identified among participants in our controlled trial [18].

The most consistently reported barriers on the modified BTPS and open-ended questions were related to competing stressors at home and difficulty finding time to complete the program. These barriers might be expected to adversely impact parent participation in all forms child treatment, not just self-directed, telehealth-based parent-mediated intervention [39]. Our qualitative data also indicated a need for therapist support, simplification of some of the training components, and a desire for greater online community support. Therapist support was also identified as important theme among participants in our controlled trial [18]. However, simplification of training components and increased online community support were not reported in our controlled trial, suggesting that these factors may need to be considered in more detail, especially as self-directed programs are moved into community use.

Future Research

The literature suggests a number of program design factors that may impact engagement in self-directed telehealth interventions, such as ImPACT Online [40]. First, the narrated slideshows, which were used to present the intervention content, were 27.2 minutes long, on an average. Guo and colleagues [41] have suggested that videos in an online learning environment should be no longer than 6 minutes. Although participants could stop and resume the videos at any point, breaking up the narrated slideshows may make the videos more engaging or easier to access in shorter increments. Likewise, ImPACT Online includes 12 lessons which are designed to be completed over the course of 3-6 months. This represents a significant time investment. It has been suggested that shorter, simpler interventions are better suited to online delivery than the more complex ones that require hours of online work [42]. Research identifying active ingredients of the ImPACT intervention could inform the development of a "leaner" intervention with fewer components which may be less prone to attrition.

Second, the Pew Research Center states that people are increasingly turning to their mobile phones to access the Internet [43]. Thus, making the website mobile compliant or developing an app component for those with a mobile phone would allow parents to access the lessons in any location. In addition, the use of personalized feedback or tailored messaging could be used to provide more individualized messages and content to the parent [44]. Another possibility would be to add some elements of gamification. Gamification uses elements of games in non-game contexts to support and engage individuals to complete tasks within a learning environment. These typically have been found to improve user engagement, learning, and ease of use [45]. There are myriad ways that this can be achieved, including giving points for users interacting with the content, achieving badges, and being included on a team. Past research has suggested that gamification can increase knowledge in health domains, self-efficacy, and motivation which can improve a myriad of health outcomes [46].

Finally, online communities may help improve peoples' use of health content and interventions [47]. ImPACT Online included a moderated asynchronous forum; however, it was rarely used. It has been suggested that this type of online community may require a minimum threshold of activity to support ongoing site utilization [48]. Indeed, this was a reported limitation of the program. Currently, there are a multitude of online support groups available online, especially for parents of children with special needs [49]. Thus, it may be more practical to utilize currently available platforms. For instance, a closed and secret Facebook group is easier to develop, maintain and engage parents [50]. In addition to the parents being able to provide social support and exchange information, it is another way moderators can redirect parents back into the ImPACT Online website and content.

Future research that can evaluate which strategies are most likely to increase parent engagement in ImPACT Online and similar interventions is needed. In addition, as we did not collect

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data on other aspects of parent learning such as procedural fidelity, parent well-being, or child gains, future research should investigate how this program impacts important parent and child outcomes in real world settings.

Acknowledgments

This project was supported by Idea Development Award #W81XWH-10-1-0586 from the Department of Defense's Autism Research Program, grant #R40MC277040100 from the Maternal and Child Health Bureau of the Health Resources & Services Administration, and a RAIND grant from Michigan State University. We would like to thank the parents and children who partipated in this work.

Conflicts of Interest

None declared.

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Edited by G Eysenbach; submitted 10.02.17; peer-reviewed by B Bie, Y Mejova; comments to author 12.04.17; revised version received 04.05.17; accepted 05.05.17; published 12.07.17.

Please cite as:
Ingersoll B, Shannon K, Berger N, Pickard K, Holtz B
Self-Directed Telehealth Parent-Mediated Intervention for Children With Autism Spectrum Disorder: Examination of the Potential Reach and Utilization in Community Settings
J Med Internet Res 2017;19(7):e248
URL: http://www.jmir.org/2017/7/e248/
doi:10.2196/jmir.7484
PMID:28701294

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Original Paper

Adherence to Web-Based Self-Assessments in Long-Term Direct-to-Patient Research: Two-Year Study of Multiple Sclerosis Patients

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Abstract

Background: Direct-to-patient research via Web-based questionnaires is increasingly being used. Missed data or delayed reporting of data may negatively affect the quality of study results. It is insufficiently known to what degree patients adhere to agreed self-assessment schedule over the long term and whether questionnaires are filled out in a timely manner.

Objective: The objective of this study was to investigate patients' adherence to a self-assessment schedule with low-frequency long questionnaires versus that with a high-frequency short questionnaire.

Methods: In this study, the 36-item MS Impact Profile (MSIP) questionnaire measured (perceived) disabilities and the 54-item MS Quality of Life-54 (MSQoL-54) questionnaire measured health-related quality of life at 6-month intervals. Additionally, the 2-item Medication and Adherence (MA) questionnaire documented medication and adherence to disease-modifying medication every month. An experienced MS nurse assessed the Expanded Disability Status Scale (EDSS) score via phone. For both the self-assessment schedules, we calculated the percentage of patients who had completed all the questionnaires in the first 2 years (completion adherence), the percentage of patients who completed all the questionnaires within set time frames (interval adherence), the relationship between adherence and the EDSS score, and the timing of EDSS assessment.

Results: Of the 331 patients who enrolled themselves, 301 patients completed at least one questionnaire. At month six (M6), M12, M18, and M24, the MSIP was completed by 83.4% (251/301), 71.8% (216/301), 68.1% (205/301), and 58.5% (176/301) of the patients, respectively; the MSQoL-54 by 82.1% (247/301), 71.8% (216/301), 66.8% (201/301), and 57.1% (172/301), respectively; and the MA questionnaire by 80.1% (241/301), 70.4% (212/301), 62.1% (187/301), and 53.5% (161/301), respectively. For the MSIP, 56.8% (171/301) of the patients were 2-year completion adherent; 55.5% (167/301) and 53.5% (161/301) of the patients were completion adherent for the MSQoL-54 and MA questionnaires, respectively. Whereas 85.5% (142/166) of the patients were interval adherent for the MSIP and MSQoL-54, 25.5% (41/161) were interval adherent for the MA questionnaire, with 73.9% (119/161) exceeding the maximum MA monthly interassessment interval. Completion adherence for the monthly short MA questionnaire was higher in patients with moderately high disability (EDSS 5.0-5.5) than for those with no or minimal disability (EDSS 0-2.5) (OR 5.47, 95% CI 1.08-27.69; P=.040). Completion adherence was also higher in patients with EDSS assessment within 6 months after baseline than in those with later assessment (OR 1.810, 95% CI 0.999-3.280; P=.050).

Conclusions: The 2-year completion adherence to Web-based self-assessments did not differ between the low-frequency long questionnaires and a high-frequency short questionnaire, but the interval adherence was substantially higher for the low-frequency

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long questionnaires. Personal contact with a member of the research team regarding a clinically relevant professional-reported outcome early in the study might positively affect the long-term completion adherence in direct-to-patient studies.

(J Med Internet Res 2017;19(7):e249) doi:10.2196/jmir.6729

KEYWORDS

Internet; patients; multiple sclerosis; surveys and questionnaires; self-assessment; patient compliance; quality of life

Introduction

Multiple sclerosis (MS) is a chronic inflammatory demyelinating and degenerative disease of the central nervous system, mainly affecting persons in young adulthood. In about 80% of the patients, the first phase is characterized by a pattern of recurrent episodes of symptoms (relapses), typically followed by complete or partial remissions. This phase of MS is referred to as relapsing remitting MS (RRMS) [1]. Although disease-modifying drugs (DMDs) reduce the frequency and severity of relapses, after about 20 years, most persons with RRMS progress to the secondary progressive (SP) phase, experiencing a steady and unstoppable increase in disability [2,3]. In about 10% to 15% of the patients, symptoms start insidiously and develop slowly without relapses. This form of MS is referred to as primary progressive MS (PPMS) [1]. In both SPMS and PPMS, the continuous increase in disability results mainly from degenerative processes. The multifocal localization of the lesions accounts for the wide variety of symptoms that may arise in the course of the disease; these symptoms often interfere with physical, cognitive, social, or occupational activities. Over the long term, the MS-related disabilities often represent a substantial burden to the patients and their environment.

To enable neurologists to better prognosticate the disease course in individual patients, they need to be informed in more detail about the degree of and variation in long-term disabilities. To obtain this information, patient-reported outcomes (PROs) are increasingly being used in addition to physician-based measures such as the Expanded Disability Status Scale (EDSS). A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else [4]. A PRO that is increasingly being used in clinical research is health-related quality of life (HRQoL), an overall measure of well-being from a patient's perspective that provides a comprehensive measure of health status [5].

The Internet has empowered patients to directly participate in research projects without the involvement of their physician or physician's setting [6,7]. The rapid adoption of the Internet by MS patients, the limited costs of Web-based contacts, and the easy access to large numbers of potential participants are all in favor of a direct-to-patient study design [6,8]. The data that can thus be obtained include PROs on various symptoms, (perceived) disabilities, HRQoL, and treatment, and these data may complement neurologist- or nurse-reported data about diagnosis, disease course, and magnetic resonance imaging [6].

In view of the scarcity of long-term data on (perceived) disabilities and HRQoL in MS patients in the Netherlands, we conceived the prospective, direct-to-patient, interactive, Dutch MS study [9]. The study participants enrolled themselves and agreed to complete two long questionnaires on (perceived) disabilities (36 items) and HRQoL (54 items) at 6-month intervals and a short questionnaire on medication and adherence to DMD treatment (two items) at monthly intervals [9].

One of the crucial aspects of long-term direct-to-patient research is the participants' adherence to the predetermined assessment schedule. A reduction in the amount of data that patients provide may seriously affect the validity and meaningfulness of the study results [10,11]. Conceivably, the same amount of data can be acquired by the infrequent use of long questionnaires or the frequent use of short questionnaires. In fact, different factors might determine the adherence to a self-assessment schedule: a high-frequency short questionnaire could be bothersome to patients due to the frequent interference with their daily life or frequent confrontation with their disabilities and limitations, whereas a low-frequency long questionnaire might be cumbersome because of requiring more time to complete, and thus, potentially increasing MS-related fatigue.

In a previous patient-centered Web-based study involving RRMS patients who were included by their neurologists, we investigated the adherence to monthly Web-based self-assessments after the start of DMD treatment [12]. It was found that 75.5% of the patients completed two short questionnaires at all monthly time points over the course of 1 year, although only 1 in 5 patients adhered to the monthly intervals between consecutive self-assessments [12]. To gain information about the long-term adherence of MS patients to low-frequency completions of long questionnaires versus high-frequency completions of short questionnaires in a direct-to-patient research setting, this study analyzed the 2-year adherence data in the Dutch MS study [9]. Given the study design, participation in this study was not a priori integrated into patient care. As the embedding of research activities in care processes may positively affect patient adherence and adherence may decrease over time, it was hypothesized that at least for the high-frequency short questionnaire, the 2-year completion adherence would be less than 75%.

Methods

Dutch Multiple Sclerosis Study

The Dutch MS study is a prospective, Web-based, direct-to-patient, interactive study of long-term disabilities, perception of disabilities, and HRQoL in patients with MS in the Netherlands. The innovative study design is characterized by Web-based patient-driven enrollment, Web-based data acquisition, the use of PROs, and the use of personal study data by patients and authorized health care professionals for self-assessment and assessment, self-monitoring and monitoring,

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or multidisciplinary care. The objectives of the study, design, target population, recruitment, ethical aspects, data acquisition, technical aspects, outcome measures, assessment schedule, organization, and funding have been described in detail elsewhere [9].

Patients were informed about the study via websites of three patient organizations and of the MS4 Research Institute [13]. By regular mail, neurologists and MS nurses were sent an informative letter with patient brochures, which they were asked to hand out to their patients. The brochure was also sent to the patrons of the National MS Foundation, the Netherlands, as an attachment to the foundation's quarterly journal and related mailings. In the journal, study information was presented by the principal investigator (PJ). Information about the study was published twice in health specials of large national and regional Dutch newspapers. The protocol was submitted to the Ethics Committee *Medisch Ethische Toetsing Onderzoek Patiënten en Proefpersonen* in Tilburg, the Netherlands (nr M379). The committee concluded that a review was not indicated, as the study did not qualify for being tested according to the Dutch Medical Research Involving Human Subjects Act [14,15]. The study is being conducted in agreement with the Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects version 2013; 64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013) [16], and the Dutch Medical Research Involving Human Subjects Act [15].

Technically, the study is a modular application on the Curavista eHealth platform (Curavista bv, Geertruidenberg, the Netherlands), built on an Oracle database with Java-scripting, XML-applets, and AJAX protocols (Oracle Corporation, Redwood City, CA). Data processing is 256-bit encrypted with virtual private network tunneling. The databases and software are physically secured in a dedicated data center in the Netherlands [9]. On the day of the scheduled assessment, patients receive a notification by an email indicating that a questionnaire is available for completion. If the questionnaire is not completed on the scheduled date, reminders are sent after 4 and 7 days.

Disabilities, perceptions of disabilities, and HRQoL are measured every 6 months via the Multiple Sclerosis Impact Profile (MSIP) and the Multiple Sclerosis Quality of Life-54 (MSQoL-54) questionnaires. The MSIP is made available first and the MSQOL-54 one week later. The medication that is being taken and the adherence to DMD treatment are secondary outcomes; these are measured every month via the Medication and Adherence (MA) questionnaire. Every 6 months, the completion of the MA questionnaire coincides with the completion of the MSIP and MSQoL-54. The completion of the combined MSIP and MSQoL-54 takes about 30 to 45 min; completion of the MA questionnaire takes less than 5 min.

Questionnaires

Multiple Sclerosis Impact Profile

The MSIP is a measure of MS-related disabilities and perception of disabilities with established psychometric properties [17,18]. It is based on the International Classification of Functioning, Disability and Health and reflects an objectified view of the prevalence and severity of the impact of MS. The MSIP comprises 36 questions assessing disability (Q1a-Q36a) and perception of disability (Q1b-Q36b) in the following domains: muscle and movement functions; excretion and reproductive functions; activities involving basic movements; activities of daily living; participation in life situations; environmental factors; mental functions; and the symptoms fatigue, pain, speech, and vision [17,18].

Multiple Sclerosis Quality of Life-54

HRQoL is assessed with the MSQoL-54 questionnaire, a psychometrically validated MS-specific multidimensional inventory of patient-centered health status [19]. The MSQoL-54 consists of the 36-item Short Form health survey as a generic core measure to enable comparisons with other patient populations and to the general population, supplemented with 18 additional questions exploring items relevant to MS patients in the areas of health distress (four items), sexual function (four items), satisfaction with sexual function (one item), overall quality of life (two items), cognitive function (four items), energy (one item), pain (one item), and social function (one item) [19].

Medication and Adherence Questionnaire

The MA questionnaire gives an update of medications that are taken, the number of DMD doses missed in the past month, and the date and reason of DMD discontinuation (if applicable).

Disability Assessment by Phone

The EDSS is a widely used disability measure in MS. The EDSS quantifies disability in eight functional systems and allows neurologists and qualified nurses to assign a functional system score in each of these systems [20]. The functional systems are as follows: pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral, and other. The EDSS steps 0.0 to 4.5 refer to MS patients who are fully ambulatory, and EDSS steps 5.0 to 9.5 are defined by the impairment to ambulation. A version of the EDSS that can be used as a structured interview by phone and has been validated for serial assessments in a research setting was used in the Dutch MS study [21,22]. All patients were sent an email in which they were asked if they agreed to a disability assessment via an interview by phone. The emails were sent in order of enrollment. If patients agreed, they were asked to provide information about the days of the week and the time of the day they were available for the assessment by phone. Patients were free regarding when to contact the study team and when to schedule the EDSS interview. In addition to answering the questions of the structured interview during the phone contact, the patients had the opportunity to ask study-related information or discuss study aspects with the assessing researcher, an experienced nurse specialized in MS.

Study Outcomes

The outcomes of this analysis are the adherence to the assessment schedules of the MSIP, MSQoL-54, and MA questionnaires during the first 2 years of the study. Regarding the MSIP and the MSQoL-54, patients were classified as completion adherent for the respective questionnaire if they had

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performed all five scheduled 6-month assessments during the first 2 years. Patients were classified as completion adherent for the MA questionnaire if they had performed all scheduled monthly assessments during the first 2 years. Patients were classified as overall completion adherent if they had performed all scheduled MSIP, MSQoL-54, and MA assessments in this period.

Patients who were completion adherent for the MSIP or MSQoL-54 were classified as interval adherent if they met the following three criteria: (1) median interassessment interval was 180+10 days or less, (2) maximum interassessment interval was 180+20 days or less, and (3) month 24 (M24) completion was within 30 days after the scheduled date. Patients who were completion adherent for the MA questionnaire were classified as interval adherent if (1) the median interassessment interval was 30+3 days or less, (2) the maximum interassessment interval was 30+6 days or less, and (3) the M24 completion was within 30 days after the scheduled date.

Statistical Analysis

The numbers of patients who completed the respective questionnaires at the various time points were calculated, as well as the intervals between two consecutive assessments and between the baseline and M24 assessment. The intervals between two consecutive assessments (days) were presented as mean, standard deviation (SD), median, minimum, maximum, and interquartile range (IQR). Friedman's analysis of variance and the Wilcoxon signed-rank test were used to test whether the intervals for consecutive time points differed between the MSQoL-54, MSIP, and MA questionnaires. The numbers of patients who were completion- or interval adherent are expressed as the percentage of patients who actually started participating in the study by completing at least one of the questionnaires. To compare the completion adherence rates and interval adherence rates of the three questionnaires, Cochran's Q test was performed. To test for significant associations between sex, age, EDSS score, and the timing of EDSS assessment on the one hand, and completion adherence and interval adherence regarding the low-frequency long questionnaires (MSIP, MSQoL-54) and the high-frequency short questionnaire (MA) on the other hand, we used logistic regression analysis. All tests were performed in Statistical Package for the Social Sciences for Windows version 24 (IBM Corporation, Armonk, NY).

The EDSS score was categorized into no to minimal disability (scores 0-2.5), fully ambulatory with moderate disabilities (scores 3.0-3.5), fully ambulatory with little to moderate effect on daily activities (scores 4.0-4.5), ability to walk about 100 to 200 m without aid and fully or severely impaired in performing daily activities (scores 5.0-5.5), ability to walk about 20 to 100 m with aid (scores 6.0-6.5), and severely disabled in walking or fully restricted to bed or chair (scores above 7.0). The timing of EDSS assessment by phone was dichotomized into assessment within 6 months after baseline self-assessment and later than 6 months after baseline self-assessment. A *P* value of .05 was applied for significance.

Results

Patients

A total of 331 patients had enrolled themselves in the study at least 2 years before the date of analysis (July 2015), from March 23, 2011 to March 15, 2012. Of these, 301 (90.94%) had actually started participating in the study by completing at least one questionnaire at baseline, whereas 30 (9.06%) patients had effectively not started participation. Of the 331 patients, 246 (74.32%) were female, 67 (20.24%) were male, and for 18 (5.40%) the sex was unknown. The mean age was 45.59 (SD 11.05) years, the median was 45.13, the minimum was 17.18, the maximum age was 70.57, and the IQR was 37.82-53.92 (N=310). Of the 301 patients who had completed at least one questionnaire at baseline, 234 (77.74%) were female and 67 (22.25%) were male. The mean age was 45.52 (SD 11.08), the median was 44.96, the minimum was 17.18, the maximum was 70.57, and the IQR was 37.82-53.92 (N=298).

Completions

The numbers and percentages of patients who completed the MSIP at baseline, M6, M12, M18, and M24 were 296 (98.3%), 251 (83.4%), 216 (71.8%), 205 (68.1%), and 176 (58.5%), respectively, and the numbers and percentages of patients who completed the MSQoL-54 at baseline, M6, M12, M18, and M24, were 281 (93.4%), 247 (82.1%), 216 (71.8%), 201 (66.8%), and 172 (57.1%), respectively (Figure 1). The numbers and percentages of patients who completed both these questionnaires at baseline, M6, M12, M18, and M24 were 281 (93.4%), 247 (82.1%), 215 (71.4%), 199 (66.1%), and 171 (56.8%), respectively (Figure 1).

Figure 2 shows the numbers of patients who had completed the MA questionnaire at various time points, expressed as the percentage of patients (N=301) who had started study participation. The numbers of patients who had completed the MA questionnaire at baseline, M6, M12, M18, and M24 were 301 (100%), 241 (80.1%), 212 (70.4%), 187 (62.1%), and 161 (53.5%), respectively.

Table 1 shows the numbers and percentages of patients who completed the MA questionnaire at all 25 time points, at 24 to one time point(s), or at no time point, irrespective of these being consecutive assessments.

The numbers and percentages of patients who completed the respective questionnaires at baseline and at M6, M12, M18, and M24 (five time points) at four, three, two, or one time point(s), or at no time point, irrespective of these being consecutive assessments, are shown in Table 2.

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Table 1. Numbers and percentages of patients who completed the short Medication and Adherence questionnaire at all 25 time points, at 24 to one time point(s), or at no time point, irrespective of these being consecutive assessments (N=301).

Number of completions	n (%)
25 (all)	161 (53.5)
24	166 (55.1)
23	171 (56.8)
22	176 (58.5)
21	179 (59.5)
20	183 (60.8)
19	187 (62.1)
18	193 (64.1)
17	194 (64.5)
16	200 (66.4)
15	203 (67.4)
14	208 (69.1)
13	212 (70.4)
12	221 (73.4)
11	223 (74.1)
10	227 (75.4)
9	230 (76.4)
8	233 (77.4)
7	242 (80.4)
6	249 (82.7)
5	256 (85.0)
4	262 (87.0)
3	274 (91.0)
2	279 (92.7)
1	301 (100.0)
0	30

Table 2. Numbers and percentages of patients who completed the Multiple Sclerosis Impact Profile, Multiple Sclerosis Quality of Life-54, and Medication and Adherence questionnaires at baseline and at 6, 12, 18, and 24 months (five time points) at four, three, two, or one time point(s), or at no time point, irrespective of these being consecutive assessments (N=301).

Number of 6-month completions	Multiple Sclerosis Impact Profile	Multiple Sclerosis Quality of Life-54	Medication and Adherence
	n (%)	n (%)	n (%)
5 (all)	171 (56.8)	167 (55.5)	161 (53.5)
4	203 (67.4)	202 (67.1)	187 (62.1)
3	222 (73.8)	219 (72.8)	212 (70.4)
2	252 (83.7)	246 (81.7)	241 (80.1)
1	296 (98.3)	283 (94.0)	301 (100.0)
0	35	48	30

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Figure 1. Percentages of patients who completed the Multiple Sclerosis Impact Profile and Multiple Sclerosis Quality of Life-54 questionnaires at baseline and at 6, 12, 18, and 24 months (N=301).

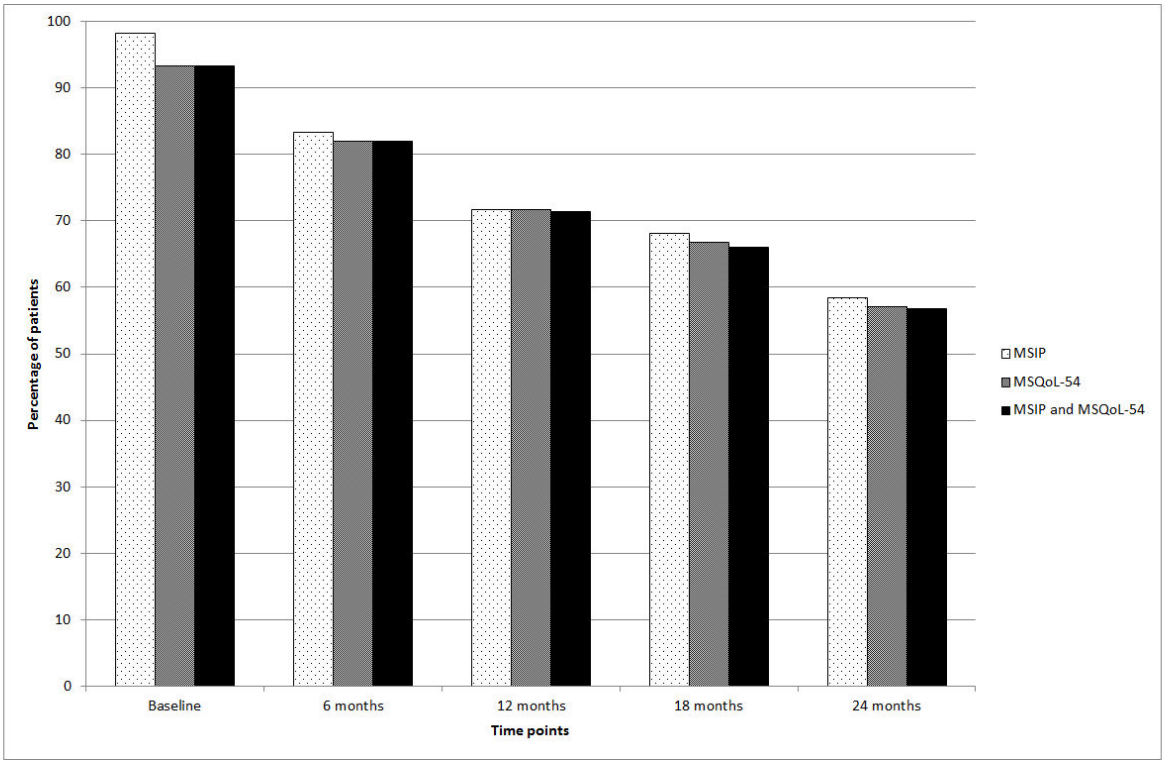
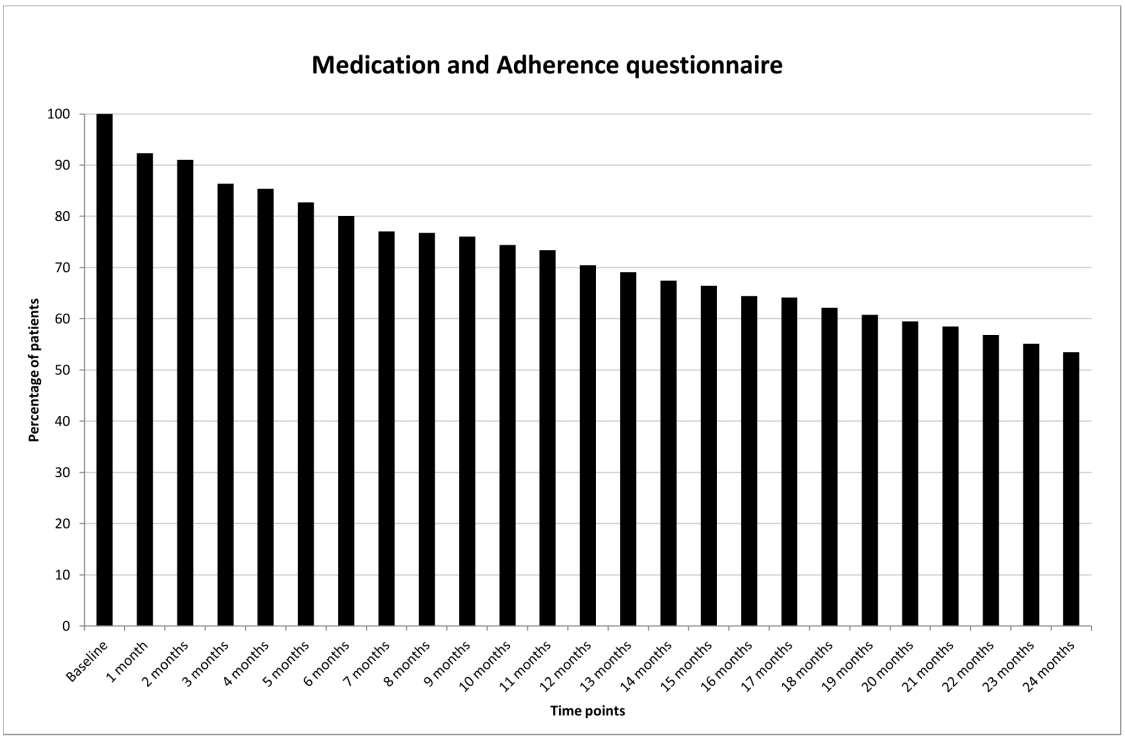


Figure 2. Percentages of patients who completed the Medication and Adherence questionnaire at baseline and at the various monthly time points (N=301).



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Table 3. Time intervals (days) between consecutive assessments.

Questionnaires		M0-M6	M6-M12	M12-M18	M18-M24	M0-M24
Multiple Sclerosis Quality of Life-54						
	Mean (SD[b])	177.82 (28.13)	188.42 (37.20)	180.25 (33.47)	180.75 (27.89)	724.05 (63.39)
	Minimum	−42[a]	99	−41[a]	0	1
	Maximum	266	545	369	257	825
	Median (IQR[c])	182 (180-184)	183 (182-185)	182 (181-184)	183 (181-186)	730 (729-733)
Multiple Sclerosis Impact Profile						
	Mean (SD)	186.39 (35.86)	188.93 (34.69)	179.73 (31.44)	180.15 (28.27)	733.23 (21.13)
	Minimum	114	166	−32[a]	0	547
	Maximum	738	552	374	305	852
	Median (IQR)	183 (182-186)	183 (182.25-187)	182 (179-183.25)	183 (181-185)	731 (730-734)
Medication and Adherence						
	Mean (SD)	188.10 (11.87)	192.26 (49.86)	220.67 (69.19)	186.46 (47.43)	763.75 (66.42)
	Minimum	182	89	150	103	675
	Maximum	285	550	700	370	1093
	Median (IQR)	185 (182-188)	183 (180-188)	197 (189-216)	188 (152-200.5)	749 (718-776)

[a]Negative value because some respondents (MSQoL-54, N=3; MSIP, N=1) did not complete the consecutive questionnaires chronologically.

[b]SD: standard deviation.

[c]IQR: interquartile range.

Intervals

The intervals (days) between two consecutive assessments and between the baseline and M24 assessment (mean, SD, median, minimum, maximum and IQR values) are given in Table 3.

Median values for the intervals between two consecutive 6-month assessments ranged from 182 to183 days for the MSQoL-54 and the MSIP. The median time between baseline and M24 was 730 days for the MSQoL-54 and 731 days for the MSIP. For the MA questionnaire, the median values for interassessment intervals ranged from 30 to 32 days and the M24 assessment was at 749 days (median). The interval between baseline and M6 significantly differed between the three questionnaires (MSIP vs MSQoL-54: z=−5.37, P<.001; MSQoL-54 vs MA: z=−8.73, P<.001; MSIP vs MA: z=−8.05, P<.001), as did the M6-M12 interval between the MSIP and MSQoL-54 (z=−2.42, P=.014) and the M12-M18 intervals between MSQoL-54 and MA (z=−11.70, P<.001) and between MSIP and MA (z=−11.44, P<.001) (see Multimedia Appendix 1). For the M18-M24 interval, no significant differences were found between the three questionnaires. Significant differences in time from baseline to M24 were found between all three questionnaires (MSIP vs MSQoL-54: z=−4.04, P<.001; MSQoL-54 vs MA: z=−6.17, P<.001; MSIP vs MA: z=−5.59, P<.001).

Adherence to Low-Frequency Long Questionnaires

Of the 301 patients who started with the study, 166 (55.1%) completed the MSIP and MSQoL-54 questionnaires at all five time points, and they were therefore completion adherent for the low-frequency long questionnaires. Of these, 159 (95.8%) completed the M24 questionnaires within 30 days of the scheduled date; 163 (98.2%) had a median interassessment interval of 180+10 days or less, and 143 (86.1%) had a maximum interassessment interval of 180+20 days or less. In all, 85.5% (N=142) of the patients who were completion adherent for the low-frequency long questionnaires were interval adherent for these questionnaires.

Adherence to High-Frequency Short Questionnaire

Of the 301 patients who started participation, 161 (53.5%) completed the MA questionnaire at all monthly time points and were thus completion adherent for the high-frequency short questionnaire. Of these, 99 (62%) performed the M24 assessment within 30 days of the scheduled date; 153 (95.0%) had a median interassessment interval of 30+3 days or less; and 42 (26%) had a maximum interassessment interval of 30+6 days or less. In all, 26% (N=41) of the patients who were completion adherent for the high-frequency short questionnaire were interval adherent for this questionnaire.

Overall Adherence

One hundred fifty-two (50.5%) patients were completion adherent for both the low-frequency long questionnaires and the high-frequency short questionnaire, and they were therefore considered overall completion adherent. In addition, 36 (24%) patients who were overall completion adherent were interval adherent for both the low-frequency long questionnaires and the high-frequency short questionnaire and were therefore considered overall interval adherent. In all, 12% of the patients who started with the study were overall completion and interval adherent.

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Comparative Analyses

The completion rates did not differ between the three questionnaires (Cochran's Q test: X^2=5.630; *P*=.063). From the above, it follows that 91.6% (152/166*100) of the patients who were completion adherent for the low-frequency long questionnaires were also completion adherent for the high-frequency short questionnaire. Conversely, 94.4% (152/161*100) of the patients who were completion adherent for the high-frequency short questionnaire were also completion adherent for the low-frequency long questionnaires. Moreover, 25% (36/142*100) of the patients who were interval adherent for the low-frequency long self-assessments were also completion adherent for the high-frequency short self-assessments. Conversely, 88% (36/41*100) of those who were interval adherent for the high-frequency short self-assessments were also completion adherent for the low-frequency long self-assessments.

There were no statistically significant differences between men and women regarding the completion and interval adherence to the low-frequency long questionnaires, the high-frequency short questionnaire, or regarding the overall adherence rates. Likewise, no association was found between age and adherence.

As for the EDSS, patients with an EDSS score of 5.0 or 5.5 were found to have higher odds of being completion adherent for the high-frequency short questionnaire than patients with an EDSS score of 0 to 2.5 (OR 5.47, 95% CI 1.08-27.69, *P*=.040). Moreover, patients who had an EDSS assessment within 6 months after baseline were more likely to be completion adherent for the high-frequency short questionnaire than those whose EDSS score was assessed later (OR 1.810, 95% CI 0.999-3.280, *P*=.050).

Discussion

In recent years, the direct-to-subject approach is being applied increasingly in clinical studies, both in trials organized by clinical research organizations and in investigator-driven academic research [23,24]. This development is paralleled by a growing number of studies that make use of the Internet for the acquisition of patient-reported data. However, it is insufficiently known to what degree patients who enroll themselves in Web-based studies do indeed perform the scheduled assessments and whether they do so on time, especially over the long term. Such knowledge is relevant, as patients who prematurely discontinue their participation or those who provide data only infrequently or delayed may hamper the validity of the study results.

To obtain insight into patients' long-term adherence to a self-assessment schedule in a setting of Web-based direct-to-patient research, we analyzed the numbers of completed questionnaires and the interassessment intervals in the first 2 years of the Dutch MS study regarding two low-frequency long questionnaires (MSIP, MSQoL-54) and one high-frequency short questionnaire (MA).

Principal Findings

First, we found that about 56% of the patients completed the two long questionnaires at all five 6-month time points (MSIP: 56.8%, MSQoL-54: 55.5%); and second, that about 54% of the patients completed the short questionnaire at all 25 monthly time points. Third, we found that over 90% of the patients who completed all questionnaires for one type of assessment also completed all questionnaires for the other type; fourth, that the number of patients who completed the questionnaires decreased gradually over time, and, fifth, that the patients who completed all of the long questionnaires at 6-month intervals in a timely fashion by far outnumbered the patients who performed all of the monthly short self-assessments in time (85.5% vs 26%).

So, interestingly, over a 2-year period no difference was found in completion adherence (completion of all scheduled assessments) between the two less frequent long questionnaires and a more frequent short questionnaire. This was so despite the evident differences in patient burden: the short MA questionnaire had to be completed 5 times more frequently than the long MSIP and MSQoL-54, and the completion time of the latter was 6 to 9 times longer than that of the MA questionnaire. This suggests that completion adherence is influenced not so much by quantitative aspects like frequency of assessments and completion time but other factors. These factors could be the perceived relevance of the questionnaires' content and the degree to which health care providers use the questionnaires' outcomes in their disease management.

It may well be that patients' adherence to the completion of Web-based questionnaires is influenced by the outcomes' relevance for the disease management such as decisions on treatment initiation, continuation, or discontinuation. It is of note that one of the characteristics of the Dutch MS study is that patients may give health care professionals access to the completed questionnaires and the automatically generated scores. Although we suggested the study participants inform their neurologists, MS nurses, and other health care professionals about this option, only 21 patients authorized one or more health care professionals. Accordingly, we think that the low utilization of the interactive aspect of the study may also explain why at 2 years about 45% of the patients failed to complete all questionnaires.

Figure 2 suggests that the number of patients who completed the short monthly MA questionnaire at a given time point decreased on average by 2.4% per month, an exception being the decrease of 7.6% at the first interval. Remarkably, the decrease over time in the number of patients who completed the 6-month long questionnaires fits in with the pattern of decreasing completions of the MA questionnaire. There was another interesting observation: the less frequent long and more frequent short questionnaires showed almost identical completion percentages at M6, M12, M18, and M24. In combination with the fact that more than 90% of the patients who were completion adherent for one type of assessment were also completion adherent for the other type and the quasi-linear decrease in the number of completion adherent patients for both types of assessment, this observation suggests that nonadherent patients completed virtually all scheduled questionnaires up to

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a certain time point, at which they decided not to complete any more questionnaires. From patients' phone calls to the help desk it became clear, rather unexpectedly, that participants were sometimes reluctant to complete the monthly MA questionnaire because no changes in medication occurred over longer periods or because they felt 'spied on' by the frequent assessments. It may therefore be hypothesized that a reluctance to complete one specific questionnaire may have affected not only the completion of that particular questionnaire but that of the other questionnaires as well.

Differences between the two types of assessment were found for interval adherence. Whereas the majority (85.5%) of patients were interval adherent for the low-frequency long questionnaires, only a minority (26%) was so for the high-frequency short questionnaire. The nonadherence in the latter group was mainly because of the fact that approximately 3 out of 4 patients (73.9%) exceeded the maximum interassessment interval of 30+6 days at least once and less so to 4 out of 10 (38.5%) patients performing the M24 assessment later than 30 days after the scheduled date. This difference in interval adherence may relate to the difference in assessment frequencies, as less frequent assessments lower the risk of one assessment exceeding the maximum interassessment interval. The difference may also be due to the predefined criteria for interval adherence: the allowed time window of 6 days for the monthly completions may have been too narrow for patients who, for example, because of an MS relapse or a concomitant disease, were temporarily unable to complete questionnaires. When comparing the intervals for the consecutive time points, no consistent differences were found between the MSQoL-54, MSIP, and MA questionnaires.

It was found that patients with the ability to walk about 100 to 200 m without aid and fully/severely impaired in performing daily activities (EDSS 5.0 or 5.5) were five times more completion adherent for the more frequent short questionnaire than patients with no or minimal disability (EDSS 0 to 2.5). We speculate that this may relate to the former patients being more housebound and thus possibly having more time at their disposal and the latter being more involved in familial, professional, and societal activities with less time for or interest in the regular completion of questionnaires. However, at higher EDSS scores (6.0 and higher), this association was not found, which could relate to the circumstance that cognitive and physical disabilities prevented these patients from performing moderately demanding tasks.

Interestingly, patients who—within 6 months after completion of the first questionnaire—had their disability assessed by an experienced MS nurse via phone were almost twice as likely to be completion adherent for the high-frequency short questionnaire than were those whose EDSS score was assessed later. This observation suggests that an early personal contact between the patient and a member of the research team—with the opportunity to ask questions about the study or about individual health status—may positively influence adherence to an assessment schedule.

Comparison to Prior Work

Whereas a first experience has been reported with direct-to-patient recruitment for enrollment into clinical trials [25], to our knowledge no studies have investigated the adherence to Web-based assessments in long-term direct-to-patient research. In general, early discontinuation of study participation has been associated with various sociodemographic and health-related factors such as being male [26], black [27], having cognitive impairment [28,29], and experiencing difficulties in activities of daily living [28]. We did not find differences in completion or interval adherence between males and females. Our finding that patients with moderately high disability were more completion adherent for the frequent short questionnaire than were patients with no or minimal disability does not contradict a previous report on higher dropout rates in very ill persons. In MS patients, disability mostly results from impaired mobility and not from deficiencies in general health.

In this study, 64.0% of the patients had completed all monthly MA questionnaires 1 year after baseline. In a previous 1-year study in MS patients who started daily glatiramer acetate treatment, we found that 75.5% of the patients completed all monthly short questionnaires on fatigue (five items) and HRQoL (eight items) [12]. This higher percentage could relate to the content of the questionnaires: fatigue is a frequent and often debilitating symptom in MS that was expected to improve during glatiramer acetate treatment, whereas the documentation of medication and missed DMD doses may be less appealing to patients. Moreover, in the glatiramer acetate study, patients were included by their treating neurologists at the time of treatment initiation, whereas in this study, patients enrolled themselves at an arbitrary point in time. Nonetheless, the median monthly interassessment intervals (30-32 days) and the median baseline-M24 interval ([2x365]+19 days) in this study compare favorably with the median interassessment intervals (32-34 days) and the median baseline-M12 interval (365+52 days) in our previous study [12].

Limitations

Our study has several limitations. First, we analyzed data from a study that was not primarily designed to (also) investigate the adherence to assessment schedules. Second, by comparing the adherence to low-frequency long questionnaires with adherence to a high-frequency short questionnaire, we investigated two variables simultaneously, and we therefore cannot identify the relative contribution of a questionnaire's frequency and length to the adherence. Third, we confined ourselves to the analysis of formal aspects of the questionnaires and did not consider their content, so it may well be that irrespective of the assessment frequency, patients experienced questions about (perceived) disabilities (MSIP) as more disturbing and less motivating than questions about DMD adherence. Fourth, although the fairly even distribution of the Dutch MS study participants throughout the Netherlands suggests that the study group is representative of the Dutch MS population, this has not been demonstrated; moreover, relatively healthy information technology users and enthusiasts may be overrepresented in the study group. Fifth, in view of the direct-to-patient study design,

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we did not verify the MS diagnosis with the patients' neurologists or whether the diagnosis was made according to the latest criteria.

As to the instruments we used, it is important to note that the e-versions of the questionnaires have not been validated. There is, however, a vast amount of literature showing that e-versions of questionnaires and scales are equivalent to paper-and-pencil versions and that both can be used interchangeably. This has been demonstrated, among others, for questionnaires about disability [30], symptoms [31,32], HRQoL [33,34], psychopathology [31,35,36], and psychology [37]. Against this background we thought it reasonable to apply e-versions of the MSIP, MSQoL-54, and the MA questionnaire. Moreover, should any discrepancies exist between paper and e-version of these questionnaires, these will be of minor relevance as we consequently used the e-versions throughout the study. As to the EDSS assessment, the scoring via interview by phone has been validated for serial assessments in research settings, but it is not interchangeable with the physician-derived EDSS, especially for the lower range of disability [22].

Finally, our definitions of completion and interval adherence were based on what we considered both realistic from a patient perspective and desirable from the researcher's point of view. To be qualified as completion adherent, we required patients to have completed all the questionnaires. Yet, the completion of five long questionnaires may be easier for patients to realize than the completion of 25 short questionnaires over the same time period. Additionally, from a research perspective, it may be questioned whether the missing of 1 out 5 or even 1 out of 25 assessments substantially hampers the data quality. Moreover, the time windows for interval adherence used by us are debatable and, in general, criteria for interval adherence will depend on the phenomenon under study and the time span covered by a questionnaire.

Conclusions

In analyzing the 2-year adherence to self-assessments in the direct-to-patient Dutch MS study, we found no differences in completion adherence (completion of all scheduled questionnaires) between the two low-frequency long questionnaires versus the high-frequency short questionnaire; however, the interval adherence (completion of questionnaires within predefined time frames) was considerably higher for the low-frequency long questionnaires. Moreover, patients with moderately high disability were more likely to be completion adherent for the high-frequency short questionnaire than patients with no or minimal disability, as were the patients who within 6 months after completion of the first questionnaire had their disability assessed by an experienced MS nurse via phone in comparison with those who had their assessment later. The latter observation may suggest that in Web-based direct-to-patient research, personal contact with a member of the research team or feedback on a clinically relevant, professionally reported outcome early in the study may positively affect the long-term adherence to self-assessments.

Acknowledgments

We are thankful to Marco Heerings, nurse specialized in MS, for performing the EDSS assessments. The Dutch MS study is funded by the National MS Foundation, Rotterdam, the Netherlands; Curavista bv, Geertruidenberg, the Netherlands; and the MS4 Research Institute, Nijmegen, the Netherlands. The role of the National MS Foundation, Rotterdam, the Netherlands, is limited to the funding of the Dutch MS study. Curavista bv, Geertruidenberg and the MS4 Research Institute, Nijmegen, the Netherlands are performing the Dutch MS study.

Authors' Contributions

PJ conceived and designed the Dutch MS study, coordinated the acquisition of the data, interpreted the data, and drafted the manuscript. IK analyzed and interpreted the data and co-drafted the manuscript. EH analyzed and interpreted the data and revised the manuscript critically for important intellectual content. SE contributed to the analysis and interpretation and revised the manuscript critically for important intellectual content. AK and EvN contributed to the design of the Dutch MS study, acquired the data, contributed to the analysis and interpretation, and revised the manuscript critically for important intellectual content. MH contributed to the analysis and interpretation of the data and co-drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

Peter Joseph Jongen has received honoraria from Allergan, Bayer, Merck-Serono, and Teva for contributions to symposia as a speaker or for consultancy activities. Anton Kool and Esther van Noort are owners of Curavista bv.

Multimedia Appendix 1

Comparison of time intervals between the MSQoL-54, MSIP, and MA questionnaires.

[PDF File (Adobe PDF File), 172KB - jmir_v19i7e249_app1.pdf]

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Abbreviations

DMD: disease-modifying drug
EDSS: Expanded Disability Status Scale
HRQoL: health-related quality of life
IQR: interquartile range
MA: medication and adherence
MS: multiple sclerosis
MSIP: Multiple Sclerosis Impact Profile
MSQoL-54: Multiple Sclerosis Quality of Life-54
PPMS: primary progressive multiple sclerosis
PRO: patient-reported outcome
RRMS: relapsing-remitting multiple sclerosis
SPMS: secondary progressive multiple sclerosis
SD: standard deviation

Edited by G Eysenbach; submitted 04.10.16; peer-reviewed by R Haase, L Lavorgna; comments to author 09.01.17; revised version received 10.04.17; accepted 26.05.17; published 21.07.17.

Please cite as:
Jongen PJ, Kremer IE, Hristodorova E, Evers SM, Kool A, van Noort EM, Hiligsmann M
Adherence to Web-Based Self-Assessments in Long-Term Direct-to-Patient Research: Two-Year Study of Multiple Sclerosis Patients
J Med Internet Res 2017;19(7):e249
URL: http://www.jmir.org/2017/7/e249/
doi:10.2196/jmir.6729
PMID:28733272

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Original Paper

Listening to Communities: Mixed-Method Study of the Engagement of Disadvantaged Mothers and Pregnant Women With Digital Health Technologies

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Abstract

Background: US health care providers are increasingly demanding patient engagement with digital health technologies to enroll in care, access personal health information, communicate with providers, and monitor their own health. Such engagement may be difficult for disadvantaged populations who may have limited health literacy, time constraints, or competing priorities.

Objective: We aimed to understand the extent of adoption and use of digital health tools and to identify key perceived psychological motivators of technology use among disadvantaged first-time pregnant women and mothers of young children.

Methods: We recruited women from health organizations serving low-income communities in the Midwest and on the East and West coasts. A total of 92 women participated in 14 focus groups. During each session, we administered worksheets that measured 3 utilization outcomes: the number of recent Web-based health-seeking activities, current use of digital health-management practices (eg, accessing personal health information, communicating with providers, and scheduling appointments), and potential adoption of digital health-management tools among low users or nonusers. Responses to the worksheets and to a pre-focus group survey on demographics, technology access, and motivators of use were examined to create user profiles. Separate regression models identified the motivators (eHealth literacy, internal health orientation, and trust in digital information) associated with these outcomes. Qualitative data were incorporated to illustrate the worksheet responses.

Results: Whereas 97% of the participants reported that they had searched for health information on the Internet in the past year, 42% did not engage in digital health-management practices. Among the low users and nonusers, 49% expressed interest in future adoption of digital health tools. Web-based health information-seeking activities were associated with digital health-management practices (P<.001). When controlling for covariates, eHealth literacy was positively correlated with the number of Web-based health-seeking activities (beta=.03, 95% CI 0.00-0.07). However, an internal health orientation was a much stronger correlate of digital health-management practices (beta=.13, 95% CI 0.02-0.24), whereas trust in digital information increased the odds of potential adoption (vs no adoption) in adjusted models (OR 5.21, 95% CI 0.84-32.53). Demographic characteristics were not important drivers of digital health use and few differences distinguished use among mothers and pregnant women.

Conclusions: Seeking health information on the Internet may be an important gateway toward engaging in digital health-management practices. Notably, different consumer motivators influence digital health tool use. The relative contributions

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of each must be explored to design tools and interventions that enhance competencies for the management of self and child health among disadvantaged mothers and pregnant women. Unless we address disparities in digital health tool use, benefits from their use will accrue predominantly to individuals with the resources and skills to use technology effectively.

(J Med Internet Res 2017;19(7):e240) doi:10.2196/jmir.7736

KEYWORDS

digital divide; health information management; consumer health information; pregnant women; mothers

Introduction

Health care providers are increasingly implementing applications that demand patient engagement with digital technologies to enroll in care, mediate the use of electronic health records, communicate with their providers, and monitor their own care. Evidence shows that health care is more efficient and effective when patients are actively involved in their own treatment [1]. Engaged patients who collaborate with their providers are more likely to be treated with respect, receive information related to their care, and become involved in their health care decisions [2,3]. Furthermore, active information seekers are more likely to engage in preventive health behaviors such as physical activity and healthy dietary behaviors [4].

The digitalization and quantification of health care has proven to be difficult for disadvantaged populations who may have limited health literacy, time resources, and competing priorities [5-7]. Several studies have shown that individuals with a lower socio-economic status and of non-white race or Hispanic ethnicity are less likely than their more affluent, white counterparts to engage in Internet health-seeking behaviors [8,9], although results documenting these disparities have been inconsistent [10,11]. Evidence further demonstrates that Web-based health search activities among adults are more common than other digital health practices that involve personal health-management or caregiving behaviors [8,12]. A recent review showed that patients' interest and ability in using patient portals is strongly influenced by demographic factors (ie, age, ethnicity, and education), health literacy, health status, and caregiver roles [13]. Yet, many applications for personal digital health management have been created with a "design it and they will come" approach that may not be appropriate or meaningful for use by individuals whose health literacy, cultural values, or trust limits their ability or willingness to use digital tools [14]. Whereas the evidence on the use of digital health technology derives mainly from the general population of adults, seniors, and adolescents, or patients with chronic diseases, information on the drivers of use by specific low-income subpopulations such as pregnant women or mothers of young children is sparse [15].

Evidence indicates that first-time pregnant women or those caring for their first infant are particularly likely to use digital health technology as they have a stronger need and desire to acquire pregnancy and child health information and seek social support [16,17]. Some women turn to digital media to compensate for the lack of information or support provided during prenatal visits [18]. Others, who disagree with the information provided to them by health professionals or perceive a lack of time to ask questions, use the Internet to bridge information gaps [19]. The overwhelming amount of Web-based information that requires women to assess what information to trust, the time and confidence required to find appropriate information, the lack of interest in evidence-based information, and feelings that more information would not help make more informed medical decisions are some identified information-seeking barriers among pregnant women [15,20].

It is unclear whether the information needs, skills, and barriers found among pregnant women are similar to those of mothers of young children. A recent study of pregnant women showed that self-efficacy and internal health locus of control contributed to health information-seeking [11], whereas others report that health information-seeking on the Internet remains less trustworthy when compared with doctors, friends, and family [15,21]. Previous studies have mainly focused on the relationship of eHealth literacy and health information-seeking on the Web and far less is known about how different motivational factors contribute to the use of digital tools for health-management purposes or digital tool adoption among pregnant women and mothers of young children [15].

To help design interventions and consumer-centered tools that improve access to and use of health services among low-income first-time pregnant women and mothers of young children, this study aimed to understand the extent of adoption and use of digital health tools and to identify key perceived psychological motivators of technology use.

Methods

This mixed-methods study conducted community engagement listening sessions involving focus groups with first-time pregnant women and mothers of children under the age of five. The study was designed to assess how participants experience and use technology for their health or their children's health and how tools such as websites, apps, wearables, social networks, video chats, and patient portals could be used to better meet their needs in managing health in the future. Each focus group session included three brief worksheets that quantified participants' recent health-related search activities on the Internet, their current use of digital technologies to support their health management, and interest in adopting these technologies in the future, respectively. The focus group guide amplified the information sought in these worksheets, assessed their use preferences, and identified key motivators and barriers to health technology use. Responses to the worksheets and to a pre-focus group survey on sociodemographic characteristics, technology ownership and access, eHealth literacy, and personal agency were used to create a profile of users and to identify determinants of use.

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Sample

Study participants were recruited from community clinics, federally qualified health centers, Women, Infants, and Children (WIC) clinics, and nongovernmental organizations serving low income communities in the San Francisco (SF) Bay Area, New York's South Bronx district, and West Louisville, Kentucky. Active recruitment by clinic providers and staff, email invitations, and flyers posted in the potential sites were used to encourage participation. A few women were also recruited by study participants. Recruitment materials invited women to participate in a focus group to share their opinions about their experience with technology for health and well-being. Eligibility criteria included being 18 years old or older, currently pregnant or a mother of a young child, residing in the study area, and being able to read, write, and speak English. The study was approved by the UC Berkeley Committee for the Protection of Human Subjects (ID: 2016-06-8837).

Procedures

Between June and November 2016, we conducted 14 focus groups, ranging from 2 to 14 participants each, with a total of 92 participants. Focus group sessions, including 2 in the Bronx, 2 in Louisville, and 10 in the SF Bay Area were held at the recruiting sites or a nearby community center; each lasted approximately 2 hours. Sessions were facilitated by one investigator trained in qualitative methods (AB), with the help of two others (HM, SG) who actively greeted participants, distributed the pre-focus group survey and worksheets and took notes. Informed consent was obtained prior to beginning the focus group sessions. Compensation between US $20 and $35, depending on the study site, was offered to the participants upon completion of the focus group. Stipends for childcare and transportation were provided at some sites. All sessions were audiotaped and transcribed.

Quantitative Measures

Three primary outcome variables measured the use of health technologies .

Number of Internet Health-Seeking Activities

This outcome was defined as the number of health-related categories searched on the Internet in the past 12 months, which included information about a specific disease or medical problem, a drug, medical treatment, test or procedure, safety concerns, pregnancy and childbirth, diet and weight, breastfeeding, caregiving, and health insurance issues. This variable was restricted to search users and treated as a continuous variable for modeling purposes and as a categorical three-part variable (<5, 5-8, 9+) for descriptive purposes, based on the median and the 75th percentile of the distribution of total number of search activities (Median=5; 75th%=8).

Current Use of Digital Health-Management Practices

This outcome was assessed by asking participants to identify from a list the practices they used, such as accessing medical information or scheduling appointments through patient portals, communicating with providers through secure email messaging or video chats, managing or tracking their own health or their children's health with apps or wearables, receiving text message appointment or medication reminders or health education, writing Web reviews of medical treatments or providers, or engaging with social networks or patient groups for health-related reasons on the Internet. Users were categorized as high users or adopters if they engaged with digital technology tools in 4 or more health-management practices, which put them in the 75th percentile or above, low users if they engaged in 1 to 3 practices with technology tools, and nonusers if they reported no current use of digital health tools. The total number of digital health-management practices used was treated as a continuous variable for modeling purposes.

Potential Adopters

Potential adopters were those who were highly interested in using digital technology for specific health-management practices in the future, but were currently either nonusers or low users. Interest was gauged by asking the extent to which participants were interested in engaging in different practices, such as receiving text message appointment reminders, by using a 4-point Likert scale (not at all interested, moderately interested, very interested, extremely interested). Participants who stated that they were not at all interested in 2 or more practices were classified as having low interest. Potential adopters were compared with high users and non-adopters.

Independent variables consisted of 3 motivational factors that were amenable to change, namely eHealth literacy, internalized health orientation, and satisfaction with the trust in digital information. eHealth literacy was measured using the eHealth Literacy Scale (eHEALS), an eight-item self-reported measure of perceived eHealth literacy. The tool provides an estimate of an individual's combined knowledge, confidence, and perceived skill at finding, evaluating, and applying electronic health information to health problems [10]. Based on a 5-point Likert-type scale (1=strongly disagree and 5=strongly agree) participants indicate their level of agreement with eHealth statements, with higher scores indicating higher eHealth literacy. Score totals ranged from 8 to 40. The reported Cronbach alpha coefficient of the tool in our study is .88, which is similar to that in other studies: .88 [22] and .89 [10].

Internal health orientation refers to an individual's motivation to engage in healthy attitudes, beliefs, and behaviors [23], and this study was based on an index of three consumer orientations: *"I am responsible for my own health," "I am actively taking care of my health,"* and *"I should be in control of who has access to my health data."* Participants were asked in the pre-focus group survey to indicate their level of agreement with these statements on a 5-point Likert-type scale (1=strongly disagree and 5=strongly agree). Score totals ranged from 3 to 15, with a Cronbach alpha value of .67. A Cronbach alpha value of .65 has been suggested as a minimum acceptable value [24].

Trust in digital information was a categorical measure of whether users of technology were satisfied ("Yes") or were unsure or dissatisfied ("No"), with the trust placed on the information obtained from digital sources such as websites or videos.

Demographic variables, health status, and computer or smartphone use or ownership were included as potential

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covariates. Demographic characteristics included childbearing status, geographic location (Bronx, Louisville, or SF Bay Area), race or ethnicity, marital status, educational level, employment status, and health insurance type. We used self-rated health (whether excellent, very good, good, or fair or poor) as our measure of health.

Data Analysis

Stata version 14.1 (StataCorp LP) was employed to analyze the quantitative data. Univariate analysis was used to characterize the study population and bivariate analyses using chi-square tests for categorical variables and one-way analysis of variances (ANOVAs) for continuous variables were performed to examine the associations between demographic characteristics and motivational factors and the primary outcomes. Given the small sample size (n=92), we consider *P* values ≤.10 as significant. Separate regression models were estimated to determine which variables were related to each of the 3 primary outcomes. Linear regression was used to identify the main correlates of the total number of Web-based health-seeking activities and the total number of digital health-management practices. Logistic regression was used to identify the associations of the motivational factors with potential adoption, no interest in adoption, and high adopter subgroups. The results of the regression models are presented as beta coefficients or odds ratios (ORs) and 95% CIs. Furthermore, by taking the log of each continuous outcome, we estimated the percentage change in the outcome with each unit change in the independent variable by exponentiating the beta coefficient. Our models first estimated the unadjusted risk of each motivational factor (Model 1) and then the adjusted risk of each factor controlling for the two other motivational factors as well as childbearing status, marital status, education, geographic location, and self-rated health (Model 2). Whereas childbearing status was forced in, the remaining demographic and health covariates were selected because they were associated with at least one of the primary outcomes or with at least one of the motivational factors (*P* ≤.10). All models adjusted for the same covariates.

Subsequently, two members of the research team (SG and HM) independently analyzed each focus group transcript to further understand the recurring themes or those that were discussed most or least extensively regarding each of the technology use outcomes identified in the quantitative analysis. To ensure analytic rigor, several verification strategies were applied, including multiple readings of the transcripts, iterative generation of themes, and checking against all focus group transcripts to assess the extent to which they were shared by participants. Illustrative examples of the themes were selected and presented.

Results

Characteristics of Study Participants and Engagement With Digital Health Technologies

More than 1 out of 4 participants (28%) were pregnant for the first time and 72% were mothers of young children (see Multimedia Appendix 1). The majority were between 25 and 34 years old, black or Hispanic, married or cohabitating with their partners, had attained some college education, were either unemployed or not in the labor force, on Medicaid (MediCal in California) and rated their health as good or very good (Multimedia Appendix 1). For the majority, housing and getting or holding a job, rather than health, were their primary reported life concerns (data not shown).

Most had access to technology—84% owned or had access to a computer and 87% owned or used a smartphone and this access was correlated with Web searching (Multimedia Appendix 1). Only 3% of the participants reported that they had not used the Internet to search for health information in the last 12 months. The majority resorted to Google searches, although YouTube, Facebook, and Yahoo were also mentioned. Among Internet users, 25% engaged in a high number of Web-based health search activities, usually with confidence and precision; 38% engaged in 5 to 8 search activities, whereas 37% reported that they had engaged in very few Web-based search activities, applied no particular search strategies, and did not want to delve deeper into information because it can be overwhelming or confusing:

> *I usually go to WebMD and Baby Center. Sometimes the information is useful. When I go to another website, and it say something way different than other websites, I don't know what to choose.*

Use of digital health-management practices was low; approximately 42% and 30% of the study participants reported no current use or low current use, respectively. Many mentioned that they preferred face-to-face contact with providers or with other mothers to seek and share information, advice, and support. Others expressed a strong need to claim their personal space:

> *I don't use social media. I like keeping things to myself and for just the people I know.*

About half of the current nonusers or low current users of digital health-management practices expressed little interest or intention to use patient portals, text reminders, or text messaging to connect with providers:

> *I signed up to use a portal, but I never used it. I forgot about it...I just prefer calling and visiting the center. When it comes to my health, I'd rather come and talk to someone in person and same for my child.*

> *I'm slightly interested in My Chart but I'm not trippin' about it because my daughter's nurse comes to the house...and I trust the nurse because I can see what she is doing.*

However, among the current nonusers or low current users of digital health-management practices, 49% were classified as potential adopters because they expressed high interest in engaging with digital health-management tools in the future. Some potential adopters were already using the patient portal, but infrequently or for one specific purpose, such as scheduling appointments, emailing doctors, or getting text reminders. Several mentioned that they would like to use the portal, but had not been taught how to do so:

> *I'm interested in connecting more with my doctor and my kids' doctor, but who is there to help me do it? If*

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> *we don't have time to sign up and they don't have time to help us, then I won't do it.*

Although potential adopters mentioned that they relied on Internet searches (mainly Google) and apps like Baby Center, they often preferred TV (Dr. Oz), books, and face-to-face encounters with providers:

> *When I was first pregnant, I searched for a lot of apps because I wanted to know everything. But mostly, people just talk about their concerns online...I just call my advice nurse.*

Only 27% were high users of digital health-management practices for their own or their children's health. They mostly used a variety of apps such as What to Expect, Bump, Baby Center, and fitness and ovulation apps:

> *I use pregnancy apps and get updates everyday like how big my baby is this week. There's also a community part that I use sometimes to talk to other [pregnant] women who are experiencing the same things I am. I watched a lot of pregnancies on YouTube...it's neat. I tried to sign up for insurance online, but kept getting road blocked.*

High users of digital health-management practices also tended to interact with the patient portal and liked the multiple functions it offers:

> *I like that I've been able to see exactly how things over time have happened [in the portal].*
>
> *I find the portal useful. I might not be able to make it in person because of transportation issues or I might not have my phone on. It's an alternative to contacting my doctor without having to sit and wait. It's easier to get messages through.*

Participants' number of Internet search activities, current use of digital health-management practices, and intention to use digital health-management tools did not vary significantly by demographic characteristics, with the exception of geographic location (Multimedia Appendix 1). However, a higher proportion of mothers than first-time pregnant women engaged in a higher number of Internet search activities (P=.10) . Educational level was associated with both high and low use of digital technology for health-management practices (P=.05) and number of Internet search activities (P=.10). For instance, proportionately more women with some college education, but fewer with a bachelor's degree or higher qualification, were current high users of digital health-management practices. By contrast, women with incomplete or no high school education were the most likely to not engage in digital health-management practices. Furthermore, a higher proportion of married or cohabiting women reported interest in adopting digital health technology (P=.05).

Motivational Drivers of Digital Health Technology Use

Number of Internet Health-Seeking Activities

The number of Internet health-seeking activities in the past 12 months was positively and significantly associated with the eHEALS score (Table 1). For every unit increase in eHEALS, the number of searches increased by 3% (beta=.03, 95% CI 0.00-0.06). This relationship, although marginally significant, persisted (beta=.03, 95% CI 0.00-0.07), reflecting a 3% change for every unit increase in eHEALS when adjusting for internal health orientation, trust in digital information, and other demographic covariates (ie, childbearing status, marital status, education, geographic location, and self-rated health).

Current Use of Digital Health-Management Practices

Current use of digital health-management practices (no use, low use, or high use) was significantly associated with the number of search activities (P<.001) (data not shown). Nonetheless, it was not significantly associated with eHEALS scores (Table 2). Whereas the total number of digital health-management practices was marginally correlated with eHEALS scores in unadjusted models (beta=.03, 95% CI 0.00-0.07), this correlation was no longer significant after adjusting for the covariates shown in Table 2. In contrast, internal health orientation scores were positively and significantly correlated with the total number of digital health-management practices in both unadjusted (beta=.12, 95% CI 0.02-0.22) and adjusted models (beta=.13, 95% CI 0.02-0.24), such that for every unit increase in scores, the total number of digital health-management practices increased by 14%. Trust in digital information was associated both with the current level of use (P=.05) and the total number of digital health-management practices (beta=.51, 95% CI 0.05-0.96), P=.05, but was no longer significantly correlated with the total number of digital health-management practices when controlling for other covariates.

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Table 1. Associations between number of Internet search activities in the last 12 months and eHealth literacy (eHEALS), internal orientation toward health, and trust in digital information.

Motivational factor	Number of Internet search activities in the last 12 months			Model 1		Model 2[d]	
	<5	5-8	9+	beta	95% CI	beta	95% CI
	Mean or n (%)	Mean or n (%)	Mean or n (%)				
eHEALS score, mean	29.6[a]	32.4[a]	33.2[a]	.03[a]	0.00-0.06	.03[b]	−0.00 to 0.07
Internal orientation toward health score, mean	13.5	13.7	13.7	.01	−0.08 to 0.10	.02	−0.07 to 0.12
Trust in digital information[c], n (%)	23 (69.7)	30 (88.2)	18 (85.7)	.23	−0.18 to 0.64	.16	−0.28 to 0.60

[a]*P*=.05.

[b]*P*=.10.

[c]Reference category in linear regression models: not satisfied or neutral about trust in digital information.

[d]Model 2 adjusts for all variables shown in the table as well as the following covariates: childbearing status, marital status, education, geographic location, and self-rated health.

Table 2. Associations between current use of digital health-management practices and eHEALS, internal orientation toward health, and trust in digital information.

Motivational factor	Current use of digital health-management practices			Model 1		Model 2[d]	
	No use	Low use	High use	beta	95% CI	beta	95% CI
	Mean or n (%)	Mean or n (%)	Mean or n (%)				
eHEALS, mean	30.1	32.4	32.1	.03[a]	−0.00 to 0.07	.01	−0.03 to 0.05
Internal orientation toward health, mean	13.2[a]	13.4[a]	14.2[a]	.12[b]	0.02-0.22	.13[b]	0.02-0.24
Trust in digital information[c], n (%)	23 (70.3)[b]	22 (78.6)[b]	24 (96.0)[b]	.51[b]	0.05-0.96	.31	−0.21 to 0.83

[a]*P*=.10.

[b]*P*=.05.

[c]Reference category in linear regression models: not satisfied or neutral about trust in digital information.

[d]Model 2 adjusts for all variables shown in the table as well as the following covariates: childbearing status, marital status, education, geographic location, and self-rated health.

High Adopters Versus Potential Adopters

High adopters had higher mean internal health orientation scores than potential adopters or those who lacked interest in adopting technologies in the future (14.2 vs 13.1 vs 13.7, respectively), with *P*=.05 (Tables 3 and 4). A higher internal health orientation more than tripled the odds of becoming a high adopter versus a potential adopter in adjusted models (OR 3.13 95% CI 1.26-7.78). Additionally, a higher proportion of high adopters reported having trust in digital information as compared with potential adopters or with those who lacked interest in adopting technologies (96% vs 81% vs 59%, respectively, with *P*=.01). Whereas the odds of high adoption versus potential adoption were not significantly associated with trust in digital information, the odds of potential adoption versus no adoption were 3 times higher among women who trusted the health information found from digital health sources compared with those who did not trust the information. The odds of potential adoption were even higher and marginally significant when adjusting for demographic covariates and the other motivational factors (OR 5.21, 95% CI 0.84-32.53). Potential adopters stated that they were “extremely interested” in accessing a repository for all their health-related information, engaging in secure email messaging with their physicians, getting text messages for appointment reminders, and being able to map local community resources such as housing and childcare (data not shown).

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Table 3. Associations between intention to use digital health-management tools and eHEALS, internal orientation toward health, and trust in digital information for potential adopters versus no or low interest.

Motivational factor	Intention to use digital health-management tools		Potential adopter versus no interest or low interest			
	No interest or low interest	Potential adopter	Model 1		Model 2[e]	
	Mean or n (%)	Mean or n (%)	OR	95% CI	OR	95% CI
eHEALS, mean	30.4	31.5	1.04	0.94-1.15	1.03	0.86-1.23
Internal orientation towards health, mean	13.7[a]	13.1[a]	0.82	0.58-1.16	0.58	0.28-1.22
Trust in digital information[d], n (%)	13 (59.1)[b]	35 (81.4)[b]	3.03[c]	0.96-9.52	5.21[c]	0.84-32.53

[a]*P*=.05.

[b]*P*<.001.

[c]*P*=.10.

[d]Reference category in linear regression models: not satisfied or neutral about trust in digital information.

[e]Model 2 adjusts for all variables shown in the table as well as the following covariates: childbearing status, marital status, education, geographic location, and self-rated health.

Table 4. Associations between intention to use digital health-management tools and eHEALS, internal orientation toward health, and trust in digital information for high interest versus potential adopters.

Motivational factor	Intention to use digital health-management tools		High adopter versus potential adopter			
	Potential adopter	High adopter	Model 1		Model 2[e]	
	Mean or n (%)	Mean or n (%)	OR	95% CI	OR	95% CI
eHEALS, mean	31.5	32.1	1.02	0.93-1.12	0.92	0.75-1.14
Internal orientation towards health, mean	13.1[a]	14.2[a]	1.59[a]	1.07-2.37	3.13[a]	1.26-7.78
Trust in digital information[d], n (%)	35 (81.4)[b]	24 (96.0)[b]	5.49	0.64-46.75	2.55	0.04-164.47

[a]*P*=.05.

[b]*P*<.001.

[c]*P*=.10.

[d]Reference category in linear regression models: not satisfied or neutral about trust in digital information.

[e]Model 2 adjusts for all variables shown in the table as well as the following covariates: childbearing status, marital status, education, geographic location, and self-rated health.

Discussion

Principal Findings

Among the low-income pregnant women and mothers of young children who participated in this study, we found very high access to smartphones and computers which, as expected, was positively correlated with use of the Internet for health information-seeking. Whereas 97% of participants reported that they had searched the Internet for health information in the past year, 25% reported that they had conducted a high number of search activities, despite health concerns not being their highest priority in life. These proportions are much higher as compared with the overall proportion of adult women who reported that they searched for health information on the Internet. A previous study using a nationally representative sample from the National Health Interview Survey found that between 2009 and 2013, 50% of women had used the Internet for health information-seeking [25]. A Pew Research Center study found that in 2013, 62% of Americans had looked for health information on the Internet within the past year [26].

When compared with other Web-based searches, we found a much lower use of the Internet or other digital tools for health-management practices such as for accessing personal health information or scheduling appointments through patient portals, communicating with providers through secure email messaging or video chats, use of health tracking apps or wearables, or engaging with social networks or patient groups on the Internet. Only 27% of participants engaged in 4 or more digital health-management practices, whereas 42% engaged in none. Previous studies by Pew and others have confirmed this disparity in functional use in non-pregnant populations [8,12].

Notably, Internet health information-seeking behaviors were closely associated with digital media use for health management, suggesting that health information-seeking may be an important gateway toward using digital health-management practices. As a somewhat larger percentage of mothers of young children than first-time pregnant women engaged in Internet search activities, pregnant women's Internet use should be considered an important target for intervention.

The number of Internet search activities was positively correlated with eHEALS scores, even after controlling for the

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two other motivational factors, demographic variables, and health status. Digital health literacy has been identified as an important driver of health technology usage in other studies [10,27]. Healthy People 2020 goals strive to increase health literacy skills and recognize the influence of health literacy on health status and the quality of care [28]. However, as the findings of this study show, eHealth literacy was a weaker predictor of the total number of digital health-management practices or of potential adoption of digital health tools, indicating that other motivational factors are more important drivers of these outcomes. Specifically, we found that an internal health orientation was a strong and significant correlate of total number of digital health-management practices, whereas trust in digital information increased the odds of potential adoption (vs no adoption) of digital health technology, after controlling for other variables in our models. Two previous studies have shown that individuals with a high consumer orientation or internal locus of control have a higher motivation to search and comprehend health information [11] and to adopt digital health [29]. A recent systematic review of qualitative studies on consumer engagement with digital health also found that personal agency over one's health was associated with digital tool use [27]. According to Song and colleagues [30], our current health care system values the informed patient who is "responsible, self-aware, vigilant and savvy" and personal agency helps to actualize these norms.

Whereas prior research on digital health use has focused predominantly on the role of eHealth literacy, other motivational factors have received less attention. Future studies using prospective designs with larger samples of first-time pregnant women and mothers of young children could shed further light on the links between internal consumer orientations, trust, and digital engagement. A better understanding of these associations could lead to the development of better tools and higher consumer engagement.

Demographic characteristics were not important drivers of digital health use in this study population. Whereas geographic location was associated with the outcomes in the bivariate analyses, it was not a significant predictor of the outcomes in the multivariate models. A 2015 nationally representative survey of digital health adoption conducted by Rock Health also found that demographics was not associated with digital health adoption, whereas a consumer orientation, based on similar beliefs as those examined in our study, had a robust relationship with digital health adoption [29]. We also found that first-time pregnant mothers did not differ significantly from mothers of young children in their current use of digital health-management practices or potential adoption of digital health tools.

Competent health communication and proficient use of health information technology are considered essential attributes of an informed consumer. Yet, many health programs aimed at engaging patients through technology struggle to reach underserved populations. Improving engagement with digital health among vulnerable pregnant women and mothers may require the following actionable steps: (1) fostering provider encouragement of Internet health seeking information, (2) encouraging providers to query patients about their Internet search behaviors, (3) enabling trainings to increase public awareness of different digital health tools, and (4) bolstering women's personal agency.

Firstly, provider encouragement of Internet health-seeking information must be fostered. Web searching may be an important gateway toward active management of women's own health or that of their children and may help bolster women's roles as active informed patients. Similar to a previous systematic review, we found that clinical endorsement from trusted providers enhances consumer engagement [27].

Secondly, providers should be encouraged to query patients about their Internet search behaviors. Assessing consumers' comfort in using tools that require eHealth allows for the identification of skill gaps and interests in adopting digital technologies.

Thirdly, trainings should be conducted to increase public awareness of different digital health tools (including patient portals). The working of these tools should be explained and the potential benefits and risks to safety, security, and sense of privacy should be identified. Trainings should build skills, confidence, and trust in the use of these tools, and they could be targeted at consumers and providers.

Finally, women's personal agency should be bolstered so that they can confidently assume that they are responsible for and can influence their own and their child's health. Many women already use social support groups and express interest in Web-based services that are localized, social, and link to community resources.

Failure to address the disparities in digital use found in this study suggests that the benefits from the use of digital health solutions will accrue only to those individuals with the resources and skills to use technology effectively. This could exacerbate inequities in already vulnerable populations. Strategies to eliminate digital health inequities could benefit from further research on the drop off in the number of users in the transition from Internet searches to digital health-management practices. The findings from such research would further inform strategies for designing interventions that promote adoption and routine use of digital health-management practices and patient interactions with the health care system.

Limitations

This study has several limitations. We used a small convenience sample of low income, English-proficient, urban dwellers, which does not allow us to generalize the findings to other pregnant women or mothers. We mostly recruited publicly insured women enrolled in primary care clinics and other programs. Evidence indicates that individuals who experience difficulties in accessing health care for reasons unrelated to their insurance status are more likely to report using the Internet for health information [5]. We relied on self-reports and measures that corresponded to perceived skills and attributes, not to actual skills, knowledge, motivation to use digital health-management tools, or adoption of and engagement with digital health technologies. Furthermore, our cross-sectional study design does not allow us to assess temporal or causal relationships. Further research with prospective or experimental designs is needed to corroborate our findings.

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Our study also had strengths. We restricted the study population to pregnant women and mothers of young children, allowing us to focus on an important life stage, which presents unique opportunities for behavior change and adoption of digital health technology. Unlike many studies that have focused on a particular patient population in a specific setting and a single technology [27], we sampled a diverse group of participants from various clinics and programs from communities in several geographic locations. Furthermore, we expanded our scope beyond Internet health searches to include use of digital health technology for health management and used a mixed-methods approach to gather information.

Conclusions

This study showed that Web-based health information searches were widespread, whereas use of digital health-management practices was far less common in this sample of low-income, first-time pregnant women and mothers. The results demonstrate a significant relationship between Internet health search activities and engagement in digital health-management practices. Whereas higher eHealth literacy was strongly associated with Web search activities, an internal health orientation was more strongly associated with the number of digital health-management practices, and trust in digital information was associated with potential adoption of digital tools. The relative contributions of these consumer motivations for use of digital health technologies need to be further explored to design better tools and interventions that address this population's interests and enhance the competencies to manage self and child health.

Acknowledgments

We thank Valerie Steinmetz for help with data collection and Ndola Prata for her contributions to study design. This study was partially supported by the Wallace Center for Maternal, Child, and Adolescent Health at the University of California, Berkeley, and by the Aetna Foundation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Demographic, health, and technology ownership characteristics of users by health technology use outcomes.

[PDF File (Adobe PDF File), 87KB - jmir_v19i7e240_app1.pdf]

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Abbreviations

ANOVAs: Analysis of variances
CI: Confidence interval
eHEALS: eHealth literary scale
OR: Odds ratio
SF: San Francisco
WIC: Women, Infants, and Children

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Edited by G Eysenbach; submitted 21.03.17; peer-reviewed by C Fitzgerald, T Irizarry; comments to author 12.04.17; revised version received 26.04.17; accepted 27.04.17; published 05.07.17.

Please cite as:
Guendelman S, Broderick A, Mlo H, Gemmill A, Lindeman D
Listening to Communities: Mixed-Method Study of the Engagement of Disadvantaged Mothers and Pregnant Women With Digital Health Technologies
J Med Internet Res 2017;19(7):e240
URL: http://www.jmir.org/2017/7/e240/
doi:10.2196/jmir.7736
PMID:28679489

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Original Paper

Ecological Momentary Assessment of Physical Activity: Validation Study

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Abstract

Background: Ecological momentary assessment (EMA) may elicit physical activity (PA) estimates that are less prone to bias than traditional self-report measures while providing context.

Objectives: The objective of this study was to examine the convergent validity of EMA-assessed PA compared with accelerometry.

Methods: The participants self-reported their PA using International Physical Activity Questionnaire (IPAQ) and Behavioral Risk Factor Surveillance System (BRFSS) and wore an accelerometer while completing daily EMAs (delivered through the mobile phone) for 7 days. Weekly summary estimates included sedentary time and moderate-, vigorous-, and moderate-to vigorous-intensity physical activity (MVPA). Spearman coefficients and Lin's concordance correlation coefficients (LCC) examined the linear association and agreement for EMA and the questionnaires as compared with accelerometry.

Results: Participants were aged 43.3 (SD 13.1) years, 51.7% (123/238) were African American, 74.8% (178/238) were overweight or obese, and 63.0% (150/238) were low income. The linear associations of EMA and traditional self-reports with accelerometer estimates were statistically significant (P<.05) for sedentary time (EMA: ρ=.16), moderate-intensity PA (EMA: ρ=.29; BRFSS: ρ=.17; IPAQ: ρ=.24), and MVPA (EMA: ρ=.31; BRFSS: ρ=.17; IPAQ: ρ=.20). Only EMA estimates of PA were statistically significant compared with accelerometer for agreement.

Conclusions: The mobile EMA showed better correlation and agreement to accelerometer estimates than traditional self-report methods. These findings suggest that mobile EMA may be a practical alternative to accelerometers to assess PA in free-living settings.

(J Med Internet Res 2017;19(7):e253) doi:10.2196/jmir.7602

KEYWORDS

accelerometry; behavioral risk factor surveillance system; ecological momentary assessment; self-report; data accuracy

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Introduction

Using self-report measures to assess physical activity (PA) can result in over-reporting of PA volume by respondents [1-3]. Possible explanations for this phenomenon include the respondent's desire to be perceived as "active" (ie, social desirability bias) and cognitive challenges with accurately recalling PA duration, frequency, and/or intensity. Accelerometers are an attractive alternative to self-report measures because of their ability to directly capture accumulated ambulatory PA across several days of observation. Yet, accelerometers have limitations, including their inability to detect several common PA modes such as swimming, cycling, and muscle strengthening activities. Furthermore, accelerometers are not capable of providing contextual information pertinent to PA behavior, including the domain of PA (ie, leisure time, occupational, transit, domestic/housework), biomechanical and physiological demands/types of PA (eg, aerobic, anaerobic activity, flexibility training, and balance training), location where the PA occurred (eg, home, gym, and work), and whether the person engaged in PA alone or with a partner/group/trainer [4].

A less commonly utilized approach to PA assessment, the ecological momentary assessment (EMA), may overcome many of the limitations of traditional self-report measures while providing contextual information on PA. The EMA is an approach to measurement that allows individuals to repeatedly report on their experiences in real time, in real-world settings, over time, and across contexts (eg, mode, type, and location) [5]. This unique approach to PA assessment has the potential to minimize recall bias by allowing the respondent to report their activity as it occurs, or very shortly thereafter [6]. Short recall time frames are preferable because specific behaviors can be recalled using episodic memories rather than generic memories of past events that require estimation and computation strategies to assist recall [7,8]. The use of shorter recall time frames has been more extensive among diet- and time-use researchers but has more recently garnered attention among PA measurement researchers [9,10]. An additional concern with traditional self-report PA measures is the possibility of social desirability bias [1]. As is the case with recall bias, the impact of social desirability bias may be minimized in with shorter recall time frames [1]. Therefore, the shorter recall time frame characteristic of EMA may sufficiently minimize recall and social desirability bias.

EMA techniques may also help to bridge the gap between self-report and objective assessment of PA by addressing many of the major limitations of both options (social desirability and recall bias, void of contextual information). Research has demonstrated that EMA is a feasible tool for monitoring health behaviors among at-risk groups of adolescents and adults [11,12]. Previous work has also indicated that EMA protocols are adhered to by participants [13]. Although EMA has been shown to be a practical application for PA assessment, little is known about the validity of EMA for estimating recent time spent in PA across broad intensity categories. Such information is critically important when interpreting study findings within the context of current public health guidelines for PA [14].

Therefore, the primary objective of this study was to assess the correlation and agreement between daily diary EMAs of PA and accelerometer-derived estimates of PA among a group of free-living adults. The secondary purpose was to compare the agreement between EMA and accelerometer estimates of PA with traditional self-reported PA questionnaire estimates and accelerometer estimates. It was hypothesized that EMA estimates of PA and sedentary behavior would have acceptable convergent validity measurement properties and that EMA would display better agreement with accelerometer estimates than traditional self-reported PA from questionnaires.

Methods

Design Overview and Participants

This study is a secondary data analysis of the Pathways between Socioeconomic Status and Behavioral Cancer Risk Factors Study (PATHS). The PATHS was a 7-day prospective observational study designed to characterize proximal predictors of health behavior using mobile phone–based EMA. A subset of the PATHS participants also received a mobile phone–based sedentary behavior intervention (for details see Kendzor et al, 2016) [15]. A racially and ethnically diverse community sample of adults living in Dallas, Texas, the United States of America, were recruited for participation through print advertisements in local newspapers, advertising circulars, and flyers on The University of Texas Southwestern Medical Center campus and in the Dallas metropolitan area. A total of 248 participants were screened over the telephone. Of those, 238 (96%) met the eligibility criteria and were enrolled in the study. The study participants attended an in-person visit where they met with study staff and were (1) measured for height and weight, (2) asked to complete a questionnaire on demographics and various health behaviors (including PA and sedentary behavior), (3) provided a mobile phone, and (4) fitted with an accelerometer. The participants were instructed to carry the mobile phone and wear the accelerometer for 7 consecutive days following the initial visit. After the 7-day period, they were asked to return their accelerometer and mobile phone to the study site. Participants were compensated up to US $130 for the completion of all aspects of the study. The complete PATHS study methods are described elsewhere in greater detail (Kendzor et al, 2016 [15]). This study was approved by the institutional review boards of The University of Texas Southwestern Medical Center and The University of Texas Houston Health Science Center. Informed consent was obtained from all participants.

Data Collection

Participant Characteristics

The participants completed questionnaires on laptops or tablet computers, including items on demographic and socioeconomic factors such as age, race and ethnicity, educational attainment, employment status, and income. Household income was classified as low if it was reported to fall between less than or equal to 100% of the 2012 Federal Poverty Threshold and 199% of Federal Poverty Threshold.

Weight and height were measured by study staff, and body mass index (BMI) was calculated using the standard formula (kg/m^2).

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Self-Reported Physical Activity and Sedentary Behavior Measures

Self-reported PA and sedentary behavior were measured using three instruments with varying periods of assessment: EMA, "past 24 hours"; 7 items from the 2007 Behavioral Risk Factor Surveillance System (BRFSS), "usual week"; and ten items from the 2011 International Physical Activity Questionnaire (IPAQ), "past 7 days."

For the EMA, participants were provided with a LG Optimus T Smartphone with the Android 2.2 operating system, on which they were prompted to complete daily diary assessments of health behavior (including PA) over a 7-day observation period. The EMA program was developed by and accessed through the e-Health Technology resource provided by the Duncan Family Institute at the MD Anderson Cancer. Participants completed daily diary assessments once daily, 30 min after their self-reported usual wake time.

First, participants were asked to select the time spent over the past 24 hours in moderate-intensity PAs via 8 response options that ranged from 0 to ≥70 min, in increments of 10 min. Participants were provided with examples of moderate-intensity PAs (eg, brisk walking and bicycling) to aid with recall. Next, participants were asked to report the time spent per day in vigorous-intensity PAs. Again, examples of vigorous-intensity PAs (eg, running and aerobics) and 8 response options were provided to facilitate recall. Summary estimates were expressed as the mean value within response categories for moderate- and vigorous-intensity PA separately. For example, if the participant reported 20 to 29 min of moderate-intensity PA over the previous 24 hours, 24.5 min was used. These values were summed across all days of observation and expressed as time spent per week in moderate-, vigorous-, and moderate- to vigorous-intensity PA (MVPA).

As part of a larger survey administered to participants during the initial visit (ie, before EMA administrations and accelerometry), 7 items from the 2007 BRFSS PA questionnaire were utilized to assess usual leisure-time PA; these items were adapted for self-administration. Participants were asked to report the duration (minutes per day) and frequency (times per week) of PA within broad intensity categories (ie, moderate- and vigorous-intensity PA). The summary estimate reflecting moderate- to vigorous-intensity leisure-time PA was computed as the product of the reported duration and frequency (minutes per week) summed across intensity categories. The PA questions from BRFSS have previously been shown to be reliable and valid [16].

Ten items from the 2011 IPAQ were also included in the initial survey to assess occupational- and transportation-related PA in the past week [17]. For occupational PA, participants were asked to report the frequency (days per week) and duration (hours per day) they engaged in moderate-intensity PA, vigorous-intensity PA, and walking (not including for transportation to/from work) for at least 10 min at a time as a part of their work. Similarly, for transportation-related PA, the participants were asked to report how many days per week and hours per day they spent walking and bicycling to/from work, given the trip was at least 10 min. The IPAQ has been previously shown to be a reliable and valid instrument for assessing PA [17]. Two items from the IPAQ were used to assess the usual time spent sitting during the last 7 days in hours per day.

The IPAQ was scored to calculate a comparable summary estimate (total minutes per week) to the other PA measures. First, the total number of hours per week of each of the questions was calculated by taking the product of the reported number of days per week and the total time (hours) spent per day engaging in each of the activity intensities. Then, the total number of hours per week was multiplied by 60 to determine the total number of minutes per week of each of the questions. Finally, the sum of the total number of minutes per week for each of the PA intensity was calculated; walking for work and transport and bicycling for transport were considered moderate-intensity PAs [18]. Logically, activities described as vigorous in intensity (eg, heavy lifting, digging, and climbing stairs) and moderate in intensity (eg, carrying light loads) were categorized as such. The IPAQ MVPA summary estimate is the sum of the moderate- and vigorous-intensity PAs calculated by the respective questions.

Self-reported sedentary behavior, separate from what was queried in the IPAQ, was assessed with 8-items that inquire about the time, in hours per day, spent watching television and using the computer during the week and on the weekends [19].

Device-Based (Accelerometer) Physical Activity and Sedentary Behavior Measures

Device-based PA was assessed using the ActiGraph GT3X accelerometer (ActiGraph). The ActiGraph is a small (3.8 x 3.7 x 1.8 cm) triaxial piezoelectric accelerometer that is typically worn at the waist. Data outputs from the ActiGraph accelerometer are activity counts, which quantify the amplitude and frequency of detected accelerations. Activity counts are summed over a researcher-specified time interval (ie, epoch). In this study, a 60-second epoch was reported. The sum of the activity counts in a given epoch is related to activity intensity and can be categorized on the basis of validated activity count cut points [20]. Technical specifications, as well as the reliability and validity of the ActiGraph have been described previously [20,21]. Participants were asked to wear the ActiGraph (dominant hip) everyday, during all waking hours. After the 7-day study period, the participants returned the accelerometer to study staff. The data from the accelerometer were downloaded and screened for wear time using methods reported by Troiano et al [22]. Briefly, device nonwear time was defined as 60 consecutive min of 0 counts, with an allowance for 1to 2 min of detected counts between 0 and 100. Wear time was determined by subtracting derived nonwear time from 24 hours [22,23]. A minimum of 10 hours of wear time per day was required for data to be considered for further use in calculating daily estimates of PA/inactivity. Weekly summary estimates were computed by averaging daily estimates across the total number of days worn for participants with ≥4 days (out of 7 days) with ≥10 hours per day of wear time.

Statistical Analysis

First, descriptive univariate analyses were conducted on measured parameters, and all continuous estimates were assessed

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for normality using histograms and Shapiro-Wilk tests. Continuous estimates were reported as means with standard deviations (SD) and medians with 25th and 75th percentiles, depending on normality; frequencies and percentages were reported for categorical variables. Next, the linear associations between and within self-reported (ie, EMA, BRFSS, and IPAQ) and device-based estimates were computed using Spearman rank-order correlation coefficients. Significance of the Spearman correlation coefficient was tested using Holm's sequential Bonferroni adjustment. Then, the agreement between the inverse hyperbolic tangent transformed (*z*-transformation) self-reported and device-based estimates were assessed using Lin's concordance correlation (LCC) coefficients with 95% CIs. Generally, LCCs are considered poor if they are less than .90 [24]. A visual representation of agreement of MVPA estimates was also obtained via Bland-Altman plots of the log transformed mean of MVPA from the self-report instruments and device-based assessment (x-axis) with difference in log transformed MVPA from the self-report instruments and device-based assessment (y-axis). All analyses were completed on a complete case analysis basis. The alpha level denoting statistical significance for all tests was set at .05. All statistical analyses were conducted via Stata/IC version 13.1 (StataCorp LP).

Results

Participant Characteristics

As shown in Table 1, the mean age of participants was 43.3 years. Of the 238 participants, 160 (67.2%) were female, 123 (51.7%) were black or African American, and 178 (74.8%) were overweight or obese. Most participants reported at least some college education (173/238, 72.7%) and 57.1% (136/238) were employed full-time. Almost two-thirds (150/238, 63.0%) of the participants were classified as low income. Overall, participants completed 92.9% (95% CI 0.915-0.941) of 1666 possible EMA daily dairy assessments via mobile phone over the 7-day study period. Additionally, 79.8% (190/238; 95% CI 0.742-0.847) participants wore the accelerometer for at least 10 hours on at least 4 days over the 7-day study period.

Physical Activity and Sedentary Behavior

The median (25th, 75th percentiles) and the mean (SD) duration of time (minutes per week) spent in each of the activity intensities as measured by self-report and accelerometer are shown in Table 2. Tests for normality revealed that PA estimates were all non-normal and positively skewed, and all sedentary time estimates, except for those derived from accelerometer, were non-normal and positively skewed as well. Across all self-reported sedentary measures, participants underreported the time spent sedentary when compared with accelerometer-determined sedentary time. On the basis of accelerometer data, participants spent 3400.8 (SD 864.0) min per week sedentary, a median (25th, 75th percentile) of 120.5 (65.0, 218.0) min per week in moderate-intensity PA and 0.0 (0.0, 2.0) in vigorous-intensity PA, which amounted to 121.5 (66.0, 225.0) min per week of MVPA.

Correlations

Regarding self-reported time spent sedentary, the BRFSS and IPAQ sedentary estimates were shown to be highly correlated (r=.77, P<.001) whereas all other self-report measures presented acceptable associations (r=.35-.37, P<.01) with each other. When compared with accelerometer-determined sedentary time, only the corresponding EMA estimate was significantly correlated (r=.16, P<.05). Because of complete case analysis for missing data, the sample sizes for tests of correlations may differ (see Table 3 for the sample size for each statistical test). Tests for differences revealed that participants who failed to adhere to the EMA and accelerometry protocols did not differ significantly (P>.05) from those who adhered to the protocols, based on age, race, BMI, employment status, and income.

With regard to the moderate-intensity PA summary estimates, participants over-reported the time spent in moderate-intensity PA when measured using BRFSS and IPAQ. Among the traditional self-report estimates only, the instruments displayed acceptable correlations (r=.33-.44, P<.01). Although all the traditional self-report estimates were significantly correlated to the accelerometer estimate (r=.17-.29, P<.05), the EMA estimate performed the best with a correlation coefficient of .29 (P<.01).

For the estimates reflecting vigorous-intensity PA, all of the traditional self-report and EMA measures overestimated the amount of time spent in vigorous-intensity activity when compared with accelerometer-derived estimates. Within the traditional self-report and EMA measures, correlations were low (.18-.29) but significant (P<.01). When compared with accelerometer-derived vigorous-intensity PA, none of the traditional self-report or EMA measures were significantly correlated (r=−.13 to .10, P>.05).

Finally, for MVPA, participants over-reported the amount of time spent in MVPA when compared with accelerometer estimates. The traditional self-report and EMA measures presented acceptable correlations within each other (r=.35-.46, P<.01). When compared with accelerometer-derived estimates of MVPA, the EMA estimate displayed an acceptable correlation (r=.31, P<.01) whereas the correlations with traditional self-report measures were low but significant (r=.17-.20, P<.05).

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Table 1. Characteristics of Pathways between Socioeconomic Status and Behavioral Cancer Risk Factors Study participants, 2012.

Characteristic	Total (N=238)
Age in years, mean (SD[a])	43.4 (13.1)
Sex, n (%)	
Male	78 (32.8)
Female	160 (67.2)
Ethnicity/race, n (%)	
White	73 (30.7)
Black or African American	123 (51.7)
Asian	8 (3.4)
American Indian, Alaska Native	2 (0.8)
Hispanic/Latino	28 (11.8)
More than one race	4 (1.7)
Body mass index[b]	
Mean (SD)	30.6 (7.8)
Underweight, n (%)	3 (1.3)
Healthy weight, n (%)	57 (24.0)
Overweight, n (%)	70 (29.4)
Obese, n (%)	108 (45.4)
Employment status, n (%)	
Employed (full-time or part-time)	136 (57.1)
Unemployed	41 (17.2)
Other[c]	61 (25.6)
Educational attainment, n (%)	
No high school or GED[d]	22 (9.2)
High school or GED	43 (18.1)
Some college or more	173 (72.7)
Household income, n (%)	
Below 2011 Federal Poverty Threshold[e]	150 (63.0)

[a]SD: standard deviation.

[b]Body mass index calculated as the reported weight in kilograms/(height in meters)^{2}and classified based on World Health Organization cut points for adults.

[c]Other occupational statuses include homemaker-not employed, student-not employed, retired-not employed, unable to work or disabled, other.

[d]GED: general education development.

[e]Household income≤100% Federal Poverty Threshold (FPT) to 199% FPT.

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Table 2. Duration of time spent in each physical activity intensity range as determined by five measurement devices among Pathways between Socioeconomic Status and Behavioral Cancer Risk Factors Study participants, 2012.

Intensity	Measurement device	Mean (SD[a]) (minutes/week)	Percentiles (minutes/week)		
			25th	50th	75th
Sedentary	EMA[b]	2320.2 (1998.8)	1080.0	1980.0	3120.0
	Self-report	2862.3 (1676.4)	1680.0	2511.5	3655.0
	IPAQ[c]	2897.1 (1559.6)	1800.0	2640.0	3720.0
	Accelerometer	3400.8 (864.0)	2813.0	3502.5	3996.0
Moderate	EMA	141.5 (98.4)	71.5	111.5	201.5
	BRFSS[d]	414.7 (657.6)	75.0	213.5	450.0
	IPAQ	754.7 (1312.9)	75.0	232.0	840.0
	Accelerometer	155.8 (139.0)	65.0	120.5	218.0
Vigorous	EMA	92.4 (82.5)	31.5	64.3	127.0
	BRFSS	212.9 (431.8)	0.0	63.5	240.0
	IPAQ	147.6 (429.6)	0.0	0.0	10.0
	Accelerometer	7.4 (25.7)	0.0	0.0	2.0
MVPA[e]	EMA	233.9 (163.3)	113.0	183.0	314.0
	BRFSS	627.6 (1592.4)	120.0	360.0	765.0
	IPAQ	902.3 (1592.4)	75.0	246.0	924.0
	Accelerometer	163.2 (151.4)	66.0	121.5	225.0

[a]SD: standard deviation.

[b]EMA: ecological momentary assessment.

[c]IPAQ: International Physical Activity Questionnaire.

[d]BRFSS: Behavioral Risk Factor Surveillance System.

[e]MVPA: moderate- to vigorous-intensity physical activity.

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Table 3. Spearman correlation coefficients between five physical activity measurement devices among Pathways between Socioeconomic Status and Behavioral Cancer Risk Factors Study participants, 2012.

Intensity	Measurement device	Spearman correlation coefficients[a]					
		Accelerometer[b]		IPAQ		BRFSS	
		ρ (*P* value)	n	ρ (*P* value)	n	ρ (*P* value)	n
Sedentary	EMA[d]	.16 (.03)	168	.37 (<.001)	227	.35 (<.001)[c]	227
	Self-report	.07 (.33)	190	.77 (<.001)	238		
	IPAQ[e]	.08 (.27)	190				
Moderate	EMA	.29 (.001)	168	.42 (<.001)	206	.33 (<.001)	206
	BRFSS[f]	.17 (.02)	190	.44 (<.001)	238		
	IPAQ	.24 (.001)	190				
Vigorous	EMA	.09 (.26)	168	.28 (<.001)	206	.29 (<.001)	206
	BRFSS	.10 (.15)	190	.18 (.006)	238		
	IPAQ	−.13 (.08)	190				
MVPA[g]	EMA	.31 (<.001)	168	.42 (<.001)	206	.35 (<.001)	206
	BRFSS	.17 (.02)	190	.46 (<.001)	238		
	IPAQ	.20 (.006)	190				

[a]Significance tested using Holm's sequential Bonferroni adjustment.

[b]Accelerometer data were classified as sedentary, moderate, or vigorous using Freedson's cut points.

[c]This statistic indicates the Spearman correlation coefficient and *P* value for EMA and the self-reported measure of sedentary behavior from Healy et al (2011) [19].

[d]EMA: ecological momentary assessment.

[e]IPAQ: International Physical Activity Questionnaire.

[f]BRFSS: Behavioral Risk Factor Surveillance System.

[g]MVPA: moderate- to vigorous-intensity physical activity.

Agreement

Agreement between the traditional self-report and EMA measures and device-based PA and sedentary behavior measures are shown in Table 4. Considering the time spent sedentary, when compared with accelerometer-derived estimates, each of the self-reported estimates showed no statistically significant agreement. With regard to the moderate-intensity PA estimates, BRFSS and IPAQ displayed low nonsignificant agreement to the accelerometer-derived estimates ([LCC=.12, 95% CI −0.02 to 0.26] and [LCC=.04, 95% CI −0.10 to 0.19], respectively) and low accuracy (bias correction factor [BCF]=0.42 and BCF=0.19, respectively). Only EMA estimates of moderate-intensity PA presented significant agreement (LCC=.32, 95% CI 0.19 to 0.46) and accuracy (BCF=0.94). Additionally, only EMA produced an acceptable measure of precision (r=.32, P<.001). The BRFSS and IPAQ estimates of vigorous-intensity PA had poor and statistically nonsignificant agreement to accelerometer estimates ([LCC=.02, 95% CI −0.12 to 0.16] and [LCC=−.05, 95% CI −0.19 to 0.09], respectively). EMA had poor agreement but a CI not containing a null result (LCC=.28, 95% CI 0.15 to 0.41) and a significant level of precision (r=.29, P<.001). None of the self-reports of vigorous-intensity activity had an accuracy estimate considered acceptable (BCF<0.90). Among the MVPA estimates, traditional self-report measures did not significantly agree with the accelerometer estimates, but there was agreement with EMA (LCC=.28, 95% CI 0.16 to 0.41). For MVPA, EMA was the only estimate to produce significant levels of precision (r=.32, P<.001) and an acceptable level of accuracy (BCF=0.90).

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Table 4. Convergent validity of physical activity and sedentary behavior measurement devices as measured by Lin's concordance correlations, Pathways Between Socioeconomic Status and Behavioral Cancer Risk Factors Study, 2012.

Intensity	Measurement device	Accelerometer estimates[a]				
		LCC[b]	95% CI	Pearson *r*	*P* value	BCF[c]
Sedentary	EMA[d]	.07	−0.02 to 0.16	.12	.11	.61
	Self-report	.05	−0.06 to 0.16	.07	.35	.76
	IPAQ[e]	.06	−0.05 to 0.18	.08	.28	.80
Moderate	EMA	.32	0.19 to 0.46	.32	<.001	.94
	BRFSS[f]	.12	−0.02 to 0.26	.12	.09	.42
	IPAQ	.04	−0.10 to 0.19	.05	.54	.19
Vigorous	EMA	.28	0.15-0.41	.29	<.001	.21
	BRFSS	.02	−0.12 to 0.16	.02	.78	0.12
	IPAQ	−.05	−0.19 to 0.09	−.05	.50	.14
MVPA[g]	EMA	.28	0.16 to 0.41	.32	<.001	.90
	BRFSS	.08	−0.06 to 0.22	.09	.25	.30
	IPAQ	−.00	−0.03 to 0.03	−.002	.98	.18

[a]Accelerometer data were classified as moderate or vigorous using Freedson's cut points.

[b]LCC: Lin's concordance correlations.

[c]BCF: bias correction factor.

[d]EMA: ecological momentary assessment.

[e]IPAQ: International Physical Activity Questionnaire.

[f]BRFSS: Behavioral Risk Factor Surveillance System.

[g]MVPA: moderate- to vigorous-intensity physical activity.

Finally, Lin concordance correlation plots (Figure 1) and Bland-Altman plots (Figure 2) were also constructed to provide a visual representation of agreement between accelerometer-derived estimates of MVPA and the self-report measures. There does not appear to be a trend or pattern of the data points for any of the plots. For all the plots, the majority of the data points appear to be within the limits of agreement, yet none of the plots have all points within the limits of agreement. However, the limits of agreement do appear to be narrower for EMA than the other traditional self-report measures.

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Figure 1. Lin concordance correlation plots of physical activity measurement devices to evaluate the agreement between the device and accelerometer in measuring moderate-, vigorous-, and moderate-to vigorous-intensity physical activity (MVPA).

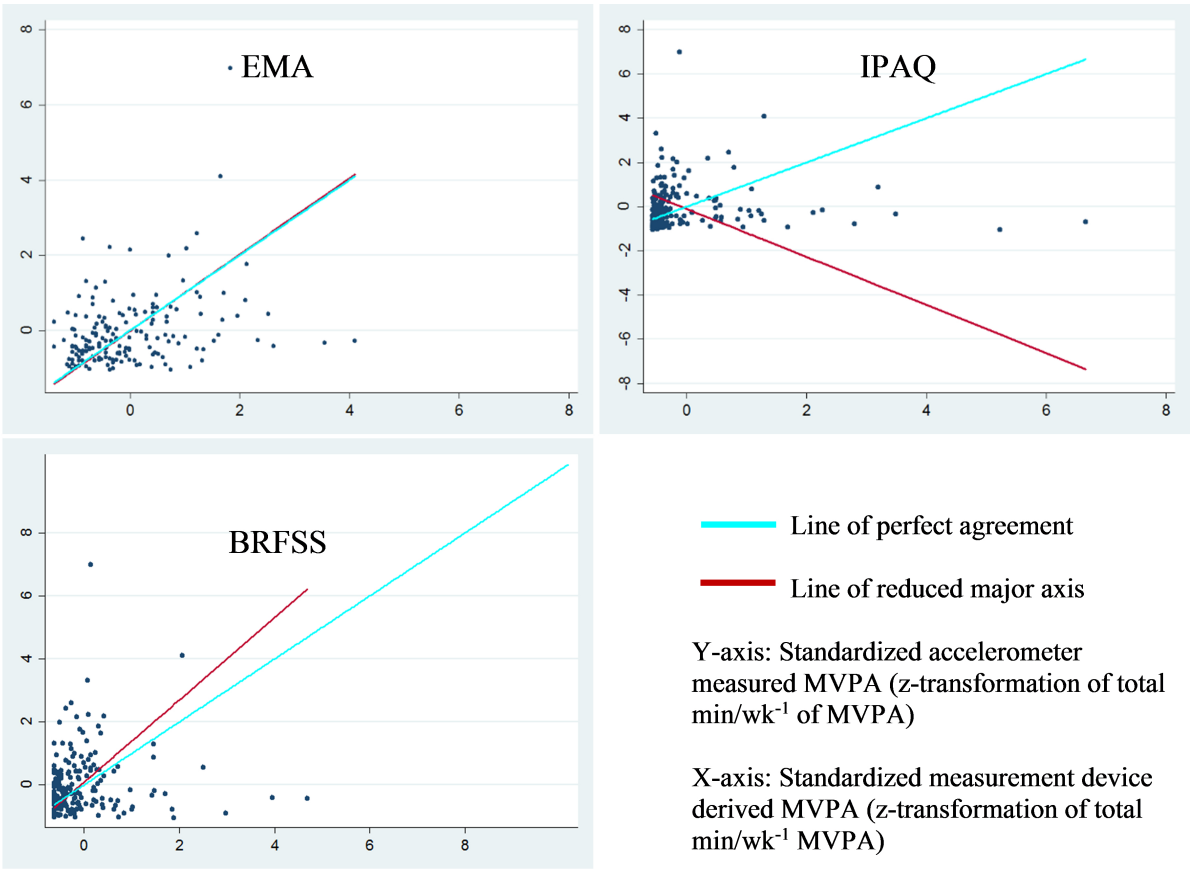
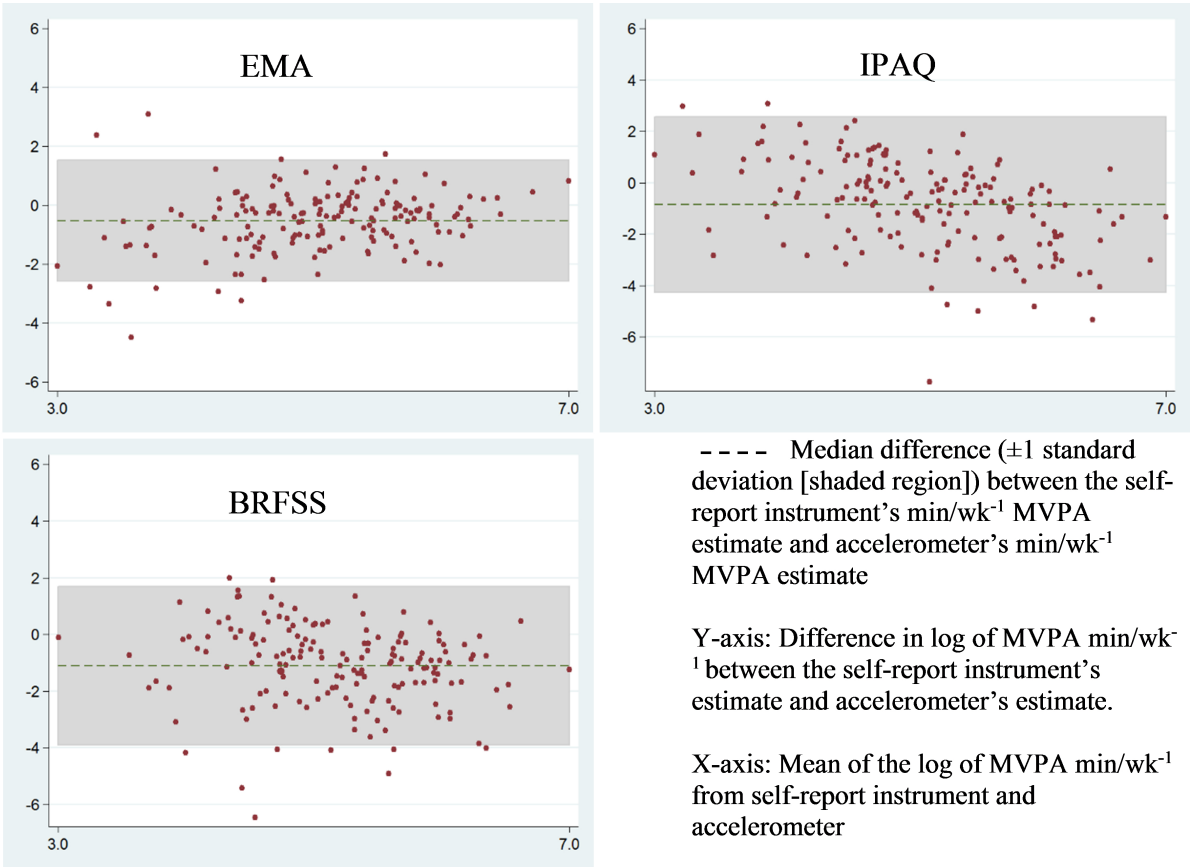


Figure 2. Bland-Altman plots (difference plots) of physical activity measurement devices to evaluate the agreement between the device and accelerometer in measuring moderate-, vigorous-, and moderate-to vigorous-intensity physical activity (MVPA).



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Discussion

Principal Findings

The results of this study indicated that EMA performed better than other forms of PA self-report measures when compared against accelerometry. The BRFSS and IPAQ measures indicated over-reporting of an average of 464.4 and 902.3 min per week of MVPA, respectively, compared with EMA over-reporting MVPA by an average of 70.7 min per week. Similarly, EMA performed better than the other self-report measures in the areas of correlation (moderate-intensity PA and MVPA) and agreement (moderate- and vigorous-intensity, and MVPA). Additionally, the strong participant compliance to the EMA (93%) protocol further supports the feasibility of EMA as a method to assess PA and sedentary behaviors. This finding, considering the diverse sample in this analysis, underscores the ease-of-use of mobile phones in assessing PA and other health-related behaviors.

These findings align with other studies that have found EMA to be a valid tool to estimate PA when compared with an objective assessment device. Dunton et al (2005) concluded that among adolescents, heart rates and accelerometer counts were significantly greater during EMA diary-reported PA than during non-PAs [25]. Similarly, Atenza and colleagues (2006) found in a pilot study that older adults' reporting of minutes and frequency of moderate PA via EMA diary exhibited acceptable correlations to a standardized PA questionnaire for older adults (Community Healthy Activities Model Program for Seniors) [13]. Other studies from Dunton et al and Rofey et al have compared multiple randomly administered daily EMAs (rather than once per day diary) to accelerometer steps in children and adults and have concluded that EMA is a valid instrument to capture PA and sedentary behavior [12,26,27]. However, the aforementioned studies neither assessed the intensity of the PA nor the duration of the PA or sedentary time as was done in this study. Generally, previous studies and the findings of this study support the validity of EMA to measure PA and sedentary behavior.

Previous work in the measurement and evaluation of PA has primarily used correlation coefficients to assess reliability and validity. In this study, with the use of an accelerometer as a comparison measure, the calculated Spearman correlation coefficients support the convergent validity of EMA. The Spearman statistic presented for moderate-intensity PA, for example, is evidence that the EMA estimate of time spent engaging in moderate-intensity PA has a linear relationship, in direction and magnitude, with the accelerometer-derived estimate of time spent engaging in moderate-intensity PA. However, a drawback to this approach is that when only plotting the linear relationship between two estimates, the test is unable to detect departures from the plotted line that would indicate poor reproducibility or shifts in the data. For a more complete explanation on the drawbacks on the use of correlation coefficients to evaluate reproducibility and validity, see Lin (1989) [28]. Lin proposed the use of an index that combines measures of precision (Pearson correlation) and accuracy (bias correction factor [BCF]) to provide a superior measure of agreement by not relying on only one aspect of agreement but evaluating the agreement on the basis of both aspects [28]. The analyses in this study were able to determine that for sedentary behavior and PA, the EMA assessment performed the best in terms of agreement as measured by LCC when compared against an accelerometer. Although none of the LCC statistics for PA reached an acceptable threshold of .90, only EMA estimates for moderate-intensity PA, vigorous-intensity PA, and MVPA were statistically significant. Additionally, the estimates for moderate-intensity PA and MVPA can be considered to have acceptable correlations to the accelerometer [29]. Recently, Lin's concordance correlations have been utilized to assess agreement in PA measurement [30] and have been further used in other areas of health behavior/outcomes research [31-33]. The LCC estimates for each estimate of self-reported PA was well below the acceptable threshold (.90) of agreement. It should be noted that the self-reports of PA are intended to measure the behavior of PA whereas accelerometry measures ambulatory movement. Furthermore, accelerometry is not considered the gold-standard assessment of PA behavior but rather an estimate of ambulatory movement that is less prone to bias [4].

This study compared estimates of PA derived from accelerometry with various self-report measures (ie, BRFSS, IPAQ, and EMA). These are estimates of total PA, whereas each of the self-report tools measures various different domains of PA. There are four proposed domains of PA that make up an individual's total PA: (1) leisure-time PA, (2) transit-related PA, (3) occupation-related PA, and (4) household/domestic-related PA [34]. Each of the self-report PA assessment tools utilized in this study measured different domains of PA: EMA, leisure-time PA; IPAQ, occupation- and transportation-related PA; and BRFSS, leisure-time PA. None of the tools assessed domestic/household-related PA. Our results indicate that participants tended to overestimate their PA, regardless of domain. This finding aligns with many previous studies that indicate the possibility of social desirability bias or recall bias requiring complex computations, which may be inflating the self-reported PA estimates [1,35,36].

Strengths and Limitations

This study has strengths and limitations. The population sample primarily included non-white and low-income urban-dwelling adults. This is a subgroup that is less frequently included in validation studies; however, much of the focus in PA research is directed at this subgroup for their disparate prevalence of many of the illnesses related to physical inactivity. Participants were enrolled as a convenience sample, and they may have inherent volunteer bias. Additionally, the PA assessment devices (self-report surveys and device-based) capture different aspects of PA (self-report instruments: PA behavior; device-based: PA–related movement) while attempting to compare one against the other as a means to validate. Finally, the time when PA was assessed differed across instruments (BRFSS, "usual week"; IPAQ, "past 7 days"; EMA, "past 24 hours"; accelerometer, as it occurred). Previous reviews have found that self-report questionnaires asking about the previous week showed slightly higher correlation than those asking about a usual week [37]. Additionally, the accelerometer and EMA were measuring PA during the same 7-day period, which could account for the

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higher correlations and measures of agreement. Though these data are not temporally matched, the validity of the IPAQ versus the accelerometer was determined within a relatively tight, 2-week window. Intuitively, one would not expect PA behavior to change drastically within a 2-week period unless there was a rare event (eg, sudden illness and vacation). Previous studies have shown that PA does not significantly differ within 2-week windows [38]. Though this aspect was not assessed in this study, we anticipate that very few (if any) participants experienced an event that would result in meaningful differences in PA.

Conclusions

In conclusion, direct "real-time" assessment of PA can remove many of the inherent biases found in self-reporting of PA that can result in overestimation. However, device-based PA assessment can require expensive equipment and lacks contextual information on the PA. The EMA is a proposed self-report measure of PA that may minimize bias by reducing recall time while also providing context. This study suggests that mobile EMA is a practical tool for assessing PA behavior. Overall, mobile EMA performed better than the other more traditional forms of self-report of PA assessment, indicating its potential ability to overcome bias. Future research should focus on a larger, more representative sample and longer EMA protocols to determine if the compliance to the protocols remains after a certain period of time.

Acknowledgments

This research was supported primarily by American Cancer Society grant MRSGT-10-104-01-CPHPS (to DEK). Additional support for manuscript preparation came from American Cancer Society grant MRSGT-12-114-01-CPPB (to MSB). Dr. Knell was funded for manuscript preparation through a postdoctoral fellowship at the University of Texas School of Public Health Cancer Education and Career Development Program, National Cancer Institute/NIH Grant R25 CA57712.

Conflicts of Interest

None declared.

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Abbreviations

BCF: bias correction factor
BMI: body mass index
BRFSS: Behavioral Risk Factor Surveillance System
EMA: ecological momentary assessment
IPAQ: International Physical Activity Questionnaire
LCC: Lin's concordance correlation
MVPA: moderate-, vigorous-, and moderate-to vigorous-intensity physical activity
PATHS: Pathways between Socioeconomic Status and Behavioral Cancer Risk Factors Study
PA: physical activity
SD: standard deviation

Edited by G Eysenbach; submitted 01.03.17; peer-reviewed by CKF Wen, P Ma; comments to author 19.04.17; revised version received 24.05.17; accepted 24.05.17; published 18.07.17.

Please cite as:
Knell G, Gabriel KP, Businelle MS, Shuval K, Wetter DW, Kendzor DE
Ecological Momentary Assessment of Physical Activity: Validation Study
J Med Internet Res 2017;19(7):e253
URL: http://www.jmir.org/2017/7/e253/
doi:10.2196/jmir.7602
PMID:28720556

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Original Paper

Readability of Wikipedia Pages on Autoimmune Disorders: Systematic Quantitative Assessment

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Abstract

Background: In the era of new information and communication technologies, the Internet is being increasingly accessed for health-related information. Indeed, recently published patient surveys of people with autoimmune disorders confirmed that the Internet was reported as one of the most important health information sources. Wikipedia, a free online encyclopedia launched in 2001, is generally one of the most visited websites worldwide and is often consulted for health-related information.

Objective: The main objective of this investigation was to quantitatively assess whether the Wikipedia pages related to autoimmune disorders can be easily accessed by patients and their families, in terms of readability.

Methods: We obtained and downloaded a list of autoimmune disorders from the American Autoimmune Related Diseases Association (AARDA) website. We analyzed Wikipedia articles for their overall level of readability with 6 different quantitative readability scales: (1) the Flesch Reading Ease, (2) the Gunning Fog Index, (3) the Coleman-Liau Index, (4) the Flesch-Kincaid Grade Level, (5) the Automated Readability Index (ARI), and (6) the Simple Measure of Gobbledygook (SMOG). Further, we investigated the correlation between readability and clinical, pathological, and epidemiological parameters. Moreover, each Wikipedia analysis was assessed according to its content, breaking down the readability indices by main topic of each part (namely, pathogenesis, treatment, diagnosis, and prognosis plus a section containing paragraphs not falling into any of the previous categories).

Results: We retrieved 134 diseases from the AARDA website. The Flesch Reading Ease yielded a mean score of 24.34 (SD 10.73), indicating that the sites were very difficult to read and best understood by university graduates, while mean Gunning Fog Index and ARI scores were 16.87 (SD 2.03) and 14.06 (SD 2.12), respectively. The Coleman-Liau Index and the Flesch-Kincaid Grade Level yielded mean scores of 14.48 (SD 1.57) and 14.86 (1.95), respectively, while the mean SMOG score was 15.38 (SD 1.37). All the readability indices confirmed that the sites were suitable for a university graduate reading level. We found no correlation between readability and clinical, pathological, and epidemiological parameters. Differences among the different sections of the Wikipedia pages were statistically significant.

Conclusions: Wikipedia pages related to autoimmune disorders are characterized by a low level of readability. The onus is, therefore, on physicians and health authorities to improve the health literacy skills of patients and their families and to create,

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together with patients themselves, disease-specific readable sites, disseminating highly accessible health-related online information, in terms of both clarity and conciseness.

(J Med Internet Res 2017;19(7):e260) doi:10.2196/jmir.8225

KEYWORDS

autoimmune diseases; eHealth; telemedicine; readability; Wikipedia

Introduction

In the era of so-called eHealth, characterized by the spreading of new information and communication technologies, including the dynamic Web 2.0, every day millions of people surf the Internet as a source of health information [1-4]. They search for online material concerning the symptoms and clinical manifestation of a recently diagnosed disease, its possible management, the adverse effects of treatments, the details of diagnostic procedures, and its prognosis.

Recent surveys conducted among patients with autoimmune disorders found the Internet to be one of the most important sources of health information on their condition [5]: YouTube, for example, is a source of information on rheumatoid arthritis, with a wide viewership and a potential to affect patients' knowledge and attitudes [6]. Another study found that Web activities were influenced by the media coverage and publicity about a celebrity's illness. In particular, the death of Harold Allen Ramis, a famous American actor, director, writer, and comedian, due to complications of an autoimmune inflammatory vasculitis, resulted in an increase in vasculitis-related Google searches, Wikipedia page accesses, and tweet production, peaking in February 2014 [7].

The need for high-quality, accurate, but at the same time freely and easily accessible health care information on autoimmune disorders to better inform patients, their families, and the general population is of crucial and urgent importance, in that these disorders are characterized by a relevant societal and clinical burden [8]. The European Commission has acknowledged readability, that is to say the legibility of a written text and the ease with which a reader can understand and comprehend it, and accessibility as one of the 6 quality criteria of health-related websites [9].

Since its launch in 2001, the free online encyclopedia Wikipedia has become the most popular general reference site on the Internet, and it is constantly accessed as a popular source of health care-related information. Wikipedia contains more than 30 million articles, which are available in up to 287 languages, including over 4.6 million English-language articles [10]. With the impressive figure of more than 18 billion page views and nearly 500 million unique visitors per month, the English version of Wikipedia ranks fifth in the list of most surfed websites worldwide [11].

Noteworthy, most Wikipedia articles dedicated to autoimmune disorders rank first or among the first results in a Google search. As such, these articles are highly likely to be one of the most read and consulted sources of online information on autoimmune disorders for millions of English-speaking Internet users globally. The aim of this study was to quantitatively assess the readability of Wikipedia pages related to autoimmune disorders, using a systematic search strategy and validated readability instruments.

Methods

We obtained and downloaded a list of autoimmune disorders from the American Autoimmune Related Diseases Association (AARDA) website [12].

For each autoimmune disorder, we retrieved and downloaded the corresponding Wikipedia page for further processing.

In particular, we removed sections such as copyright information, references, and images from all pages. We analyzed Wikipedia articles for their overall level of readability using 6 different quantitative readability scales: (1) the Flesch Reading Ease, (2) the Gunning Fog Index, (3) the Coleman-Liau Index, (4) the Flesch-Kincaid Grade Level, (5) the Automated Readability Index (ARI), and (6) the Simple Measure of Gobbledygook (SMOG).

Generally speaking, readability scores reflect parameters like sentence length, number of sentences, and the number of syllables or characters per word. Generally, polysyllabic words, long, complex sentences, and articulated paragraphs are penalized.

In more detail, the Flesch Reading Ease readability index reports readability scores ranging from 0 to 100, with higher scores indicating a more easily accessible and readable text. Material with a score of 70 is usually considered to be appropriate for most adults, while text with a score between 30 and 50 is considered difficult to read, and text with a score between 50 and 60 is perceived as fairly difficult.

The other 5 readability indexes—the Gunning Fog Index, the Coleman-Liau Index, the Flesch-Kincaid Grade Level, the ARI, and the SMOG—report a number that corresponds to an academic grade level (ie, to the number of years of formal education that a person would need in order to be able to understand the text easily on the first reading). The Gunning Fog Index is based on average sentence length and the number of complex words: a value less than 12 indicates a text that can be read and understood by a wide audience, being universally understandable if the value is less than 8. The Coleman-Liau Index is based on the average numbers of letters and the average number of sentences: a text whose score is less than 7 can be universally comprehended. The Flesch-Kincaid Grade Level relies on the average number of words and the average number of syllables: a text with a score of 7-8 is legible by a wide audience. The ARI is based on the average number of letters and the average number of words: a score less than 14 indicates a text understandable by a wide audience, while a value of 14

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indicates a text that requires a university education. The SMOG is based on the average number of polysyllables and the average number of sentences: a commonly recommended grade level is in the range 7-8.

Further, we analyzed eventual correlations between readability scores and epidemiological and clinical parameters of the autoimmune disorders under study. In particular, we investigated the following parameters: age at onset (≤20 years, 20-40 years, 40-60 years, 60-80 years); the incidence and prevalence figures according to the literature; clinical and pathological features (organ-specific vs systemic disease); and the McGonagle classification (classic polygenic autoimmune disease; polygenic autoinflammatory disease; mixed-pattern disease) [13]. We hypothesized that Wikipedia pages describing complex, unfamiliar, and less common diseases would be characterized by lower readability scores than would Wikipedia articles focusing on more common disorders. Further, since readability requires literacy skills, we expected a certain degree of correlation with onset age.

We computed continuous data as mean (SD). For investigating the correlation between readability and clinical, pathological, and epidemiological parameters, we performed analysis of variance or Student *t* test as univariate analyses. For multivariate analysis, we carried out regression analyses.

Further, we analyzed each Wikipedia page taking into account its different sections focusing on the following: pathogenesis of the disease (termed “pathogenesis”), management (termed “treatment”), diagnosis (termed “diagnosis”), and prognosis (termed “prognosis”). Paragraphs not falling into any of these categories were grouped in a section termed “other.”

We conducted statistical analyses using the commercial software IBM SPSS version 23.0 (IBM Corporation). Graphs were generated using the commercial software MedCalc Statistical Software version 16.8.4 (MedCalc Software bvba).

Results

We retrieved 134 diseases from the AARDA website. Table 1 reports reading level assessments of the autoimmune disorder-related Wikipedia pages we analyzed. The mean Flesch Reading Ease score indicated that Wikipedia pages related to autoimmune disorders would require at least a university graduate school level, being very difficult to read and understand. The other readability scores suggested that overall readability corresponded to a 14th to 15th academic grade level. All the readability indices confirmed that the sites were suitable for a university graduate reading level (Table 1).

Both univariate and multivariate analyses (Table 2,Figure 1, Figure 2, Figure 3, and Figure 4) demonstrated no correlation between readability scores and clinical parameters, epidemiological features of autoimmune disorders in terms of etiopathogenesis, incidence (common vs rare), and age of onset (0-20 years vs 20-40 years vs 40-60 years).

Table 1. Readability scores of autoimmune disorder-related Wikipedia pages.

Readability index	Mean	SD
Approximate representation of the US grade level needed to comprehend the text		
Automated Readability Index	14.06	2.12
Coleman-Liau Index	14.48	1.57
Flesch-Kincaid Grade Level	14.86	1.95
Simple Measure of Gobbledygook	15.38	1.37
Number of years of formal education required to easily understand the text on first reading		
Gunning Fog Index	16.87	2.03
Reading Ease Index (score 0-100)		
Flesch Reading Ease	24.34	10.73

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Table 2. Multivariate regression analysis of the readability scores for the autoimmunity disorder-related Wikipedia pages.

Readability index	Parameter	B	SD	*t* statistic	*P* value
Gunning Fog Index					
	Intercept	17.032	1.174	14.507	<.001
	Classic polygenic autoimmune disease (McGonagle classification)	0.310	0.781	0.397	.69
	Polygenic autoinflammatory disease (McGonagle classification)	0.225	0.852	0.264	.79
	Organ-specific versus systemic	–0.413	0.554	–0.746	.46
	Common versus rare	–0.508	0.627	–0.810	.42
	Age 0-20 years	–0.858	1.083	–0.792	.43
	Age 20-40 years	0.227	0.943	0.240	.81
	Age 40-60 years	–0.130	0.984	–0.132	.90
Coleman-Liau Index					
	Intercept	15.162	0.849	17.852	<.001
	Classic polygenic autoimmune disease (McGonagle classification)	0.655	0.565	1.159	.26
	Polygenic autoinflammatory disease (McGonagle classification)	0.165	0.617	0.267	.79
	Organ-specific versus systemic	–0.858	0.401	–2.140	.04[a]
	Common versus rare	–0.335	0.453	–0.738	.47
	Age 0-20 years	–1.237	0.783	–1.579	.13
	Age 20-40 years	–0.304	0.682	–0.445	.66
	Age 40-60 years	–0.706	0.712	–0.992	.33
Flesch-Kincaid Grade Level					
	Intercept	14.389	0.930	15.464	<.001
	Classic polygenic autoimmune disease (McGonagle classification)	0.832	0.619	1.343	.19
	Polygenic autoinflammatory disease (McGonagle classification)	0.729	0.676	1.079	.29
	Organ-specific versus systemic	–0.736	0.439	–1.674	.11
	Common versus rare	–0.395	0.497	–0.795	.43
	Age 0-20 years	–0.192	0.858	–0.224	.83
	Age 20-40 years	0.411	0.747	0.550	.59
	Age 40-60 years	–0.152	0.780	–0.195	.85
Automated Readability Index					
	Intercept	13.365	1.058	12.636	<.001
	Classic polygenic autoimmune disease (McGonagle classification)	0.437	0.704	0.621	.54
	Polygenic autoinflammatory disease (McGonagle classification)	0.430	0.768	0.560	.59
	Organ-specific versus systemic	–0.445	0.500	–0.890	.38
	Common versus rare	–0.422	0.565	–0.748	.46
	Age 0-20 years	0.144	0.975	0.147	.88
	Age 20-40 years	0.553	0.849	0.651	.52
	Age 40-60 years	0.127	0.887	0.143	.89
Simple Measure of Gobbledygook					
	Intercept	15.095	0.708	21.332	<.001
	Classic polygenic autoimmune disease (McGonagle classification)	0.310	0.471	0.658	.52
	Polygenic autoinflammatory disease (McGonagle classification)	0.303	0.514	0.589	.56
	Organ-specific versus systemic	–0.180	0.334	–0.539	.59
	Common versus rare	–0.170	0.378	–0.450	.66

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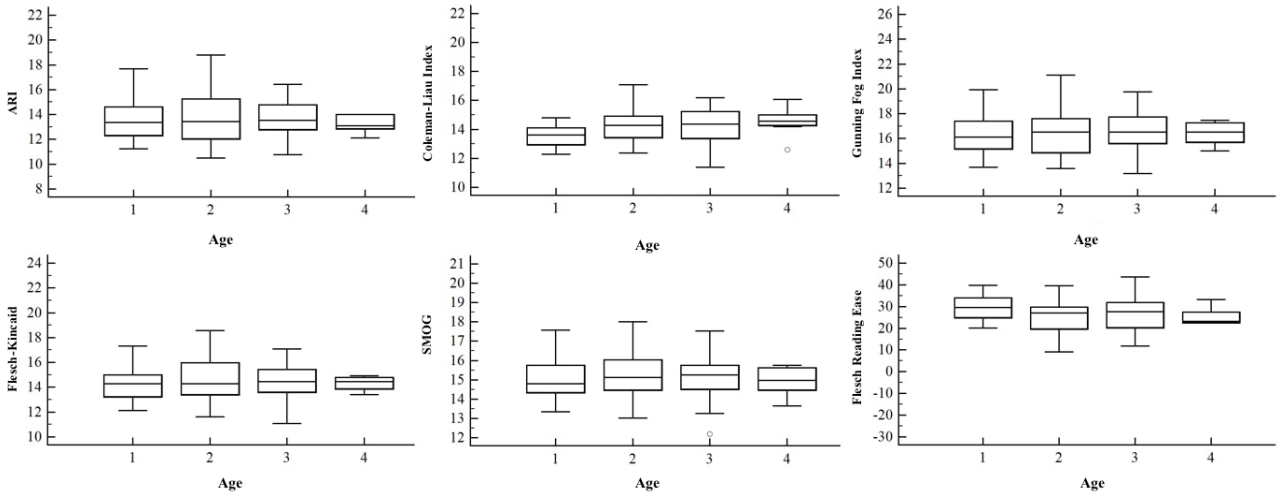
Readability index	Parameter	B	SD	*t* statistic	*P* value
	Age 0-20 years	–0.264	0.653	–0.404	.70
	Age 20-40 years	0.288	0.568	0.506	.62
	Age 40-60 years	–0.065	0.593	–0.110	.91
Flesch Reading Ease					
	Intercept	22.710	5.227	4.344	<.001
	Classic polygenic autoimmune disease (McGonagle classification)	–6.342	3.479	–1.823	.08
	Polygenic autoinflammatory disease (McGonagle classification)	–4.004	3.796	–1.055	.30
	Organ-specific versus systemic	6.268	2.469	2.539	.02[a]
	Common versus rare	2.253	2.791	0.807	.43
	Age 0-20 years	5.976	4.821	1.240	.23
	Age 20-40 years	0.294	4.198	0.070	.95
	Age 40-60 years	3.941	4.383	0.899	.38

[a]Statistically significant.

Table 3 shows readability indices broken down by section, and Multimedia Appendix 1 shows pairwise comparisons, corrected with Bonferroni correction for multiple comparisons. Statistically significant differences in readability indices were found among the different sections of the Wikipedia pages related to autoimmune disorders. In particular, considering the Flesch Reading Ease scores, the most readable sections concerned prognosis, while the least readable parts were the diagnostic paragraph(s). The prognostic sections differed from all the other parts, while the diagnostic sections did not differ from the parts on pathogenesis and management. Treatment sections were significantly different only from prognosis sections, while the sections on pathogenesis were significantly different from the prognosis and sections in the "other" category. Finally, these other sections differed from paragraph(s) concerning pathogenesis, diagnosis, and prognosis.

We noted similar, consistent trends for the other readability indices (Table 3,Multimedia Appendix 1).

Figure 1. Correlation between age (where 1 is 0-20 years, 2 is 20-40 years, 3 is 40-60 years, and 4 is 60-80 years) at onset of autoimmune diseases and the readability scores of their corresponding Wikipedia pages. Error bars indicate SD. ARI: Automated Readability Index, SMOG: Simple Measure of Gobbledygook.



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Table 3. Readability scores of autoimmunity disorder-related Wikipedia pages broken down by section.

Readability index	Section	Mean	SD
Flesch Reading Ease			
	Other	32.15	11.18
	Pathogenesis	25.06	15.27
	Treatment	27.93	12.68
	Diagnosis	23.40	17.41
	Prognosis	40.89	12.62
Gunning Fog Index			
	Other	15.45	2.41
	Pathogenesis	17.61	2.71
	Treatment	16.49	2.05
	Diagnosis	17.98	4.60
	Prognosis	14.22	2.37
Flesch-Kincaid Grade Level			
	Other	13.53	2.30
	Pathogenesis	15.02	2.90
	Treatment	13.92	2.01
	Diagnosis	15.39	4.77
	Prognosis	11.87	2.22
Coleman-Liau Index			
	Other	12.69	2.15
	Pathogenesis	13.77	2.39
	Treatment	14.44	2.36
	Diagnosis	13.95	1.91
	Prognosis	10.79	2.82
Simple Measure of Gobbledygook			
	Other	12.21	1.97
	Pathogenesis	13.13	2.12
	Treatment	12.14	1.43
	Diagnosis	13.24	3.14
	Prognosis	10.85	1.67
Automated Readability Index			
	Other	12.88	6.10
	Pathogenesis	14.40	3.47
	Treatment	13.52	2.16
	Diagnosis	14.85	5.87
	Prognosis	10.17	2.96

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Figure 2. Correlation between pathological characteristics (0=organ-specific, 1=systemic) of autoimmune diseases and the readability scores of their corresponding Wikipedia pages. Error bars indicate SD. ARI: Automated Readability Index, SMOG: Simple Measure of Gobbledygook.

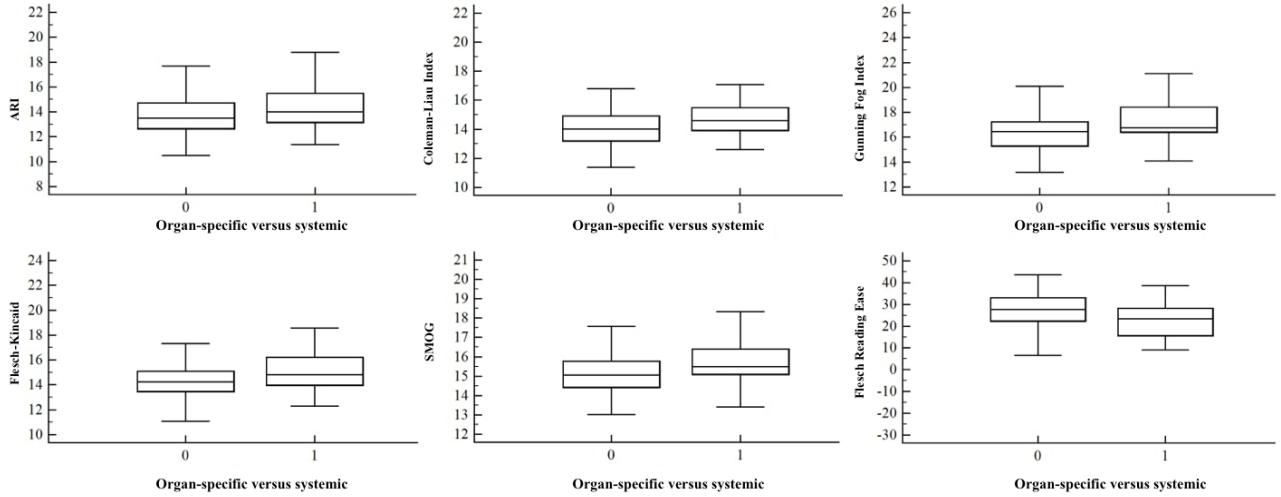


Figure 3. Correlation between the epidemiology of autoimmune diseases (0=not rare, 1=rare) and the readability scores of their corresponding Wikipedia pages. Error bars indicate SD. ARI: Automated Readability Index, SMOG: Simple Measure of Gobbledygook.

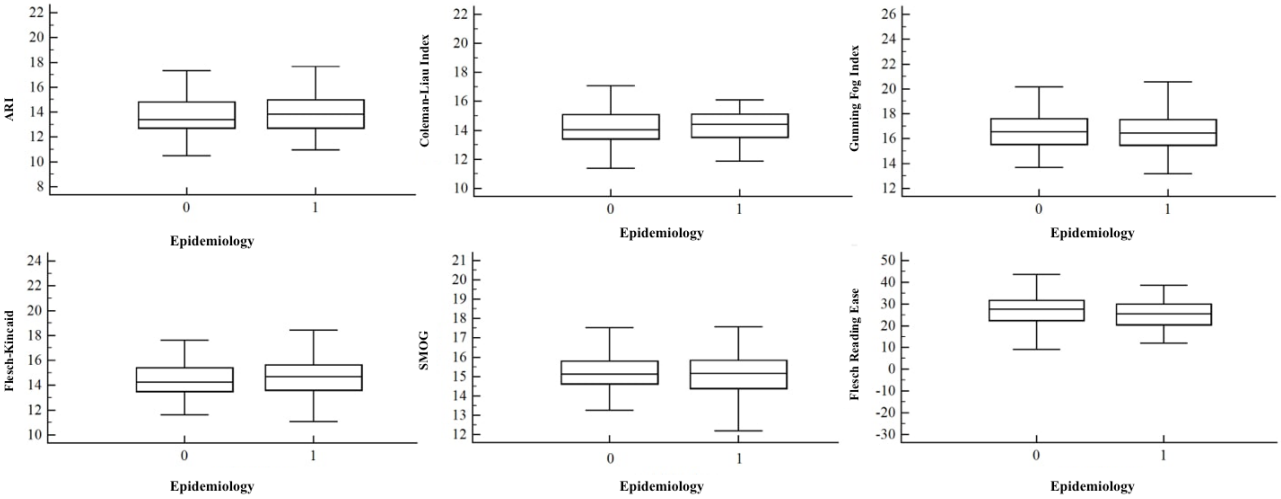
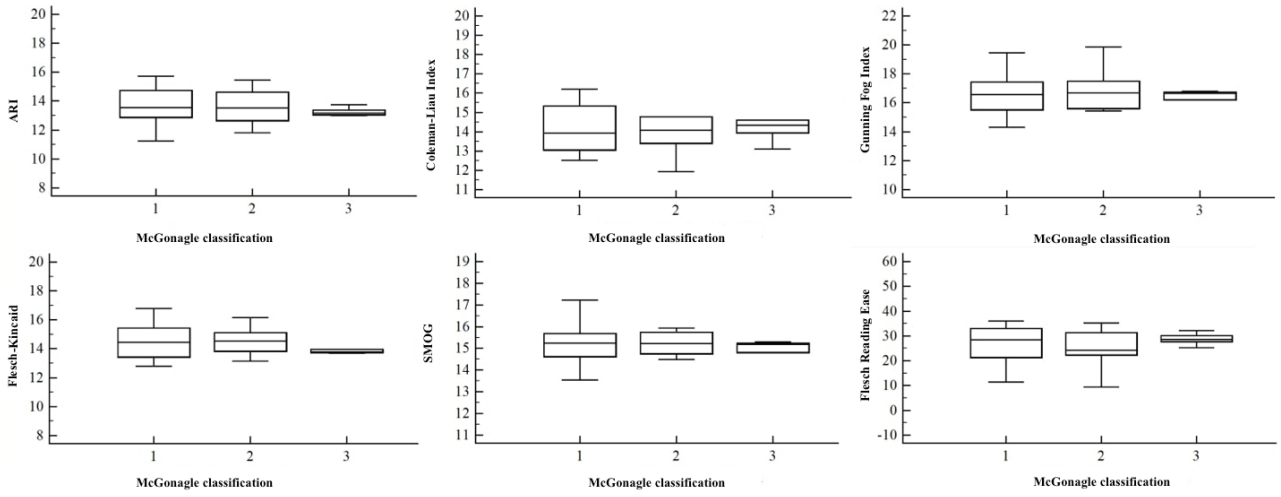


Figure 4. Correlation between McGonagle classification of autoimmune diseases (1=classic polygenic autoimmune disease, 2=polygenic autoinflammatory disease, 3=mixed-pattern disease) and the readability scores of their corresponding Wikipedia pages. Error bars indicate SD. ARI: Automated Readability Index, SMOG: Simple Measure of Gobbledygook.



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Discussion

Principal Findings

To the best of our knowledge, this is the first systematic appraisal of the readability of autoimmune diseases-related Wikipedia material. In this investigation, we found that Wikipedia pages related to autoimmune disorders were characterized by a low level of readability, and this readability level was not correlated in any way with the clinical, pathological, and epidemiological characteristics of the disorders. In other words, the epidemiology (onset age, incidence, prevalence) and clinical presentation of the diseases were not reflected in the readability scores.

Our findings of a low readability of Wikipedia pages are in line with the findings of other studies. In the extant literature, Azer et al [14] found that pages related to cardiovascular diseases were characterized by a readability score of 14.3 (SD 1.7) measured with the Flesch-Kincaid Grade Level, consistent with the readability level typical of university students. Candelario and colleagues, assessing medication guide-related Wikipedia pages, found that Wikipedia medication pages were characterized by a Flesch Reading Ease score of 52.93 and a Flesch-Kincaid Grade Level of 10.26, indicating that the Wikipedia pages were more difficult to read than their corresponding product medication guides [15]. Seth and coworkers [16] systematically investigated the readability of lymphedema-related online material and assessed 152 patient articles. They found an overall mean reading level of 12.6, with individual website reading levels ranging from 9.4 (cancer.org) to 16.7 (wikipedia.org). Interestingly, they noticed that online material describing conservative management differed from that reporting a surgical option in a statistically significant way (reading level of 12.7 vs 15.6, respectively, $P<.001$) [16]. Brigo and coworkers [17] computed the readability level of websites concerning epilepsy and obtained a difficult to fairly difficult readability level of 44.0±8.2, as measured with the Flesch Reading Ease instrument, with text readability corresponding to an 11th academic grade level (mean 11.3, SD 1.9). In particular, focusing on the Wikipedia pages, the average Flesch Reading Ease score was 25.6 (SD 9.5), with the other readability scales corresponding to a 14th grade level (mean 14.3, SD 1.7) [17]. Thomas et al [18] assessed the readability of Wikipedia pages related to renal diseases and found that they were written at a university reading level. Similar findings were obtained by other scholars. Tulbert and colleagues [19], in their analysis of dermatological online resources, compared 3 popular websites providing patient-education material (WebMD.com, Wikipedia.org, and MedicineOnline.com) versus the online material produced by the American Academy of Dermatology. Rajagopalan and coworkers [20], in their appraisal of patient-oriented cancer information on the Internet, compared Wikipedia with a professionally maintained database and found that the latter was more readable (Flesch-Kincaid Grade Level 14.1 vs 9.6, respectively). Azer [21] assessed 39 Wikipedia articles related to gastroenterology and hepatology and computed a mean overall readability score of 26 (SD 9.0) (range –8.0, SD 55.7 to 44.4, SD 1.4). Volsky and coauthors [22], in their analysis of pediatric otolaryngology online resources, compared Wikipedia, eMedicine, and MedlinePlus. They found that Wikipedia was the least readable resource. Brigo and Erro [23] analyzed the Wikipedia page related to Parkinson disease and found a low readability level (Flesch Reading Ease score 30.31).

Very recently, a collateral Wikipedia project named Simple English Wikipedia has been developed and implemented with the aim of helping users to better read and understand uncommon, unfamiliar, or complex topics, by simplifying the Wikipedia articles. Pages written in simple English use fewer words and easier grammar than those written in standard English. Although generally aimed at students or children, Simple English Wikipedia may be helpful for people with low literacy skills, even though these pages are less accessed than those written in standard English. Therefore, the initiative of the Simple English Wikipedia should be further encouraged. For example, a direct link to it should be added in each corresponding standard English Wikipedia article, thus supporting and facilitating consultation of Simple English Wikipedia.

Other similar ongoing projects include the WikiProject Epilepsy, specifically focused on epilepsy-related Wikipedia pages. Under the leadership of the International League Against Epilepsy and a committee of well-known scientists including Günter Krämer, Selim Benbadis, and Nicola Maggio, existing epilepsy-related entries are being critically revised and edited, and as well new entries are being created to provide the public with a comprehensive, clearly accessible database including both articles and video sequences of seizure episodes with commentary.

Another project, a collaboration of the Imperial College School of Medicine (ICSM) and the WikiProject Medicine (the so-called ICSM Wikipedia Easter Project), aimed to bring together medical students and professors, librarians, and technologists in a 2-day competition to edit and provide updated content for a selected medical topic. However, this project, like the WikiProject University of California, was intended as a challenge rather than as a long-lasting initiative.

Professionals working in the field of health care, helped by public and specialized libraries, as well as by other stakeholders, should make efforts to design or to bookmark online health-related material that, while preserving a high quality, accuracy, and exhaustiveness, can be easily read and understood [9].

Moreover, a particular attempt should be made to simplify information on pathologies with a low incidence and prevalence and with a complex pathogenesis, also taking into account onset age, since the Internet presents a highly valued opportunity of supporting patients with rare autoimmune diseases [24].

In the field of autoimmune diseases, to the best of our knowledge, no eHealth initiatives exist with the goal of improving the quality of disease-specific online material. Our study has contributed to drawing attention to the low readability content of autoimmune disease-related Wikipedia pages, emphasizing the urgent need to establish some forms of cooperation between doctors and patient groups working

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together to make easily accessible disease-specific websites and online materials.

Conclusions

This study addressed a topic currently neglected in the immunologic research field. While other medical fields have addressed the subject of Wikipedia readability (such as the neurological field), there is a dearth of similar studies in the specialties of immunology and autoimmunology. Our investigation was aimed at filling this gap in knowledge. Our findings underline the need for accessible and easily understandable online material dedicated to autoimmune disorders to further improve patients' health literacy and awareness of their conditions. Even though readability metrics are only an indirect measure of literacy skills, being reliable and validated, they can provide a first objective assessment of the complexity of written material, guiding the process of customizing online health-related material to the patient's reading level and, thus, enhancing patient-centered communication [25,26].

Acknowledgments

The authors wish to thank Mr Abed El Rahman Wattad for help in the preparation of the Table of Contents image.

Conflicts of Interest

None declared.

Multimedia Appendix 1

One-way analysis of variance.

[PDF File (Adobe PDF File), 37KB - jmir_v19i7e260_app1.pdf]

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Abbreviations

AARDA: American Autoimmune Related Diseases Association
ARI: Automated Readability Index
ICSM: Imperial College School of Medicine
SMOG: Simple Measure of Gobbledygook

Edited by G Eysenbach; submitted 16.06.17; peer-reviewed by C Perricone, M Martini, G Murdaca; comments to author 05.07.17; revised version received 06.07.17; accepted 09.07.17; published 18.07.17.

Please cite as:
Watad A, Bragazzi NL, Brigo F, Sharif K, Amital H, McGonagle D, Shoenfeld Y, Adawi M
Readability of Wikipedia Pages on Autoimmune Disorders: Systematic Quantitative Assessment
J Med Internet Res 2017;19(7):e260
URL: http://www.jmir.org/2017/7/e260/
doi:10.2196/jmir.8225
PMID:28720555

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Original Paper

What Patients Value About Reading Visit Notes: A Qualitative Inquiry of Patient Experiences With Their Health Information

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Abstract

Background: Patients are increasingly asking for their health data. Yet, little is known about what motivates patients to engage with the electronic health record (EHR). Furthermore, quality-focused mechanisms for patients to comment about their records are lacking.

Objective: We aimed to learn more about patient experiences with reading and providing feedback on their visit notes.

Methods: We developed a patient feedback tool linked to OpenNotes as part of a pilot quality improvement initiative focused on patient engagement. Patients who had appointments with members of 2 primary care teams piloting the program between August 2014-2015 were eligible to participate. We asked patients what they liked about reading notes and about using a feedback tool and analyzed all patient reports submitted during the pilot period. Two researchers coded the qualitative responses (κ=.74).

Results: Patients and care partners submitted 260 reports. Among these, 98.5% (256/260) of reports indicated that the reporting tool was valuable, and 68.8% (179/260) highlighted what patients liked about reading notes and the OpenNotes patient reporting tool process. We identified 4 themes describing what patients value about note content: confirm and remember next steps, quicker access and results, positive emotions, and sharing information with care partners; and 4 themes about both patients' use of notes and the feedback tool: accuracy and correcting mistakes, partnership and engagement, bidirectional communication and enhanced education, and importance of feedback.

Conclusions: Patients and care partners who read notes and submitted feedback reported greater engagement and the desire to help clinicians improve note accuracy. Aspects of what patients like about using both notes as well as a feedback tool highlight personal, relational, and safety benefits. Future efforts to engage patients through the EHR may be guided by what patients value, offering opportunities to strengthen care partnerships between patients and clinicians.

(J Med Internet Res 2017;19(7):e237) doi:10.2196/jmir.7212

KEYWORDS

patient participation; quality improvement; electronic health records; patient portals

Introduction

As the trend toward greater transparency accelerates in health care, clinicians with electronic health records (EHRs) and patient portals are inviting patients to view online laboratory results, medication lists, and more recently, visit notes [1-2]. Health care consumers are seeking more data [3], but little is known about their experiences reading and using this information. A better understanding of what motivates patients to interact with their health data may inform efforts that promote patient engagement through patient portals. Thoughtful EHR and patient

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portal design may be leveraged to strengthen patient and family-centered care and patient-clinician relationships [4-8].

Although clinicians often report negative experiences with the EHR, patient attitudes about the EHR may be more neutral or even positive [9-11]. Greater health information transparency, more rapid communication, patient-friendly educational resources, and easier access to the medical record can send a powerful message of inclusivity to patients and families. What was once the purview of clinicians alone is increasingly shared with patients and families and can lead to better informed shared decision making [12]. Today, over 15 million patients in 40 states have easy access to their visit notes (OpenNotes) through their patient portal [13]. As OpenNotes spreads, sharing health information shows promise not only for patient engagement and adherence [14-16], but also for relational benefits such as enhanced patient trust and satisfaction [17,18].

Even though millions of patients can log on to patient portals to read notes, we understand little about what they value in doing so, perhaps because information sharing has been largely one-way and passive. Opportunities to more effectively connect with various patient populations and family care partners through shared notes are vast, but relatively under-explored [19-22], and patients, families, and communities remain a largely untapped resource as health partners [8]. As patients increasingly gain access to visit notes, they may uncover errors or discrepancies in their records, and they generally lack a systematic way to report this feedback [23]. Tools to guide patients on their health data and systems to efficiently and effectively hear their feedback are needed.

To learn more about the patient experiences with their notes, we piloted an online OpenNotes patient reporting tool as part of a quality improvement initiative [23]. In a 12-month test, we asked patients to report possible inaccuracies in notes. In addition to characterizing patient-identified errors [23], we aimed to understand whether patients thought reading notes and providing feedback was valuable, and if so, why. We envisioned that what patients and care partners value about interacting with their notes could inform organizational patient engagement strategies and further drive patient and family-centered care. This paper focuses on their qualitative responses.

Methods

The OpenNotes Patient Reporting Tool

The patient reporting tool was designed together with patients and family members, as well as with Patient Relations and Health Information Management personnel, Patient Safety leadership, clinicians, and other stakeholders. This multidisciplinary team of stakeholders met every other week for nine months to plan the reporting tool and supporting patient education materials, including a patient FAQ specifically designed for the project [23]. These materials underwent several iterations after review by our team, a plain language specialist, and several additional PFAC members who tested the tool and education links. The final patient reporting tool was a 9-item form accessible through a “My Feedback” link located at the end of each visit note. Participants had to first read the note in order to use the reporting tool. Either patients or their care partners (CPs) could complete the form. Questions included whether patients (or CPs) understood the note and care plan, identified possible inaccuracies in the note, had positive feedback for their providers, and found the reporting tool valuable.

Respondents who found the opportunity to read and provide feedback on notes to be “very valuable” or “somewhat valuable” were asked: “What do you like about reading or providing feedback on your note?” We chose this broad exploratory question intentionally because there is little existing data on why patients engage with their health data, how they feel about reading notes, or what benefits they may perceive from a feedback tool linked to their notes. We used this expansive approach because we did not have a preference regarding whether patients responded to their attitudes about reading notes or about using the reporting tool, given that both could inform patient engagement strategies. We anticipated there would be some overlap in responses since patients had to read notes in order to use the tool, but we also hypothesized that some patients may value reading notes alone, and simply use the tool to share this information. Finally, although we considered asking two separate questions, we prioritized streamlining open-ended questions to prevent losing patient interest in completing the form. We anticipated that results from a single exploratory question could then inform more specific future queries as well as targeted interventions to further engage patients and care partners, based on what matters to them the most.

Participants

All patients with portal access and a visit note by a participating provider during August 2014-August 2015 were invited to participate in the feedback project. Patients received an email notification when a note became available including a link to frequently asked questions (FAQ) [23] and a dedicated email address for any project-related concerns. Patients were told that “The goal (of the project) is to help patients and their providers work together to make sure the information in each patient’s medical record is accurate and care is the best it can be. We also hope to learn what patients like about reading their notes.” Patients were also told that at the end of the QI project, all comments would be de-identified and used to promote organizational learning and quality improvements.

We launched the pilot quality improvement (QI) project with clinicians from 2 of 10 teams in our hospital-based primary care practice. OpenNotes was already implemented at our organization and providers were offered the opportunity to opt-out of participation. As part of the OpenNotes policies at our medical center, clinicians can also “hide” individual notes, such that they do not appear on the portal, although <1% do so (personal communication, Lawrence Markson, MD, Vice President, Clinical Information Systems, BIDMC). All other notes generated by the participating providers included the “My Feedback” link and an invitation for patients to use it.

Analysis

Two researchers (SKB and MG) independently reviewed and coded a subset of responses to identify common themes.

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Through discussion, the two researchers merged the themes to develop a codebook, and then coded another subset of responses. Each subset comprised an independent (ie, not previously coded) 10-20% of the data. They repeated this process until no new themes were found. All disagreements were resolved through discussion. Next, the researchers used the codebook to separately code another set of responses and tested reliability between the two researchers (κ=.74). Finally, one researcher (MG) coded the remaining responses using the same codebook.

Ethics

The proposal for implementation and evaluation of the OpenNotes patient reporting tool was reviewed by our institutional review board and determined to be a quality improvement program. Data collected were integrated into existing QI workflows and used in real time to improve care. Patient participation was voluntary. Patients were told that they, and their provider, might be contacted by Patient Relations personnel if their report pointed to a safety concern. Otherwise, the data populated an aggregate database from which we generated de-identified comments for this analysis. We informed patients that de-identified comments would be used to promote organizational learning and quality improvements. Further details of the methods and patient communications have been published elsewhere [23].

Results

We analyzed consecutive reports submitted by patients and care partners over the 12 months of the pilot period. In total, 260 reports were submitted; of which, 256 (98.5%) reports indicated that the tool was valuable, and 179 (68.8%) reports included a qualitative response to what patients liked about the OpenNotes reporting tool process. Compared with patients who submitted a report but did not respond to the voluntary qualitative question, patients who provided a response were slightly older; otherwise patient characteristics were not significantly different between the two groups (data not shown). Responses highlighted a total of 8 key themes, presented below. Four themes pertained to what patients value about the content of notes, and the other four described what patients liked about using the reporting tool (for which reading notes was implicit).

What Patients Value About Note Content

Confirm and Remember Next Steps

For many participants, notes served as an extension of the visit. One patient noted:

> *I sometimes have white coat syndrome where I am a little nervous in the doctor's office and then cannot remember all that was said. Reading the notes after my visits confirms what I have heard.*

By far the most common theme, reading visit notes helped patients to better remember next steps. Many commented on turning to notes as a reminder of tests or other recommended follow-up.

Several participants alluded to the stressful nature of the visit:

> *I think it is a great way to double check I didn't miss anything if I was not feeling well or was too overwhelmed.*

Patients liked reviewing what happened at the visit in the comfort (and pace) of their own homes:

> *Reading the note takes the burden off of me to remember the details of what we discussed and becomes a useful reference for me.*

They also liked the ability to confirm or double-check the doctor's recommendations independently:

> *If I forget something, I can go back and read the plan without having to bother the doc[tor].*

Quicker Access and Results

Patients and CPs valued the opportunity to have access to records and results, stressing the importance of being able to view this information quickly and at any time. Participants found the notes particularly valuable because they provided context. One patient commented:

> *I like knowing what the results of my tests mean. The records [laboratory results] show the numbers but the notes provide the interpretation in regards to my personal health status.*

Participants also liked having longitudinal access to notes, and the benefits of a consolidated reference, "all in one place." Like an "encyclopedia on a shelf," OpenNotes provided patients with a cohesive roadmap over the arc of their health journey:

> *It is now all on record for me to review…and not just after the consult. Allows for history."*

Patients noted a heightened sense of ownership of their records and their health when they could review and interact with their notes collectively and comprehensively over time:

> *Doctors' notes are my medical history and until OpenNotes patients had no insight into what is ultimately my medical history.*

Positive Emotions

Reading notes helped patients gain confidence in their providers, "*confirm[ing] that…care is being handled well.*" It also generated additional positive emotions like hope and encouragement. One patient wrote, "*I like reading my notes because they keep me uplifted.*" Another added, "*I feel less helpless and perhaps more hopeful.*" Participants highlighted the relational benefits of "being heard." Their comments described a powerful "validation" from reading notes, and feeling listened to and cared for:

> *We have had a funeral and a hectic week. I felt like someone cared. May seem quite simple but it was a nice human touch. I am a nurse and I am impressed.*

Sharing Information With Care Partners

The invitation to read notes and provide feedback was particularly appreciated by care partners who support vulnerable patients. In particular, they found notes essential to the coordination of care for their loved ones:

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> *We are grateful to receive "notes" to be able to review the visit and procedures (if any) performed. Especially helpful for older patients who may have hearing and/or some cognitive [or] memory loss.*

Patients liked the option to give their note to care partners too: "*I like that I'm able to share how my visit was,*" and "*I can reference info[rmation] to inform my family [and/or] wife [of] what is going on.*" Another patient added, "*I don't have to take tons of notes myself…to make sure I understood.*" OpenNotes connected care partners with information that they may not have otherwise had access to, and provided a way for them to stay updated on medication or treatment plan changes.

What Patients Value About Their Use of Notes and the Reporting Tool

Accuracy and Correcting Mistakes

Patients and care partners commonly noted that what they like about reading notes and providing feedback is the new ability to confirm the accuracy of the note and catch potential errors. As one patient noted, "*I like to see that my medical records as embodied in the notes are consistent with the conversation I have had with my doctor.*" Another noted, "*I appreciate the open exchange and the opportunity to correct any possible misunderstandings.*" Finally, some patients liked testing the accuracy of their own communication, welcoming the opportunity to clarify misunderstandings about their report of symptoms or history through the tool.

> *[Reading] my notes allows me to see how well I am communicating my issues, which leads to how well my doctors are hearing and documenting my issues. It also allows me to catch errors.*

While some clinicians worry that patient-found mistakes may lead to casting blame or trust erosion, several participants explicitly commented on understanding human fallibility and wanting to play a role, alongside their provider, in contributing to note precision: "*It is easy to make a mistake when writing a note. I like that they can be reviewed for accuracy.*" Another added: "*We can work together to make notes accurate, understood, and…a good resource for future medical care.*"

Partnership and Engagement

Patients frequently noted that they liked reading notes to "*[Make] sure that we are on the same page,*" and that the feedback tool enhanced a sense of partnership with their clinicians. Participants described notes as a window into how their provider thinks:

> *I like that level of communication and the ability to see the doctor's thought process. The more open communication there is, the better care I, as an active participant, have access to.*

Patients also saw engagement through OpenNotes and the reporting tool as a two-way street:

> *Reading the notes can only make me come to my appointments better prepared and help my team understand what issues are important to me and what I need them to hear.*

Moving away from the traditional paternalistic view of medicine, the reporting tool encouraged shared agency for health: "*It puts me in an active rather than passive position and cuts out red tape.*" Several responses addressed the value of inviting patients to provide input. One participant noted, "*Health care should be a two-way conversation; this forum provides another opportunity for that.*" Another commented, "*[The note] helps me feel that my [doctor] and I are partners in promoting my health.*"

Finally, several patients and CPs commented on the level of detail, articulation, and precision in the notes. The comprehensive nature of notes helped patients feel that their provider "knows" and cares about them, strengthening a therapeutic alliance through shared values and goals.

Bidirectional Communication and Enhanced Education

Patients and CPs often described reading notes as playing a significant role in improving communication between patients and providers, while also increasing learning. As one patient stated, "*It is an opportunity to become more knowledgeable about my condition and how I can manage it better.*" Patients and care partners emphasized the power of print, indicating that some learning styles favor written information, and the importance of an enduring reference: "*I very much appreciate the opportunity to see again in writing what was discussed.*" Patients also reported feeling more informed and gaining a better understanding of their health condition as a result of reading notes, and that the reporting tool extended "teach-back" opportunities from providers to patients, with an opportunity for bidirectional communication:

> *I like the educational and improvement potential of the process. I learn. My provider learns. All good.*

Several reports also emphasized that reading notes and providing feedback affords patients a way to share information without bothering their providers: "*It allows more frequent non-intrusive communication with doctor.*" Patients liked the chance for "*no embarrassing face to face asking of questions if [they] want to understand or know more.*"

Importance of Feedback

Patients embraced the opportunity for feedback on many levels: receiving feedback about their health and how they are doing in various aspects of their care, and giving feedback to their providers. Many patients liked the tool because it offered a new way to share positive feedback: "*I appreciate the opportunity to praise my healthcare providers.*" Others saw the tool as a safe haven for feedback:

> *This is a way to [confidentially] reflect a patient's reaction to a provider without "causing trouble." I will use it a lot.*

Another noted:

> *This new project, [OpenNotes] Feedback, is terrific. Finally. Because it is [confidential] I will use it with a mental comfort I have not had till now—over 10 years.*

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Some patients read notes as a self-feedback mechanism—a way to check how well they were communicating and understood by their providers.

Patients also valued feedback as a way to contribute to the note, for example adding missing information patients found important. Several comments reflected an understanding of quality improvement and a desire to participate in making care better: "*Having the opportunity to provide feedback is important to moving the program forward and helps stimulate innovation.*" Patients appreciated being asked for their input, irrespective of whether they identified a potential safety concern in their note:

> *I am happy that you asked for feedback—if only so that I can say how helpful it is and how pleased I am to have this site available to me.*

As above, patient comments drew a link between the invitation for feedback and the effect of inclusivity on strengthening patient-clinician relationships:

> *Being able to provide feedback is very important to me as well. I feel it keeps me connected to my health care providers.*

Discussion

Principal Findings and Implications

With little knowledge on what motivates patients to engage with their health data, we sought to characterize what patients value about reading visit notes as part of a quality improvement initiative. Our findings highlight several insights. Patients and care partners described priorities that can be leveraged to design patient portals that better support patients and families while improving quality of care. For example, participants liked reading notes to remember and confirm next steps. They felt less overwhelmed and more proactive in their care as a result of reading notes. Patients valued the ability to go back to their health information at their own pace and leisure as an enduring, longitudinal resource; open bidirectional dialogue with clinicians and the ability to ask questions with "non-embarrassing" face to face dynamics; and quicker access to notes and results, an established ambulatory care safety priority [20]. Additionally, patients reported developing a greater understanding of their condition from reading notes and liked learning about "the doctor's thought process." Taken together, the specific features that patients valued have direct implications for strengthened shared decision making and informed consent [12,24,25].

Participants also particularly valued the ability to check note accuracy and to share notes with family care partners. A feedback mechanism that encourages commentary from patients and care partners, who may catch possible documentation errors or clinically important oversights in the notes, may also improve portals and care. Poor electronic health record interoperability is a recognized problem [26], medication errors are frequent, and missing information poses a safety threat, particularly for vulnerable patients with complex care needs. As supporting family care partners of older or vulnerable patients becomes a health care priority [21], OpenNotes and the reporting tool may empower care partners with health information and provide a space for their feedback. Though some studies question whether patients would be willing to identify errors [27], our findings resonate with recent reports showing that patients and families can recognize quality problems [28,29], and suggest that at least some patients and care partners particularly value working alongside their providers to ensure their records are accurate.

Shifting the nexus of control away from clinicians alone to one that is shared with patients and families and reflects their values has been described in the literature as patient-centered care, person-centered care, and relationship-centered care, among other terms [8,30]. Here, we refer to "patient and family-centered care" although several of the other terms also apply. In our findings, patients suggested that an invitation to read notes and use the reporting tool sends a message of inclusivity and empowerment, validating patients as capable change agents. Such comments resonate with experts' support for "democratization of health care," shifting traditional power relationships in medicine, and bringing patient and family voices more consistently to health decisions, system design and patient activation tools so that they can engage in ways that "matter most to them" [8,12]. Inviting patients and families to read notes and give feedback helps to level the playing field, providing more information needed for participation in care. Recognizing that while some patients want to be included in decision-making and treated as experts or safety partners regarding their own experience [31], not all patients desire this degree of engagement [32], and hence the evolution of patient portals should work toward closing the digital divide while respecting individuals' choices. As information transparency spreads, our findings can help inform patient and family-centered strategies that further engage those patients who seek their health data (Table 1).

Portals and electronic information are never a substitute for meaningful face-to-face time with clinicians. But although doctors worry that computer use during shorter visits can make clinical interactions feel impersonal [33], patients who read notes liked "feeling heard," describing a deeper sense of caring and respect, and improved patient-clinician relationships. OpenNotes is not a solution for the shortcomings of the EHR, but it may help make the computer feel like less of an obstacle and more of a shared resource, particularly if clinicians turn it toward patients' view and actively invite them to read notes and even provide feedback after the visit. Although some health care providers worry that doing so may increase liability or erode trust, our findings suggest that this innovation may strengthen partnerships with clinicians, consistent with prior studies and data in other fields suggesting that transparent communication enhances trust [18,34].

The availability of notes may also make face-to-face time more effective. Some patients felt more attentive or present during visits because they didn't need to take copious notes, knowing they could access the documentation later. Because patients can go back to notes repeatedly and at patients' own leisure and pace, reading notes may extend the visit, and clinicians may find opportunities to take advantage of this extra "time with patients." With patients as a consistent audience to notes, clinicians may even begin to adapt note-writing in the future to be more personalized, trust-building, or even therapeutic [35].

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Table 1. What patients value about OpenNotes: further engaging patients who use the portal.

What patients value	Implications for patient and family-centered quality of care
Note content	
Confirm and remember next steps	• Improve adherence and follow up
Quicker access and results	• Unburden patients during and after visit, feel less overwhelmed
Easy and long-term access to EHR as a consolidated reference at patient's own leisure and pace	• Enable patients to track progress over time; potential for increased "ownership" of healthcare issues (patient accountability) • Facilitate patient engagement in diagnostic process
Positive emotions	• Improve patient experience
Encouragement and "whole person" care	• Foster humanism in patient care
Sharing information with care partners	• Better support care partners with comprehensive clinical information • Potentially avert medical errors or preventable readmissions for vulnerable patients due to poor information transfer
Use of notes and the reporting tool	
Accuracy and correcting mistakes	• Empower patients to identify and correct documentation errors
Partnership and engagement	• Strengthen patient-clinician relationships including enhanced trust • Activate patients in their care • Facilitate patient engagement in diagnostic process
Bidirectional communication and enhanced education	• Open transparent dialogue with emphasis on inclusivity • Non-intrusive or non-embarrassing way to ask questions • Provide enduring resource, and "power of print" for visual learners
Importance of feedback	• Involve patients in QI efforts • Create mechanism for positive patient feedback; curb provider burnout

Finally, we were struck by patients' interest in praising their providers and their description of positive emotions stemming from reading notes. At a time when clinician burnout is in the spotlight [36,37], it is intriguing to consider the potential positive relational effects of OpenNotes on both providers and patients. Creating a space for patients to provide positive feedback for clinicians may bolster morale and even influence positive culture change if amplified across practice settings. Like clinicians, patients and care partners too may be alienated, emotionally distanced and exhausted from interactions with a fragmented and depersonalized health care system [38]. Mechanical, template notes with abundant copy and paste material may exacerbate the problem, and OpenNotes may make this problem more "visible." On the other hand, restoring some patient narrative to notes may help patients feel heard. Assimilation of multiple visits through integrated note access on a single portal may help unify the patient's perception of care, particularly if clinicians refer to each other's notes, as patients learn about how the team works together. Additionally, similar to approaches to decrease burnout for clinicians, enhancing meaningful connections between patients and providers through supportive language in notes and a sense of belonging to the team may be a valuable strategy.

Although these reports reflect the perspectives of patients and care partners who are already engaged by reading notes, organizational exploration of what patients value about note transparency can have a large impact, considering that over 15 million patients have access to their notes across the country today [13]. Building a system in which people want to engage requires knowing what matters most to them. We were struck that half of the themes described by patients reflected what patients valued about reading notes alone, suggesting that simply sharing notes (even without a patient reporting tool) can help patients better remember the care plan, feel less overwhelmed, gain quicker access to results, generate positive emotions, and enable information sharing with care partners. The other themes—ensuring note accuracy, enhanced engagement and partnership, bidirectional communication and education, and the opportunity for feedback and inclusivity—are also valued by patients who read notes, and further strengthened by a patient reporting tool. These can serve as important first steps to inform patient engagement strategies through the patient portal (Table 1). Additional research and health literacy supports are needed to learn what matters most to patients and families who are not yet registered on patient portals and to make that information accessible to them in meaningful ways.

Limitations

Our findings are limited by the small size of a pilot initiative at a single institution. Respondents likely represent a self-selected population, biased toward activated patients who are registered on the patient portal, use OpenNotes, and are from one geographic area. Patients at our medical center are largely white and more likely to have a 4-year college degree or higher. This quality improvement initiative was designed specifically for one health care organization, limiting generalizability to other patient populations. Although a formal analysis of additional

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sites is beyond the scope of this report, as the OpenNotes reporting tool has expanded to other clinical settings and organizations, we are seeing similar themes surface, reflecting our findings.

Conclusion

In summary, as EHR transparency spreads, new ways for patients to engage with their data in ways that matter to them most and to comment on their records are needed. Many aspects of what patients and care partners like about reading notes and providing feedback have important implications for improving patient and family-centered quality of care, safety, and patient-clinician relationships, and can also inform future patient engagement strategies and patient portal design.

Acknowledgments

The authors thank Melissa Anselmo, Hannah Chimowitz, Tom Delbanco, Rossana Fazzina, Beth French, Amy B Goldman, Heidi Jay, Margaret Jeddry, Jing Ji, Gila Kriegel, Suzanne Leveille, Julia Lindenberg, Lawrence Markson, Roanne Mejilla, Caroline Moore, Elana Premack-Sandler, Barbara Sarnoff Lee, Ken Sands, Qiang Wang, Guoping Xu, and the Patient and Family Advisors at Beth Israel Deaconess Medical Center for their valuable contributions to the OpenNotes patient reporting tool. They also thank the patients and care partners who used the tool and shared their insights. Portions of this manuscript were previously presented at the Society of General Internal Medicine national meeting 2015, Toronto, Ontario; the National Patient Safety Foundation Congress 2016, Scottsdale, Arizona; and the 2016 American Academy on Communication in Healthcare Research Forum, New Haven, Connecticut. This study was supported by a grant from CRICO Risk Management Foundation of the Harvard Medical Institutions.

Conflicts of Interest

None declared.

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Edited by C Gibbons; submitted 22.12.16; peer-reviewed by L Garvin, G Fix; comments to author 05.02.17; revised version received 24.03.17; accepted 19.04.17; published 14.07.17.

Please cite as:
Gerard M, Fossa A, Folcarelli PH, Walker J, Bell SK
What Patients Value About Reading Visit Notes: A Qualitative Inquiry of Patient Experiences With Their Health Information
J Med Internet Res 2017;19(7):e237
URL: http://www.jmir.org/2017/7/e237/
doi:10.2196/jmir.7212
PMID:28710055

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Original Paper

Consumer Adoption of Personal Health Record Systems: A Self-Determination Theory Perspective

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Abstract

Background: Personal Health Records (PHR) systems provide individuals with access and control over their health information and consequently can support individuals in becoming active participants, rather than passive recipients, in their own care process. In spite of numerous benefits suggested for consumers' utilizing PHR systems, research has shown that such systems are not yet widely adopted or well known to consumers. Bearing in mind the potential benefits of PHRs to consumers and their potential interest in these systems—and that similar to any other type of information system, adoption is a prerequisite for realizing the potential benefits of PHR systems—research is needed to understand how to enhance the adoption rates for PHR systems.

Objective: This research seeks to understand how individuals' intentions to adopt PHR systems are affected by their self-determination in managing their own health—the extent of their ability to take an active role in managing their own health. As such, this research aims to develop and empirically validate a theoretical model that explains PHR systems adoption by the general public through the integration of theories from the information systems and psychology literatures.

Methods: This research employs a cross-sectional survey method targeted at the Canadian general public without any prior experience in using PHR systems. A partial least squares approach to structural equation modeling was used to validate the proposed research model of this study (N=159).

Results: Individuals with higher levels of ability to manage their own health (self-determination) are more likely to adopt PHR systems since they have more positive perceptions regarding the use of such systems. Further, such self-determination is fueled by autonomy support from consumers' physicians as well as the consumers' personality trait of autonomy orientation.

Conclusions: This study advances our theoretical understanding of PHR systems adoption. It also contributes to practice by providing insightful implications for designing, promoting, and facilitating the use of PHR systems among consumers.

(J Med Internet Res 2017;19(7):e270) doi:10.2196/jmir.7721

KEYWORDS

health records, personal; health care information systems; online systems; technology; intention; physician patient relationships; personal autonomy; psychological theory; social theory; behavior

Introduction

Background

A personal health record (PHR) system is an information system that comprises data as well as supporting tools and functionalities related to an individual's health. The most cited definition of a PHR system [1,2] was put forth by the Markle Foundation [3] as: "An electronic application through which individuals can access, manage, and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment."

Personal health records are created, owned, updated, and controlled by individual consumers or others authorized by them. Ideally, they contain a summary of the consumer's lifelong

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health information such as their history of previously undertaken health procedures, major illnesses, allergies, home monitoring data (eg, blood pressure), family history, immunizations, medications, and laboratory test results [4]. Such access to health records can be leveraged with the support of tools and functionalities for the purpose of better managing one's health [1,5,6]. Examples of such functionalities include allowing the consumer to communicate electronically with clinicians [1] and to share records with clinicians [7]. The PHR definition in this paper is consistent with that in International Organization for Standardization Technical Report 14292 [8]. Throughout this paper, the words "consumer," "individual," and "patient" are used interchangeably since PHR system consumers are not necessarily dealing with immediate medical concerns and can be ill or healthy.

When successfully implemented and used, PHR systems have the potential to facilitate a transformative advancement in health care delivery and management. Such advancements are likely to be in the form of "improved interactions between patients and care providers," increased "opportunities to realize innovation in care management," "a shift in the locus of control of health information" to a more shared control between patients and care providers, and improved "efficiency in care" [5,6].

In spite of numerous benefits suggested for consumers' utilizing PHR systems [9-14], research has shown that such systems are not yet widely adopted or well known to consumers [9,10,15-23]. Bearing in mind the potential benefits of PHRs to consumers and their potential interest in these systems [11,24,25]—and that similar to any other type of information system (IS), adoption is a prerequisite for realizing the potential benefits of PHR systems [26]—research is needed to understand how to enhance adoption rates for PHR systems.

By providing individuals with access and control over their health information, PHR systems can support individuals in becoming active participants, rather than passive recipients, in their own health care process [1,2,27-29]. However, for such systems to provide the right support for their user, the user must disburse an "ongoing" effort to keep their account up to date. Such an ongoing effort reduces the amounts of (and likelihood of) outdated, inaccurate, or incomplete information in the record, which could result in the wrong health care decisions being made [1]. PHR systems are examples of an emerging class of information systems that, through providing access and control to useful information with an associated need for ongoing maintenance (eg, updating one's health record regularly) which entails a significant effort, support individuals in taking a more active role in the context for which the information system is designed [30,31]. Examples of such systems in other contexts include social networking systems (social context) and personal finance management systems (financial context). We argue that users of such systems must accept and be able to take a more active role in managing the behavior supported by the information systems (eg, managing their own health). The users must espouse the appropriate personal traits and be supported by the right environmental factors to facilitate their taking on such an active role. This provides them with the appropriate level of motivation to use such systems in spite of the required ongoing maintenance effort [31]. From this perspective, understanding the adoption of such systems warrants augmenting existing information systems and PHR adoption models.

Hence, this research seeks to understand how the extent of individuals' ability to take a more active role in managing their health could affect their intentions to adopt electronic PHR systems. We further seek to understand some of the important personal and environmental antecedents that support the individual in accepting and practicing such an active role in their own health management. This is accomplished by proposing a PHR systems adoption model through the integration of theories from the information systems and psychology literatures. This model is then validated through an empirical study involving a stratified sample of 159 Canadians, leading to important results with implications for theory and practice.

Objectives

Several studies have investigated the factors responsible for the lack of PHR adoption (eg, [1,16,32-41]). Of particular interest to our study, behavioral and environmental factors are suggested to impact PHR system adoption [1]. It is widely believed that proper use of PHR systems would support a change in the role of consumers from passive recipients of treatment to active partners (with health care providers) in their health management process (eg, [1,2,27-29]). Such partnership includes, for example, consumers' seeking health information [42], managing their own health and wellness [1,5,19,43], and becoming more involved in their health care decision making [19]. As such, a PHR system can be more useful for the individual owner only if they understand and accept a more active role as well as new responsibilities related to their own health care [1]{Formatting Citation}. The influence of consumers' ability (readiness) to take such an active role in their adoption of PHR systems is not examined in the literature. As such, this study draws on information systems and psychology literature to understand how consumers' readiness to take a more active role in their health and wellness management could influence their adoption of PHR systems. The existing IS literature also calls for research that helps us understand what would give rise to "effective" IS use, rather than just IS use [44], which is in line with the arguments made above for observing the conditions (ie, considering the aforementioned role change) for effective PHR usage.

To understand how to enhance PHR adoption rates, we integrated mainstream IS adoption models with Self-Determination Theory (SDT), which is a theory of motivation from the field of psychology. SDT sheds light on the mechanisms through which individuals become able and motivated to take active (rather than passive) roles when engaging in different types of behaviors including individual health care [45]. As such, the justification for augmenting IS adoption models with SDT in this context is twofold. First, motivation is generally an important consideration in IS adoption [46,47]. More specifically, lack of proper motivation has been identified as a major inhibitor for adoption of PHR systems [1]. Second and as explained above, for PHR systems to be useful requires consumers to understand and accept (ie, being able and ready for) a change in their roles in their own health

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management, from passive to active [1]. As such, the main objectives of this research are to (1) develop and empirically validate a model to understand how individuals' perceptions of the extent to which they feel able in managing their own health (self-determination) would influence their intentions to adopt PHR systems, and (2) assess the impacts of the environmental factor of physician autonomy support and the behavioral factor of individuals' autonomous causality orientation on their perceptions of being self-determined in their health management behavior.

This paper builds, in part, on existing studies on PHR systems in order to develop and validate an adoption model for PHR systems while maintaining novelty by being the first to observe the following unique set of characteristics: (1) it (the paper) is targeted at the general public and not a specific segment of the population, (2) it focuses on integrated PHR systems—systems that gather and present data from multiple sources (eg, consumer, care provider, health care organizations) into a single view, generally through secure Internet access [2,5,48], (3) it is not disease specific (ie, relates to health and wellness management in general), (4) it is grounded in theory as it integrates mainstream IS adoption models with SDT, and (5) it employs a rigorous hypothetico-deductive method for validation of findings.

Multimedia Appendix 1 provides the positioning of this paper in relation to the existing studies in great detail.

Theoretical Development

Viability of Self-Determination Theory to Help Explain Personal Health Record System Adoption

A PHR system has the potential to empower individual owners to play a more active role in their health management [28,49-52]. Thus, a PHR system can be more useful for the individual if they understand and accept (ie, are able and ready for) this more active role (in their health management) as well as the new responsibilities associated with this active role [1]{Formatting Citation}. From psychology literature, SDT is a theory that is potentially useful for explaining ability and motivation in the context of individual health management. SDT explains the mechanism through which individuals become able and motivated to take more active (rather than passive) roles in engaging in different types of behaviors including individual health care [45]. This theory is also considered to be the guiding principle of patient empowerment [53]. It is also believed that this theory is well suited for understanding the role of information technology in consumer-based health care [49]. Finally, given the frequent calls for theory development in this context (eg, Pingree et al [54]) as well as the need for clarifying the IS "nuances" involved in IS adoption research [55], integrating SDT with mainstream IS adoption models, in order to explain the adoption of PHR systems, is both promising and necessary. As such, this integration serves the overall objective of this research.

SDT represents a broad framework for the understanding of human motivation and personality. SDT begins with the assumption that human beings are active organisms with evolved tendencies toward growing, mastering new skills, applying their talents responsibly, learning, and integrating new experiences into a sense of self. As such, they tend to behave in a "self-determined" way [45]. SDT asserts that the more a behavior is self-determined for an individual, the more the individual will be able and motivated to take an active (rather than passive) role in that behavior. However, such human tendencies and self-determination require ongoing support from the social environment. Without such ongoing support, human spirit can be diminished, and individuals might reject growth and responsibility [45].

Research guided by SDT shows the importance of "environmental" (eg, physician behavior) and "consumers' personality characteristics" in explaining differences in self-determination and motivation, "within" and "between" individuals respectively [45]. According to SDT, such differences can be most parsimoniously described in terms of their effect on the satisfaction/thwarting of three basic psychological needs for autonomy, competence, and relatedness [45,56]. The more the three needs are satisfied for an individual in the context of a given behavior, the more able and ready the individual will feel to engage in the behavior actively (ie, self-determined) [45,56]. The need for autonomy refers to an individual's desire to self-organize their behavior, when they feel the desire to do so [57,58]. Competence concerns the individual's belief about their capabilities in performing an action in a social context [59,60]. The need for relatedness refers to the individual's desire to feel socially connected and supported, especially by important others, such as managers, teachers, or health care providers (Figure 1; adapted from [45,56,61,62]).

Throughout the years, SDT has been successfully applied [45,56,57] in many research domains including work organizations (eg, [63,64]), virtual environments and media (eg, [65-67]), and health care (eg, [61,68-71]).

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Figure 1. How an individual could take an active (rather than passive) role in their health management, according to SDT.

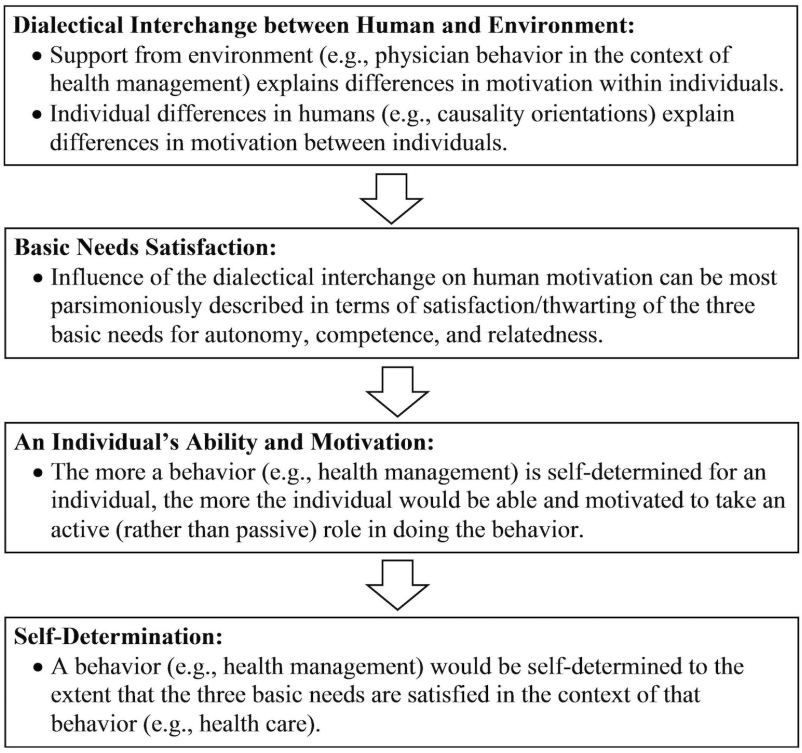


Table 1. Construct definitions.

Construct	Definition
Autonomous Causality Orientation	A person's tendency toward being autonomous (ie, self-determined) in general, across different domains and times [72].
Physician Autonomy Support	The extent to which physicians obtain and acknowledge patients' perspectives, support their ideas, offer choices in treatment options, and offer relevant information without trying to pressure them [70].
Basic Needs Satisfaction	A measure of self-determination in a given context assessed through the satisfaction/thwarting of the three basic needs for autonomy, competence, and relatedness [73].
Self-Efficacy	An individual's belief of having the capability to use computers [74,75].
Complexity	The degree to which a PHR system is perceived as relatively difficult to understand and use [76].
Perceived Usefulness	The extent to which an individual believes that a PHR system can be used advantageously in managing their health [77].
Behavioral Intention	A measure of the strength of an individual's intention to use a PHR system for managing their health [78].

Proposed Theoretical Model and Hypotheses Development

The proposed theoretical model of this study (Figure 2) is composed of two main components: PHR Technology Adoption and Self-Determination in Health Management. This section describes the development of each of these components, followed by a description of the link between them.

The definitions of all the constructs in the model are shown in Table 1. In the rest of this section, the rationale for this model is provided and the solid-line hypotheses (Figure 2) are developed with appropriate support.

The PHR Technology Adoption component of the model (Figure 2, right side) was developed based on TAM. Extensive research on IS adoption (eg, [77,79-87]) has demonstrated that TAM [77] represents the most parsimonious essence of IS adoption theories. TAM has consistently been shown to explain IS adoption across various contexts [88] and stages (pre-usage to post-usage) of IS adoption [89]. Accordingly, and given TAM's centrality in IS adoption research, it is desirable to use for covering the technology adoption side of this research.

TAM holds that an individual's behavioral intention to use an IS is mainly determined by their beliefs regarding the usefulness (Perceived Usefulness – PU) and ease of use (Perceived Ease of Use – PEOU) associated with using that IS [77]. Prior research in IS and reference disciplines has shown the role of behavioral intention as a strong predictor of actual use (eg, [81,82,90-94]). Therefore, and given the relatively small number current users of PHR systems, behavioral intention to use, rather than actual use, is incorporated as the endogenous variable in the Figure 2 model.

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As noted from Figure 2, PEOU was replaced with a similar yet distinct measure of ease of use (ie, complexity), which we deemed more suited for the context of this study. PEOU is defined as "the degree to which a person believes that using a particular system would be free of effort" [77]. PEOU, as well as its most associated measurement scales, relates to the ease (or effort) to "initially" learn how to operate a system. Example items of the measurement scale for the PEOU construct are "learning to operate the system would be easy for me" [77]. Research has shown that PEOU's effect on adoption ceases to become significant past this initial phase of learning how to operate the system [81,82]. However, proper use of a PHR system requires efforts beyond the "initial" learning effort. A PHR system owner or user must disburse an "ongoing" effort to keep their account up to date. Such an ongoing effort reduces the amounts of (and likelihood of) outdated, inaccurate, or incomplete information in the record, which could result in the wrong health care decisions being made [1]. Therefore, for the context of this study, a construct and associated measurement scale that, in contrast to PEOU, captures such ongoing effort was incorporated.

In a review of technology adoption models/constructs, Venkatesh [80] identified several constructs (including PEOU) as root constructs of effort expectancy. Relative to other identified constructs, "complexity" (CPLX) [76] better encapsulates both the effort required to "initially" learn how to use an IS as well as the "ongoing" effort to keep the system up to date. Example items from the measurement scale for CPLX include "It takes too long to learn how to use the system to make it worth the effort" (ie, effort to initially learn how to use the system), "Using the system involves too much time doing mechanical operations" (eg, data input on an ongoing basis), and "Using the system would take too much time from my normal duties" (ie, ongoing effort beyond the initial learning effort). In light of this argument, CPLX was incorporated in the Figure 2 model to represent perceptions of effort associated with using PHR systems. As such, it is used in the model as a direct negative determinant of both behavioral intention and PU [76,77,82,94,95].

Finally, a construct that has been consistently shown to determine user perceptions of IS, especially in the early stages of adoption, is that of self-efficacy [74,80,82,96]. Computer self-efficacy refers to an individual's belief of having the capability to use computers [74,75]. This definition can be extended to the belief of having the capability to use an Internet app such as an integrated PHR system (PHR self-efficacy). Since this study aims to understand the pre-usage intentions to use an integrated PHR system, it is important to consider investigating the influence of self-efficacy on adoption. Consequently, PHR self-efficacy is incorporated in Figure 2 as a direct determinant of both PU (positive) and CPLX (negative).

The second component of the proposed research model (Figure 2, left side) was developed based on SDT. As explained in the previous section (Figure 1), self-determination in a given context can be most parsimoniously described in terms of the satisfaction/thwarting of the three basic needs for autonomy, competence, and relatedness—Basic Needs Satisfaction (BNS). The authors of SDT mention that satisfaction of the three needs must happen together to have positive effects on self-determination [45,73,97]. As a result, in the current study, BNS was modeled as a second-order construct, following Deci et al [73] (Figure 3).

According to SDT, and as seen in Figure 1, self-determination flourishes in an environment that supports the satisfaction of the three basic needs for autonomy, competence, and relatedness (ie, BNS). SDT asserts specifically that the more autonomy supportive a superordinate is (eg, teacher, manager, physician as elements of social environment surrounding an individual), the more satisfied the three basic needs of a subordinate will be (eg, student, employee, patient) [45]. This influence is demonstrated in several studies in various contexts. Examples include the positive influence of physician autonomy support in the context of diabetes self-management [70,98], physician autonomy support in the context of patient weight loss [70,98,99], supervisor autonomy support in a work organization [73,99-101], and parent autonomy support in promoting children's prosocial behavior [97]. As a representative of a superordinate's autonomy orientation in SDT, in a health care context, physician autonomy support has been consistently shown to influence the satisfaction of the three needs in the physician's patient(s), which makes health management more self-determined for patients [45,102]. In addition, research in the context of PHR systems suggests that for PHR systems to be useful, health care providers in general, and physicians in particular, must support the changing roles of their patients by encouraging them to maintain their records and by appropriately trusting information provided by patients [1]. Finally, research shows that providers' use of PHR messaging would encourage the individuals to do so [103,104]. Based on this discussion, the following is hypothesized:

H1: A higher level of perceived physician autonomy support positively influences an individual's level of BNS in the context of health management.

Several studies that have employed SDT in different contexts have shown a positive association between autonomous causality orientation and BNS. Example contexts include weight loss [71], work organization [63], and promoting prosocial behavior in children [97]. Thus, the following is hypothesized:

H2: A higher level of an individual's autonomous causality orientation is positively associated with their level of BNS in the context of health management.

Hypotheses H3 and H4 in the proposed research model in Figure 2 pertain to investigating possible associations between BNS in the context of health management and an individual's beliefs regarding the use of PHR systems to help manage one's health. As mentioned earlier, for a PHR system to be useful, the individual owner should understand and accept (ie, being able and ready for) a more active role in their health management. Such an active role requires motivation [1]. SDT formulates this ability in the form of the satisfaction of the three basic needs for autonomy, competence, and relatedness [45]. Higher levels of BNS in the context of health management would result in health management behaviors to become more self-determined (for an individual) [45]. We argue that an individual who is more self-determined in their health management would have

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more positive beliefs regarding the use of PHR systems. This argument is made based on the following logical justification: (1) PHR systems are suggested to support consumers' self-determination in managing their health (eg, [24,105-110]), (2) consumers desire to become empowered and self-determined in managing their own health (eg, [24,94,111,112]), (3) higher levels of BNS make an individual better able to take a more active role in their health care [45], and (4) beliefs of usefulness and effort associated with using an IS are considered motivational factors to make use of that IS [113,114].

Based on the four justifications above, it is reasonable to hypothesize that consumers with higher levels of self-determination (associated with higher BNS) in managing their health would have more positive beliefs (eg, higher PU and lower CPLX) regarding the use of a technology that supports their reaching their goal.

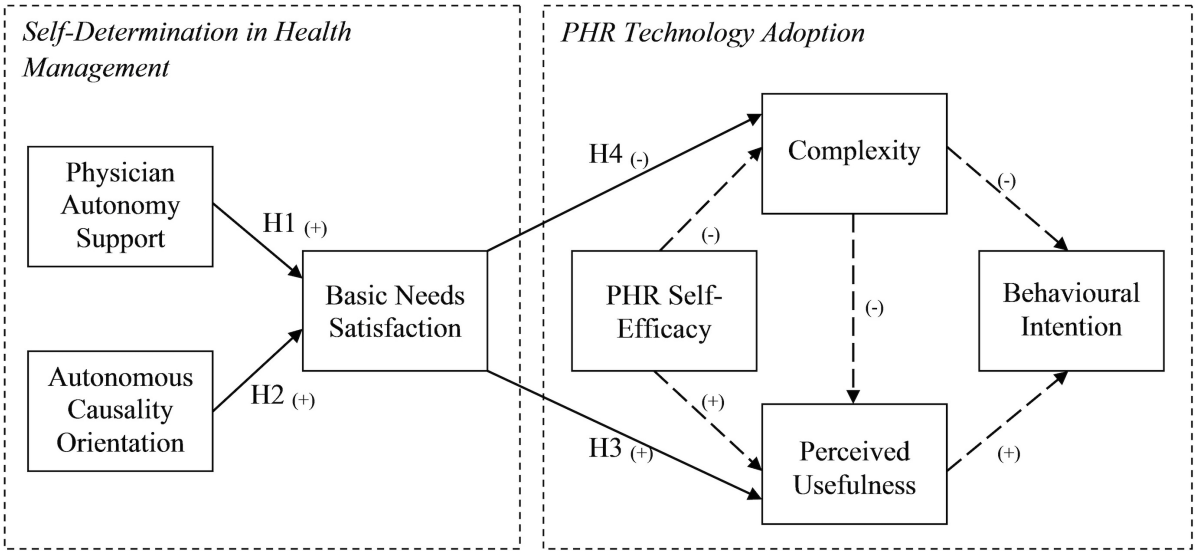
In a survey of consumers' perceptions regarding the use of PHR systems, PHR system functionalities that were rated highest (in terms of usefulness) among survey respondents were the ones that aligned with the satisfaction of SDT's three basic needs (for autonomy, competence, and relatedness) [49]. In addition, higher self-determination means higher ability and motivation to take an active role in health management [45]. They are therefore likely to perceive less effort and complexity in using a system that is designed to help them take more responsibility in their health management. Based on SDT, more self-determined individuals are likely to have more intrinsic/internalized motivation to manage their health [45,115]. Thus, they are likely to perceive less effort [116] associated with using a tool that is designed to support self-determination in health management [24,28,105]. We thus hypothesize the following:

H3: A higher level of BNS in the context of health management positively influences an individual's perceived usefulness of PHR systems.

H4: A higher level of BNS in the context of health management negatively influences an individual's perceptions of complexity of PHR systems.

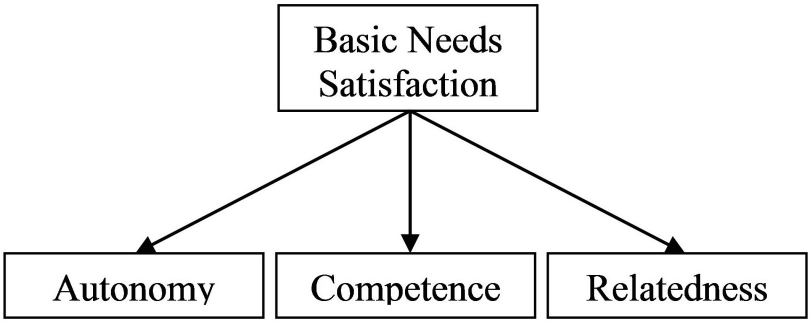
In summary, the proposed research model suggests that behavioral intention to start using a PHR system is influenced by an individual's perceptions regarding usefulness (ie, PU) and effort (ie, CPLX) associated with using the system. Prior research on IS adoption suggests that these perceptions (ie, internal beliefs about the system or individual reactions to using the system) mediate the influence that external variables might have on behavioral intention [79,83,117]. Therefore, BNS is incorporated in the research model of Figure 2, as an external variable and an antecedent of PU and CPLX. Further, physician autonomy support and autonomous causality orientation are incorporated in the proposed research model in Figure 2 as determinants of BNS [45]. The model also includes self-efficacy as another external variable influencing PU and CPLX.

Figure 2. Research model and hypotheses (arrows in bold demonstrate the main focus of this study; dashed lines on the right side of the model are included for statistical testing but are not specifically hypothesized as they have been repeatedly established in IS literature).



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Figure 3. Modeling of basic needs satisfaction as a second-order construct.



Methods

Research Design

In order to test the hypotheses in the proposed research model in Figure 2, this research employs a cross-sectional survey method. Surveys are the typical approach to empirically validate adoption models [118]. In addition, surveys are one of the most widely used methods in IS research [119]. Data collection was done through an online survey to gather measurement scales for the model factors as well as gather individual characteristics (eg, demographics, details of previous computer and Internet use) and control variables. Since the focus of this research is on understanding the "pre-usage" stage of PHR system adoption process, the online survey was administered to individuals with no prior experience in using any type of electronic PHR systems. Multimedia Appendix 2 presents the description of the online survey used in this study according to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [120].

In order to reduce the effect of common method variance and to reduce the cognitive load on participants, the entire survey was divided into two parts, such that each part would be completed by participants in one sitting. For each participant, the two sittings were on average 36 hours apart. Each of the survey parts contained only approximately half of the questions. Using LimeSurvey, an open source survey app, the two parts of the survey for this study were programmed and were hosted on the McMaster University (Hamilton, Ontario, Canada) website. Finally, for the purpose of this study, PHR systems were introduced to participants using an online video clip that was shown to participants at the beginning of Part 2.

On entering the website for Part 1 and signing the consent form to participate in the study, participants were presented with a set of questions to determine their eligibility for this study. Only persons living in Canada (the target population of this study), above the age of 18 years (ethical consideration), with a family physician (the measurement items of physician autonomy support relate directly to the participants' family physician), and with no prior experience in using electronic PHR systems of any type (our focus is on pre-usage stage of PHR system adoption) were considered eligible to participate in this study. Ineligible participants were prevented from starting the survey.

Since this study was targeted at individuals with no prior experience in using PHR systems (ie, this study was focused on a pre-usage stage of PHR adoption), an online video clip was created (described in Multimedia Appendix 2) and used to introduce such systems to study participants. The purpose of the video clip was to provide participants with introductory information about PHR systems and to show them how a PHR system can be used through a few real-life scenarios. The scenarios were developed in a way that covered the major functionalities of a typical PHR system as well as what operating a PHR account would entail (eg, keeping the account up to date). It is suggested that, in the absence of an actual system, video mockups can help shape the perceptions of consumers regarding the system [79]. Such video mockups can be used to "create realistic facades of what the system consists of." Further, introducing PHR systems to study participants using a video clip was favored over using text-based material, still images, and slides. Multimedia material, such as video clips, can introduce the dynamic features of a product (eg, a PHR system) to consumers in a richer format [121]. Increasingly, commercial websites employ video clips to present product features since using a video clip provides greater vividness in presenting product features to consumers compared to text-based material and static images [122], and as a result, can help consumers understand and evaluate the quality and performance of products sold online [123,124].

Instrument

In order to ensure content validity, measurement scales were selected from the existing literature, and in some cases, were slightly adapted to reflect the context of this study. The full measurement instrument can be found in Multimedia Appendix 2. In addition to the questions related to the proposed model, our survey also included questions related to several control variables (ie, age, gender, extent of daily Internet use, Internet experience in years, education level, perceived health status, chronic illness, frequency of doctor visit, years with family doctor, family health responsibility, prior use of paper-based health records, information privacy concerns, information security concerns, household income, and retirement status). Given our focus, which is examining the role of SDT factors in PHR system adoption, privacy and security concerns were not included in the research model in order to preserve the parsimony of the proposed model. However, since several studies have suggested consumers' privacy and security concerns to be major barriers of PHR system adoption, questions related to these two variables were included in the survey in order to control for the effects they might have had on PHR system adoption.

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Recruitment

Participants were recruited through a commercial market research firm with a consumer panel that includes over 400,000 Canadians (the target population of this study). Invitations to take part in this study were balanced based on participant location, age, and gender, according to the 2011 Canadian Census Profile provided by Statistics Canada [125]. Participants were invited via email, which helped overcome physical limitations in reaching a wider audience across the target population, to enhance the representativeness of the sample. The representativeness of the sample was further enhanced by random sampling of the target population, thus improving the generalizability of our findings [126].

Prior to conducting data collection for the study, a pre-test of the instrument was conducted by inviting PhD students and three IS faculty members at McMaster University to complete the survey and provide their feedback on the instrument. Their feedback and responses to survey questions resulted in minor revisions to the questions as well as data collection procedures. On finalizing the online survey, a pilot was conducted through the same commercial market research firm with the purpose of diagnosing any possible flaws in the data collection procedures. As a result, 20 participants filled out the survey. The pilot study did not result in any changes in either data collection procedures or the measurement instrument. Therefore, the 20 data cases were included in the final dataset for this study. Finally, prior to conducting any sort of data collection, an ethics application was approved by the research ethics board of McMaster University.

There are two criteria that would impose minimum sample size requirements on this research [127]: minimum number of data cases (ie, participants) required for running Partial Least Squares (PLS) analyses and minimum number of cases required to achieve an acceptable statistical power in detecting a desired effect size for the relationships in the proposed model. In this study, the larger of the two was determined to be 139 (cases required to achieve a statistical power of at least 80 in order to detect medium effect sizes for a model with 3 predictors) [127-130].

The recruitment of participants and the administration of the survey ran from August 1-17, 2012. In order to obtain the 139 cases, and following the recruitment firm's prior experience, a total of 6423 persons were invited, of whom 508 individuals completed Part 1, and 173 completed Part 2 as well. Thus, the response rate for Part 1 of the survey was 7.91%; for Part 2, it was 34.06%. Although the response rate fits within the acceptable range for this type of research [119], in survey research, sample representativeness is more important than response rate [131]. Stratified random sampling is an approach that increases sample representativeness [132].

In order to examine the possible existence of nonresponse bias, respondents were compared to two groups of nonrespondents (ie, those invitees who did not complete Part 1 and those who did not complete Part 2). The comparisons were conducted based on socioeconomic information as suggested by Sivo et al [119]. As such, the means of socioeconomic information for the abovementioned groups were compared using independent-samples *t* tests [133]. Results of the comparisons showed no significant difference between respondents and nonrespondents. Hence, it was concluded that nonresponse bias was not a concern for generalizing our findings.

Before conducting the main analyses of this study, this dataset was investigated for data anomalies (eg, participant's gaming patterns), univariate outliers, multivariate outliers, and cases with missing data [133]. In total, this data screening resulted in the elimination of 14 cases from the dataset. The remaining 159 valid data cases were used in all subsequent analysis procedures detailed in this paper (N=159).

Statistical Analysis

Research Model Evaluation

Structural equation modeling (SEM) was used to validate our proposed research model. SEM allows for the analysis and investigation of unobservable variables that are indirectly measured from observable variables [134,135]. In particular, SEM approach of PLS was used in this study. The choice of SEM approach depends on the objectives of the research being conducted [136]. Accordingly, PLS was chosen for this study for the following reasons. First, PLS gives optimum prediction accuracy because of its prediction orientation [137], and this characteristic of PLS is well suited to our overall objective, which is to understand what factors would explain consumers' intention to use PHR systems. Such prediction is offered in PLS by determining the portion of the variance in the endogenous variable that is explained by exogenous variables. Second, in situations where the phenomenon being researched is relatively new or where the theoretical model is in the early stages of development, the PLS approach is more suitable [129]. Both PHR systems and PHR system adoption are relatively new phenomena. Furthermore, the proposed research model was developed and evaluated for this study for the first time. Third, as mentioned earlier, the construct of BNS was modeled and measured in this study as a second-order construct. PLS is a strong and flexible approach for evaluating models with higher order constructs [127,138-140].

We conducted and reported PLS analyses following a two-step approach as suggested by Chin [138]. In the first step, quality of the measurement model was assessed in terms of reliability and validity (measurement model evaluation). In the second step, quality of the structural model was assessed as explained in the Results section (structural model evaluation). Our PLS analyses were conducted using SmartPLS software (Version 2.0.M3) due to its ease of use as well as its capability of executing the range of procedures reported in this paper [141].

Measurement Model Evaluation

As mentioned earlier, the BNS construct was modeled and measured as a second-order factor. The procedures of measurement model evaluation for the second-order factor must be the same as those performed for the first-order factor [138,142]. As a result, this section of the paper is divided into two parts of first-order measurement model evaluation and second-order measurement model evaluation.

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First-Order Measurement Model Evaluation

The measurement model evaluation (Multimedia Appendix 3) started with the assessments, and as a result, confirmation of individual item reliability and construct reliability. Next, the first-order measurement model was evaluated, and as a result, confirmed in terms of validity.

Second-Order Measurement Model Evaluation

The PLS modeling of the second-order factor (BNS) was done following Agarwal and Karahanna [142] (page 678, footnote 2) and Calvo-Mora et al [143]. Results of the evaluation of the second-order measurement model confirmed individual item reliability, construct reliability, and discriminant validity. Details are presented in Multimedia Appendix 3, which also provides the descriptive statistics for the model constructs.

Common Method Bias

The survey for this study was designed following the guidelines suggested by Podsakoff et al [144] in order to minimize the threat of common method bias. The potential presence of common method bias in our findings was assessed using the Harman's one factor test [145] and the unmeasured latent marker construct technique [144,146] (Multimedia Appendix 3). Results of conducting these two tests were not suggestive of the presence of common method bias.

Structural Model Evaluation

Figure 4 presents the results of the PLS structural model evaluation of our proposed model. As shown, all the main hypotheses (H1-H4) are supported. The non-hypothesized relations from previous IS literature were also found to be significant with the exception of self-efficacy to PU.

Our research model was further examined, and as a result, confirmed in terms of predictive relevance, and goodness-of-fit (Multimedia Appendix 3).

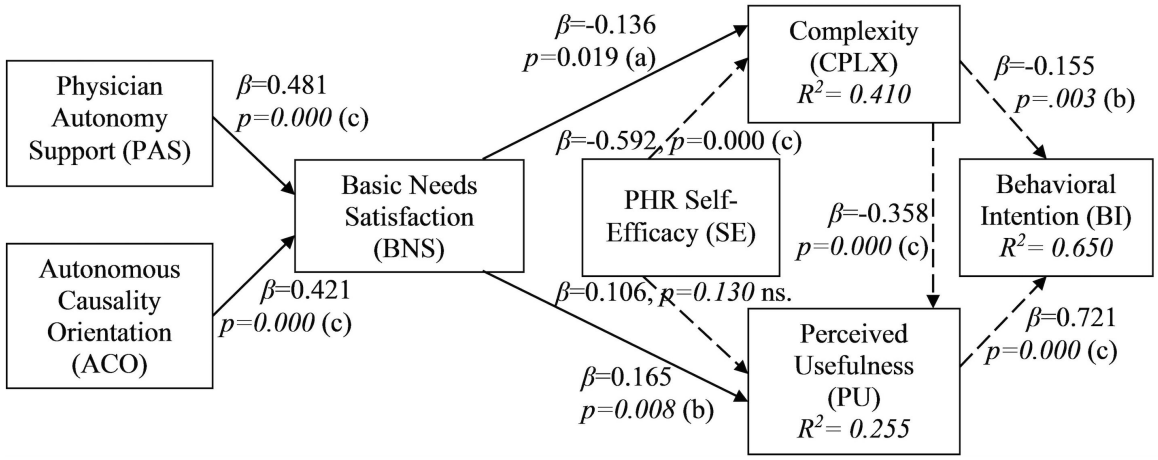
Participants in this study were also asked questions about their individual characteristics as well as several control variables (ie, age, gender, extent of daily Internet use, Internet experience in years, education level, perceived health status, chronic illness, frequency of doctor visit, years with family doctor, family health responsibility, prior use of paper-based health records, information privacy concerns, information security concerns, household income, and retirement status). The impact of these individual and control variables on the results of this study was assessed by examining variations in the R^2 for endogenous variables in the model or changes in the support for the hypothesized relations. Results of these examinations showed that the control variables and the individual characteristic variables did not change our findings. Results of control variable analysis are presented in Multimedia Appendix 3.

Results

Participant Characteristics

The characteristics of the study participants (N=159) are presented in Tables 2 and 3.

Figure 4. PLS results for the proposed research model: Significant at (a) .05; (b) .01; (c) .001 (ns=non-significant path).



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Table 2. Frequency statistics of participant characteristics.

Characteristics		Freq.	%	CC[a]	% Dev. from CC[b]
Gender					
	Female	83	52.20	51	2.35
	Male	76	47.80	49	2.44
Age group					
	18-34	48	30.2	27	11.85
	35-49	32	20.1	26	22.69
	50+	79	49.7	45	10.44
Canadian province					
	Alberta	18	11.3	10.5	7.61
	British Columbia	22	13.8	13.5	2.22
	Manitoba	6	3.8	3.5	8.57
	New Brunswick	2	1.3	2.5	48
	Newfoundland	1	0.6	1.5	60
	Nova Scotia	5	3.1	2.5	24
	Ontario	61	38.4	38.5	0.25
	Prince Edward Island	0	0	1	100
	Quebec	39	24.5	23.5	4.25
	Saskatchewan	5	3.1	3	3.33
Education level[c]					
	Secondary school or less	23	14.47		
	Some university or college	36	22.64		
	University or college degree	71	44.65		
	Some graduate work	4	2.52		
	Graduate degree	25	15.72		
Annual household income (Can $)[c]					
	Less than 40,000	35	22.01		
	40,000-79,999	68	42.77		
	80,000-119,999	36	22.64		
	120,000-159,999	17	10.69		
	160,000	3	1.89		

[a]CC: % in the 2011 Canadian census.

[b]Dev: deviation.

[c]Not included in sample stratification.

Table 3. Descriptive statistics of participant characteristics.

Characteristics	Min.	Max.	Mean	SD
Age in years	19	82	48.16	16.11
Internet experience in years	3	26	16.60	6.52
Time spent online hours per day	1	12	3.67	2.43

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Discussion

Principal Results

Findings from this study are discussed here in two parts. First, the appropriateness of the research model of this study in terms of explaining PHR system adoption is discussed, followed by a discussion of the results of hypotheses.

Appropriateness of the Research Model

In terms of the appropriateness of our research model for explaining pre-usage adoption intentions, the overall R^2 of the endogenous construct (behavioral intention) in the research model (.650) indicates that a large portion of the variance (65%) in this construct was explained by the factors in the model, thus indicating the high explanatory power of the research model. Further, the cross-validated redundancy for the endogenous variables in the research model (Q^2), as well as the absolute and relative goodness-of-fit indices, is indicative of the model appropriately explaining an individual's adoption of PHR systems.

Results of Hypotheses Testing

In terms of our hypotheses, consistent with prior research on IS adoption, PU and CPLX of PHR systems were shown to be the key antecedents of behavioral intention to use such systems. In addition, self-efficacy was shown to be a significant predictor of CPLX. In contrast, the association between self-efficacy and PU was not statistically significant. Compeau and Higgins [74] found a positive influence of self-efficacy on outcome expectations (conceptualized and measured similar to PU) where participants were recruited from individuals with various levels of experience in using the information system in question. The study was conducted on a pool of data not corresponding to a specific technology adoption stage, whereas our study focuses only on the pre-usage stage of adoption. Therefore, self-efficacy may not have a significant effect on PU in the pre-usage stage. To support this finding, it is worth mentioning that Venkatesh [80] has shown that the effect of self-efficacy on behavioral intention in pre-usage stage is fully captured by the expected effort associated with using the system. It can similarly be argued that the effect of self-efficacy on PU in the pre-usage stage is fully captured by CPLX. This statement was tested and confirmed in this study by running a PLS analysis in the absence of CPLX in the research model. The result showed a statistically significant positive relationship between self-efficacy and PU (beta coefficient=.321, P<.001), which is in support of the above argument.

As argued in the theoretical development section of this paper, CPLX was incorporated in our model instead of the commonly used PEOU construct as representative of effort associated with using a PHR system. However, PEOU data were also collected, and we ran our research model with PEOU as well. We found no difference between having either CPLX or PEOU. However, having CPLX in the model yielded stronger associations and higher explained variances compared to PEOU, which supports our theoretical arguments to use it instead of PEOU.

BNS was shown in this study to be significantly associated with PU (beta coefficient=.165, P<.01). These results suggest that individuals with higher levels of self-determination (associated with higher BNS) in their health management would find a PHR system more useful compared to those with lower levels of self-determination.

BNS was also shown to have a significant negative association with CPLX (beta coefficient=-.136, P<.05). These results suggest that individuals with higher levels of self-determination would perceive less effort in using a PHR system.

Physician autonomy support was shown to be a significant predictor of BNS in the context of health management (beta coefficient=.481, P<.001). Consistent with prior research driven by SDT in other contexts, the results suggest that individuals whose physicians are more supportive of their being more self-determined in managing their health would exhibit higher levels of BNS.

Finally, the personality trait of autonomous causality orientation was shown to be associated with BNS in the context of personal health management (beta coefficient=.421, P<.001). These results suggest that individuals with higher levels of autonomous causality orientation exhibit more self-determination in managing their health compared to those with lower levels.

Contributions

From an academic perspective, this research contributes to the literature by developing and validating a research model that explains the adoption of PHR systems, from an SDT perspective. As such, the current study highlights the importance of considering the changing role of consumers from passive recipients of care to active partners in their own care when considering the adoption of PHRs. Although this model is specific to using PHR systems for managing one's health, such a role change supported by information technology could be observed in contexts other than health care (eg, self-service technologies). Findings of this research highlight the importance of considering how information systems can facilitate the changing way people engage in certain behaviors when trying to understand the adoption of such systems. Accordingly, this study is the first to apply SDT in order to understand PHR system adoption.

Our findings also showed the importance of physician autonomy support in the adoption of PHR systems by individuals. Similarly, the importance of considering the role of personality traits of autonomous orientation in PHR system adoption was shown. Finally, the measurement scales for the constructs of SDT were adapted and validated for the context of health management and can be used in similar future studies.

This study provides valuable implications and contributions to practice in terms of the development, promotion, and facilitation of PHR systems use by consumers. The major findings in terms of the supported hypotheses, the academic value added of testing each hypothesis, and the practical implications of the findings are summarized as follows.

Perceived usefulness positively influences behavioral intention, complexity negatively influences behavioral intention, and

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self-efficacy negatively influences complexity. This study provided empirical support for a relationship not previously validated in the context of using PHR systems for health management. In addition, the study adapted and validated self-efficacy scales for PHR systems. As for practical results, we suggest considering features deemed useful by consumers in designing PHR systems (eg, monitoring and tracking features), promoting PHR systems (highlight those features in advertisements), and facilitating PHR system use (eg, provide incentive for health care providers to communicate with patients through PHR systems), designing PHR systems that are easy to use and maintain, training consumers in using PHR systems, providing technical support and facilitating usage, and providing technical features that would reduce the ongoing effort of keeping the system up to date (eg, automatic data population, smart data population, compatibility with external devices such as blood sugar readers).

BNS negatively influences complexity, BNS positively influences perceived usefulness, physician autonomy support positively influences BNS, and autonomous causality orientation is positively associated with BNS. This study adapted and validated SDT scales for the context of personal health management and provided empirical support for relationships not previously investigated as well as providing empirical support for relationships not previously validated in the context of personal health management. In terms of practice, the results suggest that health care providers must generally allow their patients to take part in their health management. That said, it must be noted that according to SDT, people with different personality orientations are motivated through different regulation mechanisms. For example, for individuals with a personality orientation toward being controlled (rather than being autonomous), rewards and punishments may promote a higher level of self-determination in health management [45], consequently facilitating higher adoption rates for PHR systems.

Limitations

This research was carried out in a Canadian context; thus, findings from the research will not be immediately transferrable to other countries with different demographics, health care system characteristics, and cultures. For example, the role of culture is believed to be influential in research related to SDT (eg, [147]), information systems in general (eg, [148]), and technology adoption in particular (eg, [149]). Hence, further research would be required before transferring the findings of this study to other countries.

Data collection for this study was conducted by employing a cross-sectional survey design. Given that perceptions and intentions (CPLX, PU, and behavioral intention) regarding the use of PHR systems could change over time, collecting data at one point could pose a threat of temporal instability in the findings. Nevertheless, the focus of the study was on only one particular stage in the adoption process where individuals had no prior experience with using PHR systems (ie, pre-usage), and the selected method of data collection was deemed to be the best approach in this case.

Future Research Directions

The current study was focused on the pre-usage stage of PHR system adoption process. In this stage, consumers may not have a full understanding of the nature of the change in their roles (from passive to active) when using an actual PHR system. Therefore, possible venues of future research may include the development and validation of a theoretical adoption model for later stages of the adoption process (ie, initial use, continued use). Using PHR systems might influence an individual's level of BNS in health management [27]. Thus, another area for future research is to investigate such an influence. In other words, research is needed to understand the influence of PHR system usage on an individual's self-determination in managing their health.

Finally, several other factors could impact PHR adoption such as trust, security, privacy, and social influence. Although influences of some of these variables were investigated through their use as control variables in this study, future studies should explore their role more formally.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Positioning of the study in relation to the literature.

[PDF File (Adobe PDF File), 65KB - jmir_v19i7e270_app1.pdf]

Multimedia Appendix 2

Measurement instruments and data collection.

[PDF File (Adobe PDF File), 86KB - jmir_v19i7e270_app2.pdf]

Multimedia Appendix 3

Statistical analyses.

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[PDF File (Adobe PDF File), 187KB - jmir_v19i7e270_app3.pdf]

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Abbreviations

BNS: basic needs satisfaction
CPLX: complexity
IS: information systems
PEOU: perceived ease of use
PHR: personal health record
PLS: partial least squares
PU: perceived usefulness
SDT: self-determination theory

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SEM: structural equation modeling
TAM: technology acceptance model

Edited by G Eysenbach; submitted 20.03.17; peer-reviewed by S Choemprayong, C Costa, P Gee; comments to author 12.04.17; revised version received 02.06.17; accepted 19.06.17; published 27.07.17.

Please cite as:
Assadi V, Hassanein K
Consumer Adoption of Personal Health Record Systems: A Self-Determination Theory Perspective
J Med Internet Res 2017;19(7):e270
URL: http://www.jmir.org/2017/7/e270/
doi:10.2196/jmir.7721
PMID:28751301

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Original Paper

Web-Based Therapist Training in Interpersonal Psychotherapy for Depression: Pilot Study

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Abstract

Background: Training mental health professionals to deliver evidence-based therapy (EBT) is now required by most academic accreditation bodies, and evaluating the effectiveness of such training is imperative. However, shortages of time, money, and trained EBT clinician teachers make these challenges daunting. New technologies may help. The authors have developed the first empirically evaluated comprehensive Internet therapist training program for interpersonal psychotherapy (IPT).

Objective: The aim of this study was to examine whether (1) the training protocol would increase clinicians' knowledge of IPT concepts and skills and (2) clinicians would deem the training feasible as measured by satisfaction and utility ratings.

Methods: A total of 26 clinicians enrolled in the training, consisting of (1) a Web-based tutorial on IPT concepts and techniques; (2) live remote training via videoconference, with trainees practicing IPT techniques in a role-play using a case vignette; and (3) a Web-based portal for therapists posttraining use to help facilitate implementation of IPT and maintain adherence over time.

Results: Trainees' knowledge of IPT concepts and skills improved significantly (P<.001). The standardized effect size for the change was large: d=2.53, 95% CI 2.23-2.92. Users found the technical features easy to use, the content useful for helping them treat depressed clients, and felt the applied training component enhanced their professional expertise. Mean rating of applied learning was 3.9 (scale range from 1=very little to 5=a great deal). Overall satisfaction rating was 3.5 (range from 1=very dissatisfied to 4=very satisfied).

Conclusions: Results support the efficacy and feasibility of this technology in training clinicians in EBTs and warrant further empirical evaluation.

(J Med Internet Res 2017;19(7):e257) doi:10.2196/jmir.7966

KEYWORDS

psychotherapy; Internet; depression; education; humans; computer-assisted instruction

Introduction

The importance of preparing mental health professionals to deliver evidence-based therapy (EBT) is now well established [1]. Accreditation bodies for academic programs in psychiatry [2], psychology [3], and social work [4] in both the United States and Canada [5] require demonstration of competence in EBTs [6]. This requirement helps to address the critical shortage of clinicians trained in EBTs, which has been identified as a major public health concern [7,8]. It also accords with the needs both of patients, who generally prefer talk therapy to medication [9], and trainees, who report wanting to spend more time delivering EBTs and to receive more EBT training than they now do [10].

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Interpersonal psychotherapy (IPT) is one of the oldest and best-studied EBTs [11,12] and one of the psychotherapies formally evaluated for efficacy by the National Institute for Mental Health (NIMH) [13]. Numerous professional and international guidelines recommend IPT for the treatment of major depression, including the American Psychiatric Association [14] and the Guidelines for Primary Care Physicians [15-17]. IPT focuses on understanding the interpersonal and social context in which the patient's symptoms arose. This brief, time-limited approach focuses on feelings, validating them in the context of social situations, and helping the patient to understand and verbalize those feelings to change interpersonal encounters. A recent meta-analysis of 90 randomized controlled trials involving over 11,434 patients found large effect sizes for IPT in alleviating major depression. IPT was also effective in preventing relapse and had a preventive effect on subthreshold episodes [18]. Effect sizes were comparable with those found with cognitive behavior therapy (CBT) [19]. IPT has also demonstrated efficacy for other diagnoses including eating and anxiety disorders and for patients ranging from adolescents to the elderly [20]. Despite the substantial empirical literature supporting the efficacy of IPT, it has been far less disseminated than CBT.

With the increasing emphasis on EBTs comes an increasing focus on how to implement and evaluate psychotherapy training. Accreditation bodies in psychiatry (Accreditation Council for Graduate Medical Education) and psychology (American Psychological Association) require not only training in EBTs but an evidence-based approach to evaluating the effectiveness of such training, that is, whether clinicians demonstrate competence in administering the treatment [3,6]. Thus, psychotherapy training involves the dual challenges of expanding the current curriculum to include EBTs and ensuring such training is effective. These shortages of time, money, and availability of trained EBT clinician teachers make these challenges daunting. The development of new methods in psychotherapy training has been suggested as one solution to these challenges [21].

New technologies may help [22]. Internet-based training (e-learning) is cost-effective, scalable, and available upon demand. It overcomes limitations of trainer availability, especially in remote locations. Clinicians can work at their own pace, repeating and reviewing as desired. Enhancing training quality are the standardization of instruction (ensuring inclusion of key empirically proven components) and the use of multi-modal learning techniques the technology affords, which have been shown to increase knowledge uptake and retention [23]. Research has found Internet-based training has greater effectiveness than paper-based manuals alone, resulting in greater long-term knowledge retention [24,25], and in one study, Internet-based training was superior to face-to-face instruction [26]. Once the learner has mastered the didactic content, new technologies can teach and assess clinical proficiency in administering the newly learned skills. Both computer simulations using virtual patients [27,28] and remote live training via videoconference have demonstrated effectiveness in teaching applied clinical skills [29,30]. Posttraining, these same technologies can be used to help ensure proper implementation in clinical practice [22,31]. Research has found posttraining consultation an essential ingredient for successful implementation of EBT skills [32] and to predict clinician adherence and competence following EBT training [32,33]. By improving access to training, new technologies can help facilitate dissemination of a variety of EBTs, including IPT and provide patients with a wider choice of treatment options.

In this pilot study, we developed the first comprehensive Internet training program for IPT to be empirically evaluated. This three-part, interactive therapist training protocol focuses on IPT for major depression and consists of (1) a Web-based tutorial on IPT concepts and techniques; (2) live remote training via videoconference, with trainees practicing IPT techniques in a role-play using a case vignette; and (3) a Web-based portal for therapists posttraining use to help facilitate integration of IPT into their clinical practice and maintain adherence and quality over time. The goal of the study was to examine the following hypotheses: (1) the training protocol would increase clinicians' knowledge of IPT concepts and skills from baseline and (2) clinicians would deem the training feasible as measured by satisfaction and utility ratings.

Methods

Procedure

Before training, trainees took a 38-item pretest on their knowledge of IPT concepts and principles. Following the pretest, they received a username and password to access the Web-based tutorial and completed it at their own pace. Trainees could email the instructors with questions about the material. After completing the Web-based tutorial, trainees took a posttest of IPT knowledge and a user satisfaction questionnaire. Trainees then received a 45-60 min live applied training session conducted via videoconference with an experienced IPT trainer (JDL, JCM, or KLB). During this session, the trainer portrayed a standardized depressed patient, whereas the trainee role-played as therapist (see below). After completing the video session, trainees completed a satisfaction questionnaire and received a link to the IPT posttraining website. The posttraining website was designed to facilitate implementation and adherence following training and to guide the clinician in structuring sessions with their first IPT patients.

Description of Training Components

Web-Based Tutorial

The training components paralleled components of IPT. In IPT, the patient and IPT therapist together define a central interpersonal problem focusing on one of four categories: grief, role transition, role dispute, or interpersonal deficits [20]. IPT has three phases: the initial phase (evaluation, case formulation, and treatment plan), the middle phase (addressing and resolving the focal problem), and the termination phase (consolidating gains and transitioning from treatment). The tutorial contains seven modules covering these and other topics on the theory and practice of IPT for depression. A description of the content and learning goals for each of the modules is presented in Table 1.

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Table 1. Learning objectives by module: interpersonal psychotherapy (IPT) tutorial.

Module	Learning goal
Welcome and overview	Describe the goals of the tutorial
Principles of IPT[a] for depression	Describe the theoretical roots for IPT
	Describe the IPT theory for the cause and treatment of depression
	Describe the role of the IPT therapist
	Describe the role of the IPT patient given depression as a medical illness
	Describe the three phases of IPT treatment, the interpersonal inventory, and developing a case formulation
3: The four IPT problem areas: grief	Explain the difference between normal grief and abnormal grief (complicated bereavement)
	Describe the therapeutic goals in treating depression resulting from abnormal grief
	Describe questions to use in order to assess the presence of abnormal grief
	Describe how to facilitate the grieving process
The four IPT problem areas: role transition	Describe a role transition
	Describe how a role transition may result in depression
	Identify when a role transition is an issue for a patient
	Explain the treatment goals in treating depression resulting from a role transition
The four IPT problem areas: role dispute	Describe the nature of role disputes
	Identify when a role dispute is an issue for a patient
	Identify the three stages in role disputes
	Describe the therapeutic goals in treating patients presenting depression resulting from a role dispute
The four IPT problem areas: interpersonal deficits	Describe when interpersonal deficits are the focus of treatment
	Describe the treatment goals in IPT in treating depression resulting from interpersonal deficits
	Describe how patients with interpersonal deficits differ from patients presenting with depression resulting from the other three problem areas
Mechanisms of change in IPT	Describe the four ways in which IPT achieves therapeutic goals

[a]IPT: interpersonal psychotherapy.

Because multi-modal learning and high levels of interactivity enhance learning [23,34], content was presented in varied formats including animations, graphical illustrations, and clinical vignettes with audio and interactive exercises. New material was often presented using "challenge questions," as learning is enhanced when a user makes mistakes applying recently acquired information and gets specific feedback explaining the rationale for the correct answer [35]. Presentation of material was guided by principles of instructional design, such as "chunking" material based on limits to working memory to enhance retention [36]. It was estimated the tutorial would take 3 to 4 hours to complete. Interactive demos of the tutorial content can be found in Multimedia Appendices 1 and 2.

Applied Training

After completing the Web-based tutorial and Web-based posttest, trainees completed a supervised clinical training session using videoconferencing. During the applied session, the trainer portrayed a standardized depressed patient, whereas the trainee role-played the IPT therapist. The goal was to offer trainees practice in applying the skills learned during the tutorial. The trainer provided feedback and suggestions in real time as appropriate. Trainees also had the opportunity to ask questions about the IPT approach. The role play was designed to portray the patient's second or third session, to provide the trainee an opportunity to practice developing an interpersonal formulation with the patient, and achieving agreement with the patient on the focal IPT problem area. We did not role play initial sessions because these typically focus on history gathering, which we finessed by providing summary information on the patient's history up front to the trainee. Starting a session with "How have things been since we last met?" is a pattern that begins with session 2. A crucial point in IPT treatment is the therapist's formulation of a focal problem area in session 2 or 3 and getting the patient's agreement on it; this then organizes the remainder of the treatment [37]. Hence, the choice of session 2-3 from a time-limited, 12-16 session acute treatment framework. Although not sufficient for advanced clinical training in IPT, the applied training allowed us to evaluate the feasibility and user satisfaction with this approach. Applied training where trainees actually implement the skills learned has been found a critical, and often lacking, component of training [38-41].

Posttraining Case Tracker Website

A limitation of many professional training programs is lack of carryover to practice [32]. To address this, after completing the

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applied training session, trainees received access to the interactive IPT website portal (IPT Case Tracker). The IPT Case Tracker was designed to facilitate the transition from classroom and initial applied training to clinical practice and to help maintain adherence to IPT in initial and ongoing clinical use. The portal contained (1) interactive tools (eg, reminders) to help clinicians structure their IPT sessions, assist with case conceptualization, and provide an overall framework for conducting IPT with specific clients; (2) checklists for presession preparation and postsession tracking of client issues, client progress, and utilization of IPT skills; (3) a printable depression measure (Hamilton Depression Rating Scale [42]) to monitor treatment progress; and (4) case consultation via email, to facilitate uptake and troubleshoot implementation questions and issues. We obtained user satisfaction with the case tracker 1 to 3 months after completion of the applied training session. See Multimedia Appendices 3 and 4 for samples of pre- and postsession checklists.

Measures

Efficacy

To assess trainees' gains in knowledge of the concepts, principles, and techniques of IPT, the authors developed a 38-item pre- and posttest covering the core concepts in the tutorial. The text contained a combination of multiple-choice and true-false questions in proportions mandated by continuing education guidelines from the American Psychological Association and the National Association of Social Work. Testing served dual functions of assessing and reinforcing learning. Trainees received rationales for the correct answers after completing the posttest to reinforce learning. Posttests were given after completion of each module. The test had good internal consistency reliability (coefficient alpha =.79).

Feasibility

We evaluated user satisfaction from two perspectives: technical implementation, and clinical content. User satisfaction with technical aspects of the training tutorial was assessed using the System Usability Scale (SUS) [43,44], a reliable, well-validated 10-item scale designed to evaluate user satisfaction with technical aspect of Web-based applications and other technologies. It provides a score on a 0-100 scale regarding the effectiveness, efficiency, and satisfaction users experience using the system. A mean SUS score of 50.9 represents a rating of "okay," 71.4 represents a rating of "good," 85.5 represents a rating of "excellent," and 90.9 represents a rating of "best imaginable."

Descriptive statistics assessed trainee satisfaction with the clinical content of the training components. Trainees rated each training component along six dimensions using a 4-point scale (strongly agree, agree, disagree, and strongly disagree). Trainees also rated global satisfaction and had opportunity for open-ended feedback. Scale items were developed in prior studies on user satisfaction with Web-based training [29,45] and have shown good internal consistency reliability (Cronbach alpha=.92). Ratings on the extent to which trainees felt the learning goals were met and global ratings of how much was learned were also obtained for the tutorial as another measure of feasibility.

Statistical Analyses

A two-tailed paired *t* test was computed to examine the mean change knowledge assessment from pretest to posttest on the Web-based tutorial. The standardized mean effect size for the *t* test was calculated using methods described by Cohen [46]. Effect sizes were considered large at 0.80, medium at 0.50, and small at 0.20 [46]. Descriptive statistics were used for the feasibility measure results.

Compliance With Ethical Standards

This study has been approved by the Allendale Institutional Review Board. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments. Informed consent was obtained from all individual participants included in the study. This article does not contain any studies with animals performed by any of the authors.

Results

Participants

Clinicians were recruited through advertisements in professional journals from National Association of Social Work and the American Psychological Association and through an announcement on the International Society for Interpersonal Psychotherapy (ISIPT) listserv. A total of 35 clinicians inquired about the study and were offered free participation. Of these, 26 (74%, 26/35) enrolled in the study and started the tutorial, and 22 (62%, 22/35) completed it. Furthermore, 18 (51%, 18/35) trainees participated in the live applied training session after completing the tutorial. The Allendale Institutional Review Board approved the study protocol, and all participants signed informed consent statements.

Of the 26 community clinicians starting the Web-based tutorial, 23 (88%) were female, 22 (85%) white, 1 (4%) African American, 4 (15%) Hispanic, and 3 (11%) other or mixed racial categories. Participants came from 15 US states and one each from Mexico, Brazil, Canada, and the United Kingdom. Mean age was 41.6 years (standard deviation [SD]=11.5, range: 26-63 years), and mean years of clinical experience was 10.5 (SD=7.6, range: 1-26 years). Eleven (42%, 11/26) were social workers, 11 (42%, 11/26) psychologists, 2 (8%, 2/26) marriage and family therapists, 1 (4%, 1/26) a psychiatrist, and 1 (4%, 1/26) a psychiatric nurse. Additionally, 24 (92%, 24/26) were actively conducting psychotherapy with clients. Only 3 (11%) reported having received any prior formal training in IPT: one through a continuing education workshop, one as part of undergraduate coursework, and one in graduate coursework. Three participants (14%, 3/26) reported having used some IPT techniques in their practice before participating in the study.

Web-Based Tutorial

Efficacy: Improvement in Knowledge of Interpersonal Psychotherapy (IPT) Concepts

The mean number of correct answers on the 38-item IPT concepts and skills quiz improved significantly from 16.5 (SD

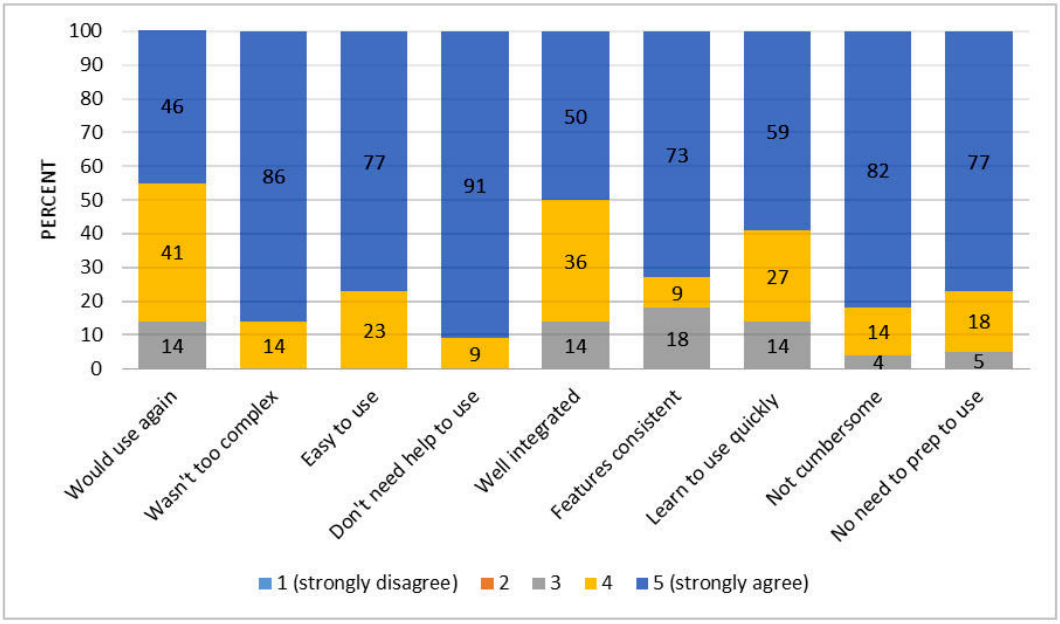
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4.6) on pretest to 27.5 (SD 4.0) on posttest, t_{21}=15.7, P<.001. The standardized effect size for the change was large: d=2.53, 95% CI 2.23-2.92.

User Satisfaction: Technical Features

The SUS evaluated user satisfaction with the technical features of the Web-based tutorial. Mean SUS score was 90.6 (SD 11.4). This corresponds to a mean rating between "excellent" and "best imaginable." Figure 1 shows ratings on individual SUS items. Users found the technical features of the tutorial easy to use and understand. The mean global rating on the user-friendliness item was 5.7 (between good and excellent; range: 1=worst imaginable to 7=best imaginable).

Figure 1. System Usability Scale ratings of user satisfaction with technical features of Web-based tutorial.



User Satisfaction: Clinical Content

Figure 2 illustrates user satisfaction with the clinical content of the tutorial. Clinicians found the concepts clearly presented in an interesting fashion and found the content useful for helping them treat depressed clients. The mean global rating of user satisfaction with the clinical content was 3.2 (range: 1=very dissatisfied to 4=very satisfied).

User satisfaction with the tutorial was also evaluated by whether clinicians felt the learning objectives of each module were met. Nineteen learning objectives were identified a priori for the seven modules (Table 1). Trainees rated whether learning objectives were met after completing each module. They rated the learning objectives as having being met 95% (18/19) of the time, on average.

Global ratings of how much the trainee learned (scale range from 1=very little to 5=a great deal) was also obtained, as required by continuing education accreditation agencies. The mean rating of trainees learning from the Web-based tutorial was 3.91.

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Figure 2. Ratings of user satisfaction: clinical content of Web-based tutorial.

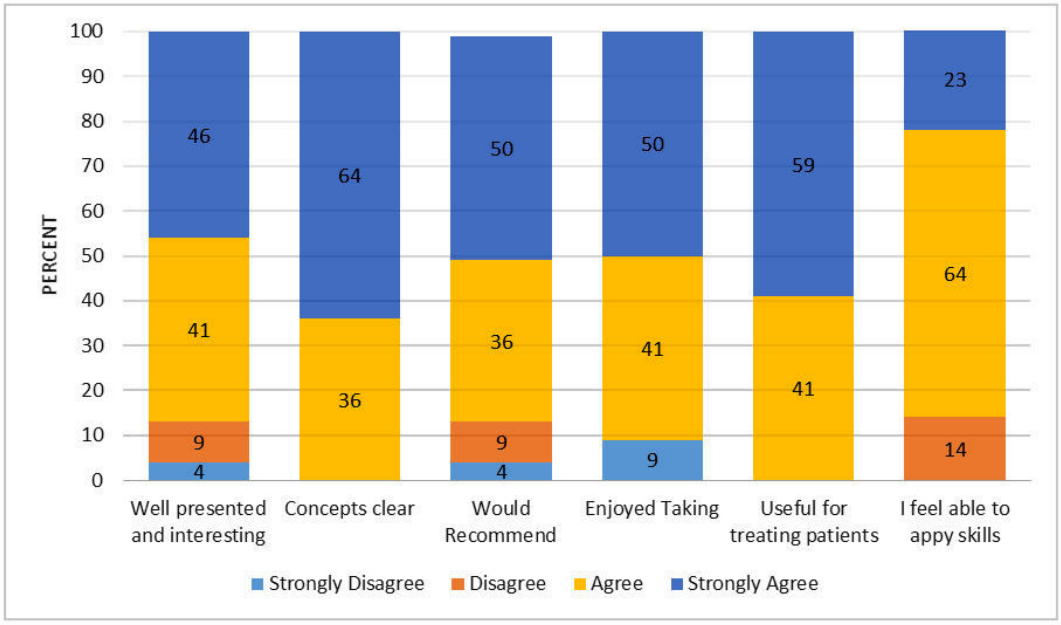
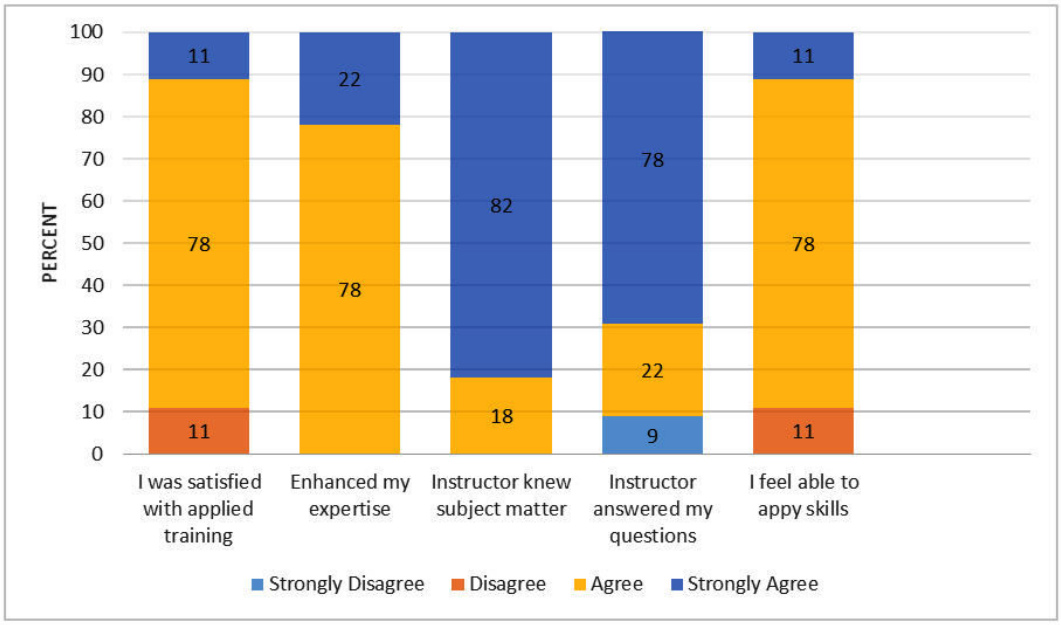


Figure 3. Ratings of user satisfaction: applied training via videoconference.



Applied Training

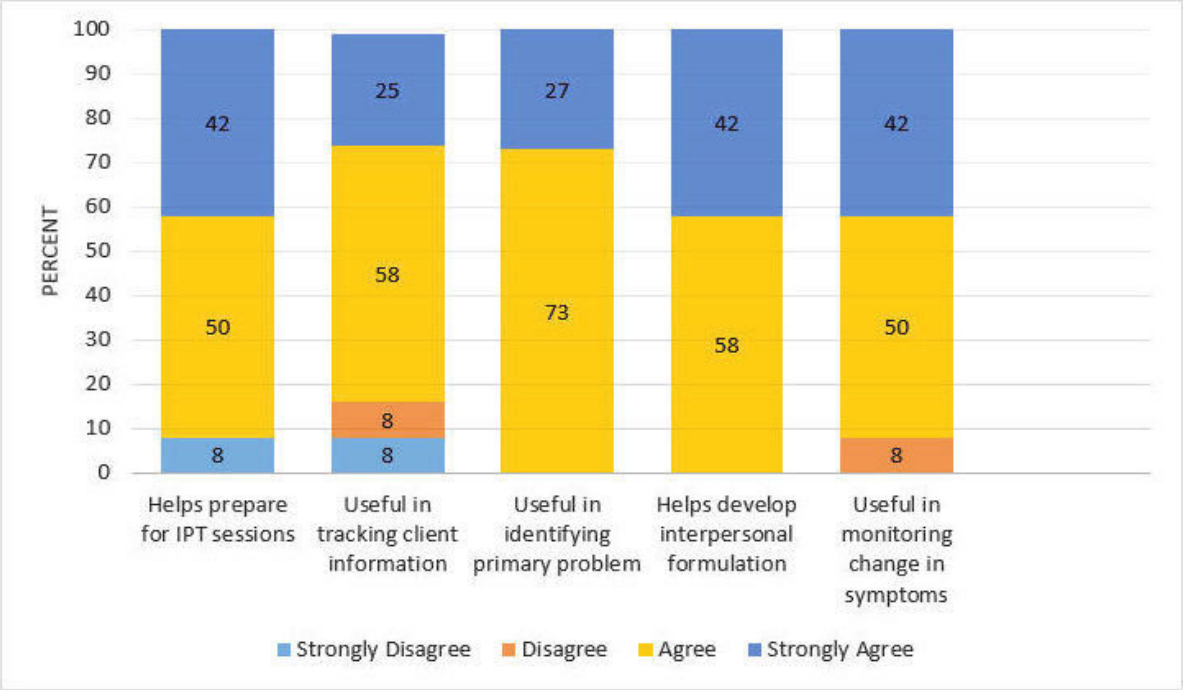
User satisfaction with the applied training session via videoconference appears in Figure 3. Overall, trainees felt the program enhanced their professional expertise and felt able to apply the skills learned to actual treatment. Mean global rating of user satisfaction with the applied training was 3.5 (range: 1=very dissatisfied to 4=very satisfied). Mean rating of learning from the applied training was 3.94 (scale range from 1=very little to 5=a great deal).

Web Portal

Figure 4 shows user satisfaction with the Web portal. Trainees thought the website helpful in preparing for IPT sessions, identifying the client's IPT focus area, developing an interpersonal formulation, and monitoring changes in the client symptoms. Overall, satisfaction rating was 3.3 (range: 1=very dissatisfied to 4=very satisfied).

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Figure 4. Ratings of user satisfaction: posttraining Web portal.



Duration of Training

The mean time it took trainees to complete the Web-based tutorial was 3.3 hours (SD=0.8, range 2.3-5.0 hours). The average module was 29.1 min (SD 18.3). The tutorial was completed over a mean of 27.4 days (SD=22.9, range 1-66 days). The mean duration for participation in the entire training protocol (start of Web-based tutorial to evaluation of Web portal) was 91 days (SD 18.5).

Discussion

Principal Findings

This pilot study provides evidence to support the efficacy and feasibility of this technologically advanced, three-part therapist training intervention on IPT for major depression. Results supported both our hypotheses: the tutorial increased trainee knowledge of IPT, and trainees reported high levels of satisfaction with the three training components. User satisfaction has critical importance: if trainees do not like a training program, find it too difficult to use, or not useful, they will not complete it. In our study, trainees described high satisfaction with both technical aspects and clinical content of the training components and had a completion rate of 85% for the Web-based tutorial and 69% for the live applied training. This ranks somewhat higher than average compared with other Web-based trainings [47]. Although we could not assess the total number of possible participants who received notification of the study training opportunity, impressions from ease of recruitment further support the potential demands and interest in this vehicle (enrollment was limited to 35 participants due to budgetary constraints).

If successfully disseminated, this intervention may assist academic training programs in solving the dual challenges they face in expanding training curricula to include EBT's and ensuring the training is effective. IPT in particular is an EBT in which most practitioners do not receive training, despite its strong empirical standing. As no treatment is universally effective, expanding training options to include multiple EBTs helps produce more well-rounded clinicians and provides more treatment options for patients, some of whom may prefer or respond better to IPT than other EBTs. IPT has been far less disseminated than CBT (which has comparable supportive evidence) and psychodynamic therapy (which has far less empirical support). IPT uses the medical model of illness which makes it very compatible with clients treated with a combination of psychotherapy and medication.

From a practical standpoint, the model this study used augments traditional approaches to training rather than replacing them [48-50]. Web-based tutorials can lay conceptual groundwork, like a textbook, but with the added advantages the technology affords in enhancing learning. Through the use of video recordings and illustrated vignettes, trainees can observe demonstrations of skills being correctly implemented in a variety of situations. Ongoing self-tests incorporated in the tutorial helps ensure and document that participants understand concepts, which has particular importance in evidence based practice. Videoconferencing can overcome logistical barriers to access to domain experts and be used for supervision, including role playing. The use of role plays with supervisors when learning new skills has been found superior to simple discussion [51]. Evaluation of clinical skills by actually observing trainees applying skills is critical to success but underutilized. In our sample, only 1 trainee reported prior live skills observation as part of their IPT training, a number

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consistent with the 10% rate reported in other studies [21,29]. Live observation has been found to enhance learning compared with observing videotapes of trainees [52].

The technology may also enhance posttraining supervision in several ways. Videoconferencing facilitates access to training supervisors. Access to a training supervisor following training has been found an essential ingredient of posttraining success superior to other forms of posttraining options such as peer consultation [53]. The technology facilitates ongoing case discussion following training, which is critical to ensure therapist efficacy in patients seen posttraining. The Web portal helps transfer learning from classroom to practice by providing a tool to help structure sessions, monitor application of and adherence to techniques, and monitor treatment outcome. It may also help prevent "therapist drift," as trainees could return to the website to refresh their knowledge and for ongoing retesting and monitoring [54]. While not included as part of this study, evaluation of ongoing posttraining therapist supervision using videoconference and Web portals would be informative.

Results from this study are consistent with other studies on the use of these technologies for training clinicians on other EBTs such as CBT [29,55]. This is the first application of this technology to IPT training to be empirically evaluated that we are aware of (there has been one Web-based training pilot for Interpersonal Social Rhythms Therapy [IPSRT], an adaptation of IPT for patients with bipolar disorder [56]). Although IPT is less structured than CBT, there was no reason to think the methodology would have less success. In this study, we did not formally assess clinical competence, as the study goal was to assess user satisfaction with the methodology and improvement in conceptual knowledge. Thus, the degree of clinical competence the trainees attained is unknown. The number of live applied sessions necessary to achieve varying levels of competence in IPT using this methodology needs exploration, as does the differential impact of didactic and applied training on clinical skills. In a prior CBT study, the Web-based tutorial sufficed to improve clinical skills from poor to minimally acceptable, but the addition of four 1-hour videoconference role play sessions further improved rated clinical skills to between adequate and good [29]. Competence was assessed using role plays conducted via videoconference, which were recorded and evaluated for clinical skills by a blind rater. Such a methodology may be one way to assess competence via Web-based training. Further studies are needed to explore the relationship between the number of applied sessions and levels of competence and the relative impact of didactic and applied on-line training with IPT.

Limitations

Limitations of this pilot study include lack of randomization and a control group, such as comparison to current standard methods of clinical instruction. The small sample size limits generalizability of results. In addition, since we did not collect patient data, it is impossible to know how the training program affected clinical practice. Although trainees received no feedback following pretesting on conceptual knowledge, there is the potential for practice effects. In the absence of a control group, it is difficult to determine the extent to which improvement in scores on the tutorial was due to training as opposed to induction bias. However, some studies have found pretests increase learning by orienting learners to subsequent information [35].

Conclusions

Future studies could include a larger sample size, as well a cohort of recent graduates from academic internships who are interested in additional psychotherapy training following graduation. Such training could count toward continuing education credits [48]. In addition, further study of the stability of training is warranted. In summary, results support the use of these technologies in training clinicians in EBTs and warrant further study to empirically evaluate these training methods compared to and in conjunction with current methodologies.

Acknowledgments

The authors would like to thank Richard DeVouno for developing the eLearning component of the Web-based tutorial. This study was funded with federal funds from the National Institute of Mental Health, National Institutes of Health, Department of Health and Human Services, under Small Business Innovation Research (SBIR) grant number R43MH106169.

Conflicts of Interest

Drs Kobak, Lipsitz, and Markowitz have intellectual property rights and a proprietary interest in the Web-based training program described in this project. Dr. Markowitz receives salary support from the National Institute of Mental Health, the Earl Mack Foundation, and the New York State Psychiatric Institute; minor book royalties from American Psychiatric Publishing, Basic Books, and Oxford University Press; and an editorial stipend from Elsevier Press.

Multimedia Appendix 1

Example of Web-based tutorial multimedia content.

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Multimedia Appendix 2

Example of clinical vignettes and challenge questions.

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[PPTX File, 2MB - jmir_v19i7e257_app2.pptx]

Multimedia Appendix 3

Example of pre-session checklist from IPT Web portal.

[PNG File, 232KB - jmir_v19i7e257_app3.png]

Multimedia Appendix 4

Example of post-session checklist from IPT Web portal.

[PNG File, 106KB - jmir_v19i7e257_app4.png]

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Abbreviations

CBT: cognitive behavioral therapy
EBT: evidence-based therapy
IPT: interpersonal psychotherapy
SUS: System Usability Scale

Edited by G Eysenbach; submitted 02.05.17; peer-reviewed by J Greist, H Swartz; comments to author 31.05.17; revised version received 04.06.17; accepted 05.06.17; published 17.07.17.

Please cite as:
Kobak KA, Lipsitz JD, Markowitz JC, Bleiberg KL
Web-Based Therapist Training in Interpersonal Psychotherapy for Depression: Pilot Study
J Med Internet Res 2017;19(7):e257
URL: http://www.jmir.org/2017/7/e257/
doi:10.2196/jmir.7966
PMID:28716769

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Original Paper

Internet-Based Assessment of Oncology Health Care Professional Learning Style and Optimization of Materials for Web-Based Learning: Controlled Trial With Concealed Allocation

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Abstract

Background: Precision medicine has resulted in increasing complexity in the treatment of cancer. Web-based educational materials can help address the needs of oncology health care professionals seeking to understand up-to-date treatment strategies.

Objective: This study aimed to assess learning styles of oncology health care professionals and to determine whether learning style-tailored educational materials lead to enhanced learning.

Methods: In all, 21,465 oncology health care professionals were invited by email to participate in the fully automated, parallel group study. Enrollment and follow-up occurred between July 13 and September 7, 2015. Self-enrolled participants took a learning style survey and were assigned to the intervention or control arm using concealed alternating allocation. Participants in the intervention group viewed educational materials consistent with their preferences for learning (reading, listening, and/or watching); participants in the control group viewed educational materials typical of the My Cancer Genome website. Educational materials covered the topic of treatment of metastatic estrogen receptor-positive (ER+) breast cancer using cyclin-dependent kinases 4/6 (CDK4/6) inhibitors. Participant knowledge was assessed immediately before (pretest), immediately after (posttest), and 2 weeks after (follow-up test) review of the educational materials. Study statisticians were blinded to group assignment.

Results: A total of 751 participants enrolled in the study. Of these, 367 (48.9%) were allocated to the intervention arm and 384 (51.1%) were allocated to the control arm. Of those allocated to the intervention arm, 256 (69.8%) completed all assessments. Of those allocated to the control arm, 296 (77.1%) completed all assessments. An additional 12 participants were deemed ineligible and one withdrew. Of the 552 participants, 438 (79.3%) self-identified as multimodal learners. The intervention arm showed greater improvement in posttest score compared to the control group (0.4 points or 4.0% more improvement on average; P=.004) and a higher follow-up test score than the control group (0.3 points or 3.3% more improvement on average; P=.02).

Conclusions: Although the study demonstrated more learning with learning style-tailored educational materials, the magnitude of increased learning and the largely multimodal learning styles preferred by the study participants lead us to conclude that future content-creation efforts should focus on multimodal educational materials rather than learning style-tailored content.

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(J Med Internet Res 2017;19(7):e265) doi:10.2196/jmir.7506

KEYWORDS

e-learning; Web-based Instruction; learning; teaching materials; information dissemination; online systems; education, distance; continuing education; medical oncology/education

Introduction

Precision medicine is the use of a patient's molecular characteristics to determine disease risk, make a precise diagnosis, determine disease prognosis, and to select the best treatment plan for the patient. In the field of cancer, researchers have been working to develop new drugs and therapeutic strategies tailored to cancers harboring particular biomarkers. Breast cancer has a long history of biomarker-driven prediction of sensitivity to targeted therapies. This study used educational materials on inhibition of cyclin-dependent kinases 4/6 (CDK4/6) to block cell growth as a therapeutic strategy being investigated in patients with hormone receptor-positive breast cancer, including those who have developed resistance to endocrine therapy. These materials were used to investigate oncology health care professional learning styles and optimization of materials for Web-based learning.

Rapidly evolving information about precision cancer medicine creates a knowledge gap in the education of oncology health care professionals regarding complex and important precision cancer medicine concepts, along with approaches for identifying therapeutic strategies for individual patients [1-4]. For example, a large survey in 2011 showed that oncology nurses did not discuss mutation testing with patients because they felt they lacked the knowledge to do so [1]. More recently, an international survey demonstrated that a majority of lung cancer oncologists understand that improved survival is associated with therapies selected after epidermal growth factor receptor (*EGFR*) mutation testing, but a quarter of lung cancer oncologists do not consider the specific *EGFR* mutation detected in making therapeutic decisions [4]. This knowledge gap needs to be addressed quickly and effectively to bring the promise of precision cancer medicine to all cancer patients. The topic of CDK4/6 inhibitors in breast cancer was chosen because it was a timely, representative topic in the field of precision cancer medicine with an active knowledge gap.

Web-based tools provide an important platform for oncology health care professionals to address this knowledge gap. Websites such as UpToDate [5] are heavily used by physicians of all types. A wealth of clinical trial information can be found at ClinicalTrials.gov [6] or on the National Cancer Institute's website [7]. We have developed the My Cancer Genome website [8] as a publicly accessible knowledge resource targeted at oncology health care providers. My Cancer Genome provides up-to-date information to oncology health care providers on the clinical relevance of mutations in cancers and gene-specific clinical trials. Launched in 2011, My Cancer Genome receives more than 10,000 site visits per week, from 211 countries and territories across the world, from an audience of health care providers, researchers, and patients/caregivers (usage statistics current as of January 2017). My Cancer Genome provides content pages on 23 cancer types, 823 genes, and 456 disease gene-variant relationships (content statistics current as of May 2017). Breast cancer educational content includes information on the therapeutic implications of alterations in several genes, including links to relevant clinical trials. A companion mobile app has also been available for Apple iOS devices since 2013.

An individual's learning style refers to how that individual prefers to gather, interpret, organize, and think about information [9]. For example, individuals may vary in their preferences for how they receive educational information. Examples include preferences for learning through visual (eg, pictures, graphs, diagrams, charts), auditory, and text-based (eg, lists, bullets, or hierarchically organized text) formats [10]. Several learning style assessments have been developed that evaluate preferences according to different learning style models [11]. A person's learning style preferences may change throughout their lifetime, and cultural factors and previous experiences may contribute to differences in preferences [11-14].

The literature on learning styles in the medical setting has predominantly focused on medical students and residents [13-18]. Learning style preferences may vary based on level of training [19,20]. For example, one small study reported differences in the prevalence of multimodal learners among Australian rural general practice registrars compared to rural medical students [19].

Tailoring education based on learning style may facilitate comprehension of the information. In a study evaluating the effect of providing medical students with instruction matched according to learning styles or in a standard format, tailored instruction was found to result in enhanced understanding of the material based on improvement in test scores, with statistically significant differences seen for kinesthetic learners [13]. Similarly, prior research has demonstrated that providing patients with health educational information customized to their health literacy and learning style preferences increased understanding and retention of the material [21-24]. However, in an updated systematic review and meta-analysis, Cook [25] found that evidence was lacking to support the use of adaptation to cognitive and learning styles in computer-assisted instruction. More rigorous studies are needed to better understand the effectiveness of tailored instruction on Web-based learning. To the best of our knowledge, no studies have been published reporting the learning style preferences of oncology health care professionals. Considering health care providers' learning style preferences when developing educational content for Web-based tools may help accelerate understanding and retention of the information.

Objectives

In this study, we developed educational information tailored to different learning styles on the topic of treatment of metastatic estrogen receptor-positive (ER+) breast cancer using CDK4/6 inhibitors. The objectives of this study were to (1) assess

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learning style preferences of oncology health care professionals and (2) evaluate the effectiveness of providing educational materials customized to learning style preferences using a fully automated, controlled study design with concealed allocation.

Methods

The CONSORT-EHEALTH checklist for this study can be found in Multimedia Appendix 1. Technical details and changes after study commencement can be found in Multimedia Appendix 2.

Ethics

This study was approved by the Vanderbilt University Medical Center institutional review board (IRB). This study received a waiver of consent from the IRB. In place of the traditional consent process, when participants clicked the link in their invitation email, they arrived at the welcome page. This page provided participants with information about the study's purpose, mechanics, and risks, with contact information for those with further questions. The welcome page also provided an estimate of the time commitment needed to participate in the study. Participants then entered their email address, personal identification number (PIN) as provided in their invitation email, and answered yes or no to the statement, "I agree to participate in this study." We did not receive any phone calls or emails from participants prior to their agreement to participate.

Study Design

A parallel study design was used to examine the effectiveness of providing learning style-tailored materials compared to control materials (Figure 1). The study opened on July 13, 2015, and closed on September 7, 2015. Participants were allocated 1:1 to the intervention or control arms when they landed on the enrollment screen. Participants were asked to complete a learning style assessment and a knowledge pretest. Participants allocated to the intervention arm viewed materials consistent with their learning style preferences, and participants allocated to the control arm viewed materials in the format used on My Cancer Genome. Following review of the educational materials, all participants were asked to complete a knowledge posttest and a feedback survey. After 2 weeks, participants who had completed the posttest were asked to take the knowledge follow-up test. The 2-week interval was chosen for consistency with the authors' related research [21,24]. After taking the knowledge follow-up test, participants could provide demographic information and fill out a form to provide the information needed to send the US $100 Amazon.com Gift Card incentive.

Data Security

Safety and security of participant data were ensured through use of REDCap (Research Electronic Data Capture) for administration of the study [26]. All study data were collected and managed using REDCap electronic data capture tools hosted at Vanderbilt University Medical Center. REDCap is a secure, Web-based app designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for importing data from external sources.

Participants

The email marketing service Medical Marketing Service, Inc was used to recruit physicians, nurse practitioners, and physician assistants. The lists were comprised of professional society members who had indicated oncology as an area of focus. Participants were assumed to be computer and Internet literate. Prior to enrollment, participants received the invitation email and could view the welcome page in REDCap. Copies of both are provided in Multimedia Appendix 3. To ensure that participants had been invited to take part in the study, each invitation email contained a unique 10-character alphanumeric PIN. Details related to the PINs are described in Multimedia Appendix 2. Following agreement to participate in the study, participants answered an eligibility question; participants were required to be in active practice in an oncology setting.

Recruitment

Potential volunteers were sent email invitations to participate in the study on July 13 and 20, 2015. The second email was sent regardless of whether they had enrolled in the study or not. In order to protect participant privacy, Medical Marketing Service was not given the list of participants who had enrolled in the study. Enrollment and follow-up occurred through study close on September 7, 2015. The trial closed on September 7 because enrollments had dropped to almost zero and we believed there were no remaining active participants. After study close, we found one remaining active participant. This participant was given the gift card incentive, but the data from this participant were not used in the analysis. It was possible for participants to enroll more than once; for more information, see Multimedia Appendix 2.

Interventions and Outcomes

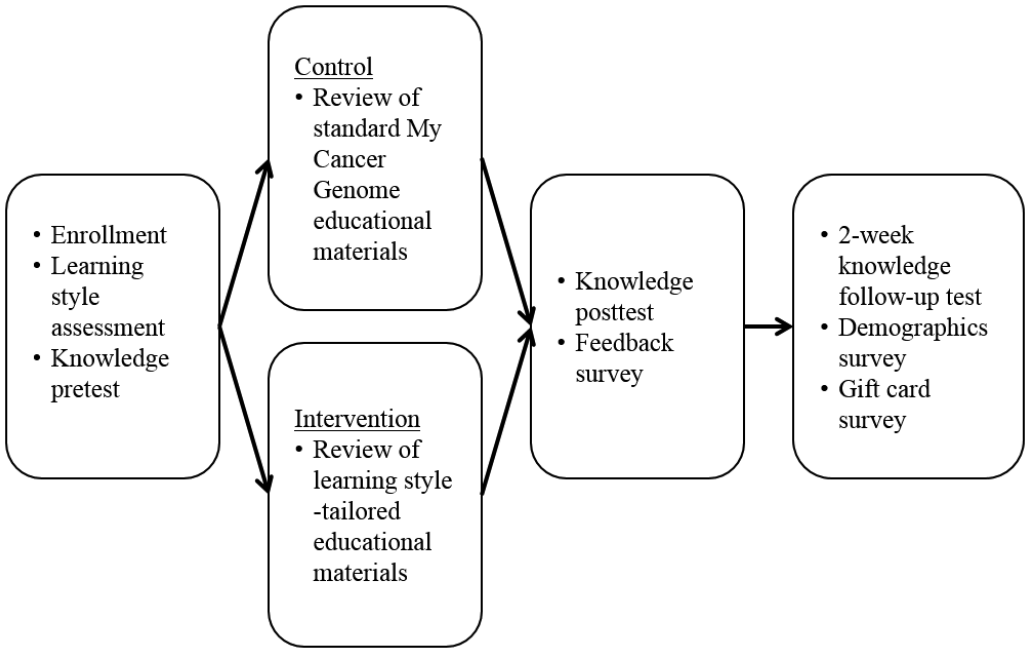
The codebook for all surveys is provided in Multimedia Appendix 4. Multimedia Appendix 5 contains information about participant tracking and related analyses.

Learning Style Assessment

Participants were asked to self-report their learning style preferences by selecting one of the following responses to complete the statement, "I am likely to remember something a year from now if: (1) I learn it by reading, (2) I learn it by listening, (3) I learn it by watching, (4) I learn it by reading and listening, (5) I learn it by reading and watching, (6) I learn it by listening and watching, (7) I learn it by reading, listening, and watching" (see also Multimedia Appendix 4). This question was modeled after a single-item self-report measure, which was used by the authors in previous research [23]. The model self-report measure determined learning style preferences based on participants' responses to whether they would recall how to do something a year from now if they learned it by reading, listening, watching, or trying things on their own; participants could select all that applied [23]. The revised question wording used in our study reflects that our educational content does not involve skill-based or kinesthetic learning.

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Figure 1. Study design.



Knowledge Tests

A 10-question test was developed to evaluate participant knowledge of the educational materials. The questions were multiple choice or true/false, and each question included a response option of "don't know." Participants were asked to complete the test immediately before (pretest) and after (posttest) viewing the information and 2 weeks later (follow-up test). The same questions were used for all three surveys, although the order of the questions and the order of multiple-choice answers were changed for each survey. The order of true/false answers was not changed. The surveys were loaded into REDCap and tested before study commencement. Each set of educational materials contained the answers to all 10 questions.

Educational Materials

New content was developed for the project for both the control and intervention arms. Copies of the educational materials are shown in Multimedia Appendix 6. Educational materials were developed by the authors, who together brought experience in the adaptation of health information according to learning preferences and in-depth knowledge of oncology [21-24,27,28]. The materials were also reviewed by two experts in breast cancer research to further ensure accuracy of the information. Intervention materials with a watching component included slides with figures, captions, and limited bulleted text. Intervention materials with a listening component included an audio recording. Intervention materials with a reading component included text. The control materials included text, figures, and tables.

Feedback, Demographics, and Gift Card Surveys

The feedback survey was presented to participants following the knowledge posttest. The feedback survey evaluated whether participants thought the information in the learning materials was easy to understand and if they learned something new. The survey consisted of five questions (see Multimedia Appendixes 4 and 7). Options for four of the questions were on a rating scale from strongly agree to strongly disagree (strongly agree, disagree, neither agree or disagree, agree, or strongly agree). For the fifth question, participants could share any other thoughts about the materials in an open-text field. Answering questions in this survey was optional.

The demographics survey was presented to participants following the knowledge follow-up test. For all participants, the survey consisted of six questions about their practice type (academic, community, both, or other), percentage of patients seen with breast cancer (<25%, 25%-50%, >50%, or unknown), age, gender, race, and ethnicity. Answering questions in this survey was optional.

The gift card survey followed the demographics survey. This survey collected information required for institutional financial reporting requirements and US federal statutory requirements. Although completing this survey was optional, participants could not receive the gift card incentive without completing it.

Study Sample

The primary objective of this study was to examine the improvement of the knowledge test score (pretest vs posttest) between experimental group (matched learning materials according to learning style) and the control group (standard learning materials). According to the prospective sample size calculation, a sample size of 250 per group would provide at least 90% power to detect a conservative effect size of 0.3 with two-sided type I error of 5%. The effect size is defined as the ratio of mean difference of test score between study groups to the standard deviation.

From Medical Marketing Service, we learned that a good open rate—the likelihood that a recipient will open and view the email—for a marketing email to oncologists is 13% (Jane Stormzand, personal communication, February 24, 2015). We

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used this number to estimate our open rate for the invitation email. We did not have data on the level of attrition to expect during the course of the study itself, so we estimated using high and low attrition rates at 80% and 40% for each of four study events: (1) agreeing to participate in the study, (2) viewing the educational materials, (3) taking the knowledge posttest, and (4) taking the knowledge follow-up test. With a high attrition rate, we would have expected only five participants to complete the study; with a low attrition rate, we would have expected 438 to complete the study. As a result, we did not limit enrollment, and we had an IRB-approved upper limit of enrollment set at 1200. Participants who did not complete required portions of the study (learning style survey, pretest, posttest, and follow-up test) were excluded.

Allocation Concealment and Blinding

The study was fully automated; therefore, the study personnel did not have access to the list of individuals invited to participate in the study and the study personnel had no control over when any individual clicked on the survey link in the recruitment email (the action that creates a numbered record in REDCap). For these reasons, we decided to use alternating ABAB allocation rather than randomization. Although not randomized, the allocation was concealed. Participants with odd-numbered records were allocated to the intervention arm, whereas even-numbered records were allocated to the control arm.

Although no expectations were set about the content of the educational materials before allocation or review of educational materials, we do not consider the participants to have been blinded because after clicking the submit button on the REDCap page with the link to the educational materials, participants were shown the survey queue, which listed whether the surveys were on the control or intervention arm. Study personnel were not blinded; this was deemed unnecessary because the outcome measures were objective measures—test scores—and because the study was fully automated. The study statisticians were blinded to group assignment.

Statistical Methods

Multiple imputation was performed using the *rms* R package to account for missing data (practice type: 2.0%, 11/552; percent of breast cancer patients seen: 1.4%, 8/552; age 4.5%, 25/552; gender: 4.7%, 26/552; race: 13.9%, 77/552; physician specialty: 7.6%, 42/552). Multivariable linear regression was used to estimate the intervention effect on (1) knowledge posttest score and (2) knowledge follow-up test score, adjusted for knowledge pretest score (baseline assessment), as well as other covariates (practice type, percentage of breast cancer patients seen, age, gender, race, and physician specialty). Hierarchical cluster analysis and redundancy analysis were performed for data reduction. Years since completing residency/fellowship was dropped from the model because it could be predicted from other variables in the model. Residual analysis was used to check the linear regression assumptions of homogeneity for variance, normality, and linearity. For each individual learning style, the Wilcoxon signed rank test was performed to test for differences between (1) knowledge pretest score and knowledge posttest score, and (2) knowledge pretest score and knowledge follow-up test score. Multiple comparisons were corrected using the Bonferroni method. All tests were significant at the overall two-sided 5% level. All statistical analyses were performed in R version 3.1.2.

Results

Participant Flow

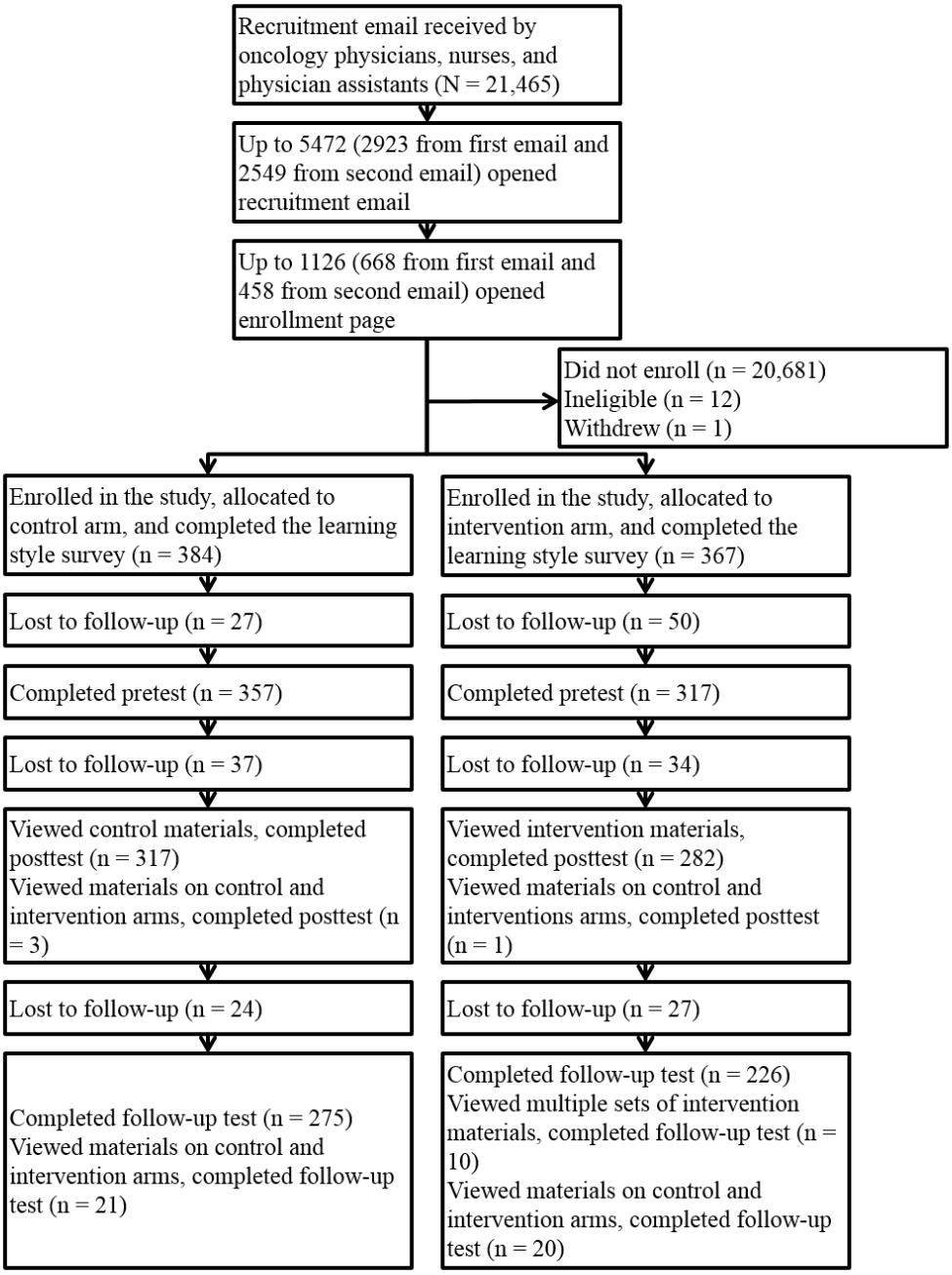
A total of 751 participants enrolled and completed the learning style survey (Figure 2). Of those, 384 were allocated to the control arm and 367 were allocated to the intervention arm. A total of 296 on the control arm and 256 on the intervention arm completed all required portions of the study, for a total of 552. Of those who completed the study on the control arm, 19 viewed educational materials on the control arm and the intervention arm due to multiple enrollments. Of those who completed the study on the intervention arm, 22 viewed educational materials on the control arm and the intervention arm, and 10 viewed multiple intervention arm educational materials due to multiple enrollments. Because participants could view any nonstudy materials they desired, in electronic or hard copy, and because participants were not prevented from re-enrolling to view additional on-study educational materials, participants who viewed multiple sets of educational materials were not excluded from analysis.

Based on the first recruitment email, the view rate of the recruitment email itself was 13.62% (2923/21,465), and the subsequent view rate of the welcome page of the study was 22.85% (668/2923). Participation rate, determined by the ratio of unique participants completing the learning style survey to those who clicked on a link in a recruitment email, was 66.70% (751/1126). Note that this underestimates the participation rate because some participants clicked links in both recruitment emails. Completion rate, determined by the ratio of participants completing the knowledge follow-up test to those who completed the learning style survey, was 73.50% (552/751). The attrition rate decreased at each step (see Figure 3), particularly following enrollment in the study. Note that the second two events underestimate attrition; these numbers represent the sum of individuals opening and clicking links in the two recruitment emails. Because some individuals opened or clicked links in both emails, the sums overestimate participation.

We found that several PINs were used for multiple study enrollments: 552 participants enrolled once, 172 participants enrolled twice, 23 participants enrolled three times, and 4 participants enrolled four times.

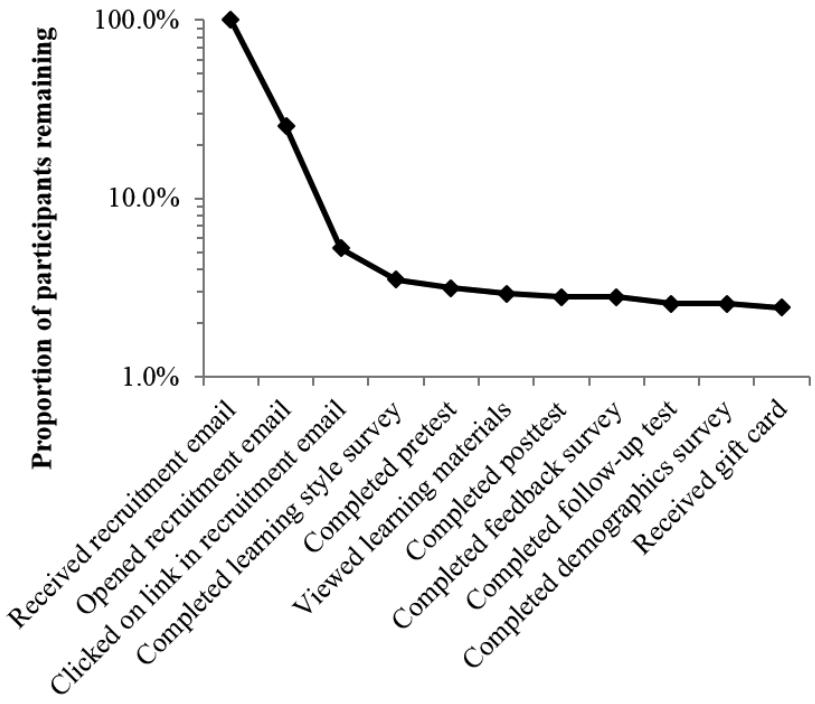
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Figure 2. Participant flow diagram.



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Figure 3. Attrition diagram.



Baseline Data

Participant characteristics are shown in Table 1. Overall, the arms were well balanced for participant characteristics, with 296 participants in the control arm and 256 in the intervention arm. The majority of participants were physicians, with slightly more in the control arm versus the intervention arm (274 vs 237). There were four fewer physician assistants and one more nurse practitioner and other participant types in the intervention arm than the control arm. Half (50.6%, 274/541) of the participants in both arms worked in an academic setting, with 39.89% (215/541) working in a community setting, and 9.6% (52/541) reporting that their practice type was both academic and community based. For the majority of participants in both arms, less than 25% of patients in their practices were breast cancer patients, and for just under a third of participants, 25% to 50% of patients in their practices were breast cancer patients.

The demographics were fairly well balanced between arms; all *P* values were insignificant at the two-sided 5% significance level, as shown in Table 1. There were more men in the control arm (202 vs 163). The majority of participants in both arms were white (68%, 323/475), with an additional 25% (119/475) of participants reporting their race as Asian. The mean age was 42.8 (SD 9.8) years for the control arm and 43.3 (SD 9.9) years for the intervention arm.

More than half the participants were medical oncologists, with more in the control arm (164 vs 133). Radiation oncologists made up 15.9% (81/510) of the participants, with more in the intervention arm (35 vs 46). The number of years since physicians had completed residency/fellowship was similar in both arms, with one-third reporting less than 5 years and one-third more than 15 years.

Learning styles were also balanced between the intervention arm and the control arm. The largest group was the watching plus listening plus reading group, making up 38.8% (214/552) of participants. The next largest group was the watching plus reading group, with 18.7% (103/552) of participants selecting this group. More participants chose listening or listening plus reading in the control arm than the intervention arm (9 vs 3 for listening, 38 vs 29 for listening plus reading).

The median follow-up interval between posttest and follow-up test was equivalent between arms at 14.2 (IQR 14.0-15.8 for control arm and IQR 14.0-15.5 for intervention arm) days.

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Table 1. Participant characteristics (N=552).

Participant characteristics	N[a]	Control (n=296)	Intervention (n=256)	*P*
Participant type, n (%)	552			.81[b]
Physician		274 (92.6)	237 (92.6)	
Physician assistant		16 (5.4)	12 (4.7)	
Nurse and other		6 (2.0)	7 (2.7)	
Practice type, n (%)	541			.42[b]
Academic	541	151 (51.9)	123 (49.2)	
Community		109 (37.5)	106 (42.4)	
Both		31 (10.6)	21 (8.4)	
Percentage of patients with breast cancer seen in participant's practice, n (%)	544			.88[b]
<25%		170 (58.4)	141 (55.7)	
25%-50%		78 (26.8)	74 (29.2)	
>50%		37 (12.7)	34 (13.4)	
Unknown		6 (2.1)	4 (1.6)	
Age (years)				
Mean (SD)	527	42.8 (9.8)	43.3 (9.9)	.57[c]
Median (IQR)		40 (35-50)	40 (35-50)	
Gender, n (%)	526			.42[b]
Male		202 (70.9)	163 (67.6)	
Female		83 (29.1)	78 (32.4)	
Race, n (%)	475			.95[b]
White		173 (67.8)	150 (68.2)	
Asian		65 (25.5)	54 (24.6)	
Other/multiracial		17 (6.7)	16 (7.3)	
Hispanic, Latino, or Spanish origin, n (%)	476			.32[b]
Hispanic or Latino		8 (3.2)	11 (4.9)	
Non-Hispanic		245 (96.8)	212 (95.1)	
Physician specialty, n (%)	510			.11[b]
Resident		6 (2.2)	11 (4.7)	
Fellow		39 (14.2)	20 (8.5)	
Medical oncologist and/or hematologist		164 (59.9)	133 (56.4)	
Surgical oncologist		10 (3.6)	9 (3.8)	
Radiation oncologist		35 (12.8)	46 (19.5)	
Pathologist		13 (4.7)	13 (5.5)	
None of the above		7 (2.5)	4 (1.7)	
Years since completed residency/fellowship, n (%)	510			.10[b]
<5		85 (31.1)	81 (34.2)	
5-9		51 (18.7)	56 (23.6)	
10-15		50 (18.3)	29 (12.2)	
>15		64 (23.4)	60 (25.3)	
Other		23 (8.4)	11 (4.6)	

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Participant characteristics	N[a]	Control (n=296)	Intervention (n=256)	*P*
Follow-up interval (days)				
Mean (SD)	552	15.3 (3.0)	15.2 (2.5)	.58[c]
Median (IQR)		14.2 (14.0-15.8)	14.2 (14.0-15.5)	

[a] N is the number of nonmissing observations.

[b] The test used was Pearson chi-square test.

[c] The test used was Wilcoxon rank-sum test.

Outcomes and Estimation

Analysis was conducted by original assigned groups. Almost 80% (438/552) of oncology health care professionals were multimodal, with the most common learning style being watching plus listening plus reading (Table 2).

There was a significant difference in both knowledge posttest score and knowledge follow-up test scores between the control arm and the intervention arm. The intervention arm showed a greater improvement of 0.4 points in the knowledge posttest score compared to the control group (the adjusted mean posttest scores were 7.861, SE 0.408 and 7.461, SE 0.414 for intervention arm and control arm, respectively; *P*=.004), and on average 0.3 points higher follow-up test score than the control group (the adjusted mean follow-up scores were 7.177, SE 0.400 and 6.805, SE 0.406 for the intervention arm and control arm, respectively; *P*=.02). Both analyses were adjusted for knowledge pretest score and other covariates. Variance analysis and parameter estimates for the knowledge posttest and knowledge follow-up test score regression models are shown in Multimedia Appendix 8. Among the seven individual learning styles, we detected a significant improvement in knowledge posttest score and a significant improvement in knowledge follow-up test score in all learning styles (adjusted *P* values <.001), except for watching and listening styles.

Participant and Investigator Feedback

Table 3 shows the results of the feedback survey by study arm. Multimedia Appendix 7 shows tables and diverging stacked bar charts of the results for each question of the feedback survey by study arm and by learning style. Of the participants who completed the feedback survey, 89.7% (489/545) agreed or strongly agreed that the information was new to them, 79.9% (436/546) found it satisfying, and 78.0% (425/545) found it easy to understand. Of the 543 participants who completed the question, 174 (32.0%) agreed or strongly agreed that the information was confusing.

Table 2. Learning styles of oncology health care professionals.

Learning style	All, n (%) (N=552)	Control, n (%) (n=296)	Intervention, n (%) (n=256)
Watching	19 (3.4)	10 (3.4)	9 (3.5)
Listening	12 (2.2)	9 (3.0)	3 (1.2)
Reading	83 (15.0)	43 (14.5)	40 (15.6)
Watching & listening	54 (9.8)	23 (7.8)	31 (12.1)
Watching & reading	103 (18.7)	63 (21.3)	40 (15.6)
Listening & reading	67 (12.1)	38 (12.8)	29 (11.3)
Watching & listening & reading	214 (38.8)	110 (37.2)	104 (40.6)

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Table 3. Feedback survey results.

Survey questions and responses	N	Control, n (%) (n=296)	Intervention, n (%) (n=256)
Was the information easy to understand?	545		
Strongly disagree		10 (3.4)	18 (7.1)
Disagree		19 (6.5)	13 (5.1)
Neither disagree nor agree		41 (14.0)	19 (7.5)
Agree		170 (58.2)	127 (50.2)
Strongly agree		52 (17.8)	76 (30.0)
Was the information confusing?	543		
Strongly disagree		20 (6.9)	39 (15.5)
Disagree		97 (33.3)	105 (41.7)
Neither disagree nor agree		61 (21.0)	47 (18.6)
Agree		105 (36.1)	55 (21.8)
Strongly agree		8 (2.8)	6 (2.4)
Was the information satisfying?	546		
Strongly disagree		4 (1.4)	13 (5.2)
Disagree		15 (5.1)	6 (2.4)
Neither disagree nor agree		54 (18.4)	18 (7.1)
Agree		175 (59.5)	150 (59.5)
Strongly agree		46 (15.6)	65 (25.8)
Was the information new?	545		
Strongly disagree		5 (1.7)	10 (4.0)
Disagree		1 (0.3)	4 (1.6)
Neither disagree nor agree		25 (8.5)	11 (4.4)
Agree		173 (59.0)	127 (50.4)
Strongly agree		89 (30.4)	100 (39.7)

Most positive comments on the feedback survey dealt with the educational materials: participants found them to be good, useful, organized, evidence-based, important, well designed, succinct, easy to understand, interesting, enjoyable, and exciting. Others appreciated the provision of a knowledge pretest or said that the information would help them explain treatment regimens to patients. We received an email from a colleague of a participant expressing interest in related studies. We received requests for the educational materials to be made available to participants following the study.

Most negative comments on the feedback survey also dealt with the educational materials: some found them to be poorly organized, busy, or confusing. Eighteen respondents suggested adding figures, tables, or videos. Of these, 14 participants had been allocated to the control arm. These participants were generally multimodal learners who perceived My Cancer Genome content as being text-based and thus lacking in graphical elements. The other four participants were allocated to the intervention arm. These participants were listening, reading, and listening plus reading learners; they each requested visual educational materials. Others felt the information was not up to date.

Discussion

The first objective of this study was to measure learning styles of oncology health care professionals. Compared to assessments of learning styles of medical students and allied health students, this cohort has a higher percentage of multimodal learners at 79.3% (436/552); those studies found rates of 61% (61/100) and 66% (90/137), respectively. The comparison is not direct because this study did not include kinesthetic as a learning style option and because this study used self-reporting to assess learning style [15,29].

The second objective of the study was to determine whether learning style-tailored learning materials fostered greater learning and retention than typical My Cancer Genome content. Although participants did learn more when viewing educational materials tailored to learning style, the mean benefit was only 0.40 points on the knowledge test. An opportunity for future research that would permit a conclusion as to whether the use of learning style-tailored materials facilitate learning in general would use materials inconsistent with learning style preferences rather than the standard format used in our study as the control

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[30]. However, care would need to be taken to account for demand characteristics, especially due to the higher level of scientific literacy of participants and the likelihood that the learning style survey at the beginning would provide a cue regarding the hypothesis being tested [31]. Instead, by providing control arm participants with access to My Cancer Genome standard content, some participants on the control arm received matched-style content, whereas others received mismatched style content. This may have reduced demand characteristics that would skew the control arm to poorer performance. Finally, a limitation of the study was that we did not assess how the quality of the materials may have impacted learning.

Several participants requested more visual elements to be incorporated into the control educational materials of typical My Cancer Genome content and into nonvisual educational materials in the intervention arm, even when those participants did not identify themselves as watching learners. Together, these participant comments, the high percentage (79.3%, 436/552) of multimodal learners, and the small but significant improvement in knowledge scores when presented with materials tailored to learning style highlight the need for Web-based educational materials to address watching, listening, and reading learners. Therefore, it will be important for My Cancer Genome to incorporate more watching and listening elements, including graphics and videos, in particular.

Given the relatively small improvement in test scores and the heavy resource demand required to create separate content for each learning style, it is probably a poor use of resources to generate new content for each learning style. Instead, the creation and embedding of graphical and video content to address multimodal learning styles may enhance current My Cancer Genome pages, address the learning gap for watching, listening, and multimodal learners, and provide the oncology community with resources for presentations and additional dissemination of learning materials. To this end, since the completion of this study, My Cancer Genome has begun to enhance its website with multimodal content. My Cancer Genome has improved its visual representations of molecular pathways involved in cancer, embedded graphics in new content related to diseases such as chronic lymphocytic leukemia and in new content related to new genetic testing modalities, such as digital droplet polymerase chain reaction, and embedded graphical-audio “knowledge pearls” explaining key concepts such as “mutation” [27]. Additionally, as a result of this study, My Cancer Genome is in the process of creating a 2.0 version of the My Cancer Genome website, which will heavily rely on multimodal data presentation to convey curated knowledge content.

In conclusion, the results of this study imply that Web-based educational materials should be multimodal: (1) most oncology health care professionals are multimodal learners, (2) the increase in learning when learning style-tailored educational materials were used is small, and (3) multiple requests for more multimodal materials were received from participants in both the control and intervention arms. These conclusions are corroborated by a significant body of evidence and confirmed by this work for oncology health care professionals [30].

Acknowledgments

We thank Yu Shyr for conducting the power analysis and sample size estimation as well as developing the initial data analysis and subgroup analysis plans. We thank Ingrid Mayer and Justin Balko for critical review of the educational materials. We thank Daniel Wenner, Ross Oreto, Daniel Carbone, Joey Schneider, and Scott Sobecki of the Vanderbilt University Medical Center Research Informatics Core for their development work to host the educational materials on My Cancer Genome. We thank the Vanderbilt REDCap team for their assistance with project development, project testing, data analysis, and bug fixes. We thank Kathleen Mittendorf for detailed review of the manuscript. This study was funded by Pfizer under an Independent Grant for Learning & Change. Pfizer had no role in the design, conduct, or publication of this study. REDCap is funded through grant support (UL1 TR000445 from National Center for Advancing Translational Sciences /National Institutes of Health).

Authors' Contributions

MAL, NBG, SVK, CMM, IAA, PL, and KJ conceived the project. MAL, SVK, CMM, IAA, PL, and KJ designed the project and developed the educational materials. CMM managed data acquisition. FY and S-CC provided statistical analysis of the data. CMM, MAL, SVK, IAA, PL, KJ, FY, and S-CC interpreted the data. CMM and IAA drafted the manuscript. All authors provided critical review of the manuscript and approved the publication version. All authors are accountable for all aspects of the manuscript, including its accuracy and integrity.

Conflicts of Interest

Authors developed and tested the educational materials, for which there are no financial interests. MAL declares two conflicts of interest: she is a member of the external scientific advisory board for Personalis, Inc and receives royalties from GenomOncology, Inc. No other conflicts are declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist.

[PDF File (Adobe PDF File), 4MB - jmir_v19i7e265_app1.pdf]

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Multimedia Appendix 2

Technical Details and Changes After Study Commencement.

[PDF File (Adobe PDF File), 475KB - jmir_v19i7e265_app2.pdf]

Multimedia Appendix 3

Emails Sent to Participants.

[PDF File (Adobe PDF File), 268KB - jmir_v19i7e265_app3.pdf]

Multimedia Appendix 4

Codebook for All Surveys.

[PDF File (Adobe PDF File), 152KB - jmir_v19i7e265_app4.pdf]

Multimedia Appendix 5

Participant Tracking and Related Analyses.

[PDF File (Adobe PDF File), 68KB - jmir_v19i7e265_app5.pdf]

Multimedia Appendix 6

Educational Materials.

[PDF File (Adobe PDF File), 7MB - jmir_v19i7e265_app6.pdf]

Multimedia Appendix 7

Feedback Survey Results.

[PDF File (Adobe PDF File), 313KB - jmir_v19i7e265_app7.pdf]

Multimedia Appendix 8

Variance Analysis and Parameter Estimates.

[PDF File (Adobe PDF File), 43KB - jmir_v19i7e265_app8.pdf]

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Abbreviations

CDK4: cyclin-dependent kinase 4 protein
CDK6: cyclin-dependent kinase 6 protein

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CONSORT: Consolidated Standards of Reporting Trials
EGFR: epidermal growth factor receptor
ER+: estrogen receptor positive
IRB: institutional review board
PIN: personal identification number
REDCap: Research Electronic Data Capture

Edited by M Focsa; submitted 14.02.17; peer-reviewed by A Cyr, Z Li; comments to author 29.03.17; revised version received 23.05.17; accepted 12.06.17; published 25.07.17.

Please cite as:
Micheel CM, Anderson IA, Lee P, Chen SC, Justiss K, Giuse NB, Ye F, Kusnoor SV, Levy MA
Internet-Based Assessment of Oncology Health Care Professional Learning Style and Optimization of Materials for Web-Based Learning: Controlled Trial With Concealed Allocation
J Med Internet Res 2017;19(7):e265
URL: http://www.jmir.org/2017/7/e265/
doi:10.2196/jmir.7506
PMID:28743680

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Original Paper

Motivational Determinants of Exergame Participation for Older People in Assisted Living Facilities: Mixed-Methods Study

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Abstract

Background: Exergames (exercise-based videogames) for delivering strength and balance exercise for older people are growing in popularity with the emergence of new Kinect-based technologies; however, little is known about the factors affecting their uptake and usage by older people.

Objective: The aim of this study was to determine the factors that may influence the motivation of older people to use exergames to improve their physical function and reduce fall risk.

Methods: Mixed methods were employed in which 14 semistructured interviews were conducted with older people (n=12, aged 59-91 years) from 2 assisted living facilities in the North West of the United Kingdom. The older people participated in a 6-week trial of exergames along with one manager and one physiotherapist; 81 h of observation and Technology Acceptance Model questionnaires were conducted.

Results: The findings suggest that the participants were intrinsically motivated to participate in the exergames because of the enjoyment experienced when playing the exergames and perceived improvements in their physical and mental health and social confidence. The social interaction provided in this study was an important extrinsic motivator that increased the intrinsic motivation to adhere to the exergame program.

Conclusions: The findings of this study suggest that exergames may be a promising tool for delivering falls prevention exercises and increasing adherence to exercise in older people. Understanding the motivation of older people to use exergames may assist in the process of implementation.

(J Med Internet Res 2017;19(7):e238) doi:10.2196/jmir.6841

KEYWORDS

technology; aged; accidental falls; rehabilitation; motivation

Introduction

The proportion of older people in the world population is increasing as never before [1-3]. Older people are at increased risk of falls due to factors such as impaired balance, gait problems, poor muscle strength, visual impairment, psychotropic medications, multiple drug use, impaired cognition, and urinary incontinence [4,5]. Approximately 28-35% of people aged 65 years and older fall each year [6]. The consequences of a fall can vary: from a bruise or sprain to traumatic brain injury, hip fracture, or even death [6,7]. These consequences can lead to decreased health and well-being and increased health care sector costs [6]. One of the best modifiable risk factors to reduce fall risk among older people is physical exercise, in particular, specific strength and balance exercises [8]. However, motivation to engage in physical activity is often low in old age.

A potential method to increase physical activity may be the use of exergames. Exergames are videogames that combine gameplay with physical exercise. This paper describes the use of MIRA-exergames [9,10] that were developed with older people, academics, and 2 falls prevention teams (including physiotherapists, geriatricians, occupational therapists, and

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rehabilitation nurses) for older people to improve their physical function and reduce fall risk. The MIRA system [9] uses Microsoft Kinect, an off-the-shelf 3D camera motion tracking device that can track the user's movements from a distance without the need for hand-held controls. The exercises used in the games were constructed from the evidence-based exercise programs Otago and FaME, designed to reduce falls among older people [11-13]. A short description of some of the exercises and games used in this study can be found in Multimedia Appendix 1. User performance was tracked by the MIRA system [9] and Microsoft Kinect.

The MIRA system [9] measures parameters such as (1) the number of exergames played including the frequency and duration, (2) progress statistics including game scores, distance, speed, and acceleration, and (3) overall movement activity during the games. This information is recorded by the MIRA system [9] and can also be remotely tracked by the physiotherapist and physician to monitor user performance. The user's therapy schedule may be adjusted as required throughout their program.

To improve their physical function and reduce falls risk, older people need to be motivated to adhere to a therapy tailored exercise program. The systematic review and meta-analysis of Sherrington et al [14] suggest that an exercise program should run for at least two hours a week, for at least six months, to obtain a minimal effective exercise dose.

Motivation can be divided into intrinsic and extrinsic motivation according to the Self Determination Theory (SDT) [15]. Extrinsic motivation can be defined as behaviour in which people engage due to an objective consequence or separable outcome of that behaviour and intrinsic motivation is behaviour which people experience as interesting, satisfying and enjoyable [15]. Sweetser and Wyeth [16] developed the game flow model of player enjoyment (Table 1) that describes the intrinsic motivators that enhance users' interest in playing computer games. This is known as the "flow" in which the person becomes immersed in the activity, losing a sense of self-consciousness and time. Enjoyment is further described as the fulfillment of 8 elements that create game enjoyment [16]. An overview of these 8 elements is presented in Table 1.

Previous literature has shown that intrinsic motivation is more important compared with extrinsic motivation to adhere to exercise for a longer period of time [17]. Nevertheless, it is unknown if and why older people are motivated to use exergames. Our goal was to explore the factors that influence the intrinsic motivation of older people to use MIRA-exergames [9] to improve their physical function and reduce fall risk.

Table 1. Definitions of the 8 elements of the game flow model of player enjoyment of Sweetser and Weyth [16].

Element	Definition
Concentration	The game should require some concentration, which can be defined as attention and workload. The more concentration the games requires, the more absorbing the game will be.
Challenge	The game should be challenging in which it matches the player's skill level, a changeable difficulty level, and an appropriate pace. If the challenge is too high in comparison with the skills of the player, this might result in anxiety. If the challenge is to low in comparison with the skills of the players, this might result in apathy. Therefore, the challenge of the game should be in comparison with the skills of the player to make the player to enjoy and finally endure the game.
Player skills	According to Sweetser and Wyeth [16], the game should support the development and mastery of the skills of the player, otherwise enjoyment is not possible. Therefore, the challenge of the game should be correlated with the skills of the player. During this element, a good explanation of the game and the associated skills is essential. The element "player skills" can be related to the need of competence.
Control	This element can be related to the concept "autonomy" of the CET[a]. Control refers to a certain sense of control during the actions of the game. During the game, the player should be able to control the actual behaviors of their character in an intricate, effective, and easy way to explore the environment and to manipulate objects in the environment. This is important to carry out the player's goals.
Clear goals	The game should have a clear goal. The goal should be made clear at the beginning of the game, this way the player knows from the start what to do. This can be done with a brief introduction movie. Each level should also contain multiple goals. These goals can be explained with so-called "briefings."
Feedback	Appropriate feedback at appropriate time is important because concentration is only possible with immediate feedback. The player should receive feedback about his or her progress, and if the player does something wrong, he or she should receive feedback about how to do it right. Scores provide the player with positive feedback and encourages the player to improve.
Immersion	Immersion refers to deep but effortless experiences of the player regarding the game. During immersion, the player forgets about his or her surroundings and everyday life. Sometimes games are seen as an escape from the real world and everyday worries.
Social interaction	According to Sweetser and Wyeth [16], games should provide and create opportunities for social interaction. It can create competition, cooperation, and connection between players. However, social interaction can also interfere with immersion because other real people can be a link to the real world. Nevertheless, social interaction is a strong element for enjoyment, if people game for social interaction. The element "social interaction" can be related to the need relatedness of the SDT[b].

[a]CET: Cognitive Evaluation Theory.

[b]SDT: Self Determination Theory.

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Methods

Design

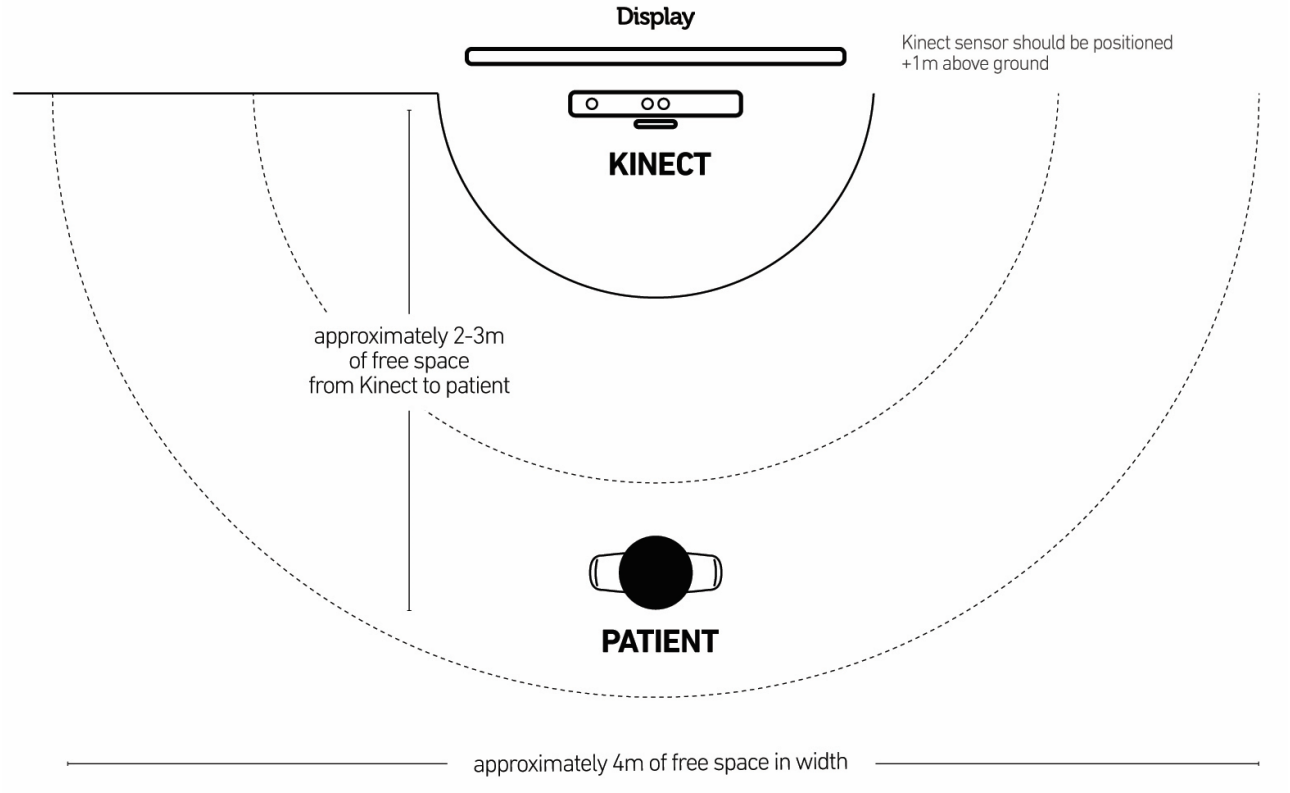
This study is a substudy of a larger study in which mixed-methods were used: interviews, Technology Acceptance Model (TAM) questionnaires, and 81 h of observation of the participants using the exergames were conducted. Data collection was conducted from May 2015 to July 2015. The interviews were undertaken at communal rooms in the assisted living facilities. Assisted living facilities are accommodations specifically designed for older people that usually consist of self-contained flats or bungalows with communal facilities, with a manager who oversees the maintenance of the facility (also known as sheltered housing or supportive housing for older people). People living in these facilities are able to receive extra care if required such as home help to assist with bathing.

The exergame program was offered to the participants 3 times a week during a period of 6 weeks under the supervision of a physiotherapist. The participants were initially assessed by the physiotherapist who then tailored the exergames program according to the ability and needs of the participant. Each schedule began with calibration to ensure the user was positioned correctly for optimum performance and effective motion tracking and a tutorial that demonstrated how to perform the exercise that follows. One session took approximately 15 min on average for each participant, starting with 5 min and building up to 20-25 min. In one housing facility, the exergames were offered in the communal lounge area during a weekly coffee morning social event. In the second housing facility, the exergames were in a separate communal room where only the older participants met together in the room. The size of the groups varied from just 1 participant to 7 participants. The exergames are played individually. Participants mostly preferred to stay and watch other participants play the exergames, although some attended for only their session. The rooms had at least 2 m space to exercise safely, access to a large television screen with a laptop connection, and chairs for support during the exercises and for rest (see Figure 1). A transportable laptop with MIRA Rehab software [9] installed and the transportable Microsoft Kinect were connected by the physiotherapist to the television screen.

Participants

In total, 12 older people in the age range of 59 to 91 years from 2 assisted living facilities in the North West of the United Kingdom, 1 physiotherapist with 3 months experience of using MIRA-exergames [9], and 1 manager of one of the assisted living facilities participated in this study. Older people were included in the program if they met the following criteria: (1) aged 59 years and older, (2) had used MIRA-exergames [9] for at least three weeks, (3) were able to speak and understand English language, (4) had the mental capacity to give informed consent, and (5) lived in an assisted living facility. Older people were excluded if they suffered from severe cognitive impairment. In addition, a qualified physiotherapist assessed the participant's medical history, safety risk, and ability to engage in the exergames (both physically and cognitively). Table 2 provides an overview of the included participants.

Figure 1. Mira-exergames system setup: The Microsoft Kinect camera is positioned directly in front of the screen. The user is positioned at 2 meters distance from the Kinect camera.



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Table 2. Participant characteristics and number of exergame sessions attended during 6 weeks.

Participant[a]	Age	Sex	Current medical condition(s)	Marital status	#sessions/6 weeks used
Ms Smith	67	Female	Depression with anxiety and bipolar disorder	Engaged	15
Mr Darcy	89	Male		Single or never married	17
Ms Colins	66	Female	Depression[b]	Divorced	13
Mr Crawford	63	Male	Disability right hand	Single or never married	6
Ms Price	80	Female		Widowed	14
Mr Rushworth	66	Male		Single or never married	16
Ms Bertram	79	Female	Mild cognitive impairment	Widowed	8
Mr Wickham	60	Male	Depression with anxiety	Engaged	15
Mr Willoughby	76	Male		Single or never married	18
Ms Bennet	81	Female	Depression	Widowed	3
Ms Dashwood	91	Female		Widowed	12
Mr Ferrars	59	Male		Single or never married	2

[a]The names of the participants are changed for anonymity.

[b]According to the DSM-IV criteria for depression and herself, this person suffers from a depression. However, this is not reported in her medical history.

Measures

The interview guide consisted of questions related to the 8 elements of game enjoyment defined by Sweetser and Wyeth [16].

The TAM questionnaire consists of 4 subscales of statements of which 2 subscales are presented in this article, which are regarding the perceived ease of using MIRA-exergames [9] and the attitude toward MIRA-exergames [18]. The statements were categorized with a 7-point Likert scale.

Data Analysis

The data were analyzed using constant comparative analysis. The interviews were transcribed, and open coding and axial coding was conducted by both researchers separately. Both researchers discussed their codes, and a coding scheme was developed from the different themes that emerge [19]. The interviews were selectively coded by both researchers separately and the coding was compared. After consensus was reached, the coding was analyzed using Atlas.ti coding program [20]. The questionnaire data were analyzed in SPSS Statistics 22. During 81 h of observation, notes were made of physical and verbal expressions until data saturation. Data saturation was reached after no new data and no new themes were observed [21].

Ethical Approval

This study is conducted in full conformance with the principles of the Declaration of Helsinki, Good Clinical Practice, and within the laws and regulations of the United Kingdom and the European Union. Before commencing participant recruitment, approvals have been obtained from the University of Manchester and NHS Research Ethics Committees.

Results

Demographical Information

Interviews and TAM questionnaires were completed by 12 of the 19 participants approached. Of the 12 older participants, 5 suffered from mental or physical impairments, which may have influenced their motivation to participate in the exergames. Three participants, a 66-year-old woman, an 81-year-old woman, and a 60-year-old man suffered from depression. A 67-year-old woman suffered from both depression and bipolar disorder, and a 79-year-old woman suffered from mild cognitive impairment, but both were able to participate in the exergames. There were no adverse events reported during the study.

Attitude Toward Exergames

In general, the majority (8 out of 12) of the older people had a positive attitude toward MIRA-exergames [9]. This was reported during the interviews but also confirmed by the TAM questionnaire. The third subscale of the questionnaire consisted of questions regarding the participant's attitude toward the exergames. The mean score for attitude was 6.19 (SD=1.21; min: 2, max: 7; reliability alpha=.86) on the 7-point Likert scale, which indicated that the residents had a positive attitude toward the exergames.

Enjoyment

In this study, 8 people said they enjoyed playing the exergames. A deep sense of enjoyment is described as a combination of 8 elements, see Table 1 [16]. Two older people did not enjoy playing the exergames. One of them felt that the exergames (and all games in general) were patronizing, and the other person had depression, which may have detracted from the enjoyment of the exergames. The remaining two of the 12 older people felt more neutral about the exergames or slightly enjoyed playing them. The results of the eight elements that define enjoyment in this study are described in detail below.

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The first element, concentration, was required by all the participants to be able to focus on the screen and to do the associated movements. It was observed that the performance decreased when the participants were simultaneously having a conversation (known as dual tasking).

The second element, challenge, was experienced by 10 participants because they experienced the exergames as something new, which they have never done before. The older participants experienced the exergames as mentally challenging because they had to remember the games and what they had to do during the games. For some, it was physically challenging to be able to undertake the movements. The participants appeared to challenge themselves to improve on their performance each session. To start undertaking the exergames was also experienced as a challenge that resulted in the participant feeling proud and a sense of achievement. Finally, it appeared that some exergames were experienced as more challenging compared with others.

The third element was a clear goal of the game. According to the older people, the general goal of using the exergames was to win as many points as possible and to do more physical exercise. The goal of the games itself were not clear for 5 of the 12 older people even when they played these games often.

The fourth element, feedback, was provided through the provision of scores and instructions given by the physiotherapist. The exergames also provide instant feedback. This included success or failure sounds, written text for encouragement and to indicate correct position for the sensor, green color code to indicate correct movement, and red for incorrect movements. At the end of each session the motion tracking analysis give feedback about points won, duration of session, range of movement, number of repetitions, average speed and acceleration that can be viewed by the participant and the physiotherapist. According to the participants, additional feedback about their progress from the physiotherapist was important. Six older participants were also doubtful if they would be able to play the exergames on their own without the support of the physiotherapist. Five residents believed they would be able to use the exergames by themselves after doing it together with the physiotherapist.

The fifth element, immersion, was experienced by 9 residents. Immersion appeared to create a positive experience among some of the residents because the exergames were found to provide an escape from reality.

The sixth element, control of the character, was experienced by all the residents. For example, when they moved their arm up, the character in the game went up.

It was observed that all residents had the skills to play the exergames, which refers to the seventh element. The residents reported that the difficulty-level of the exergames set by the physiotherapist was correct for them. The TAM questionnaire also confirmed the perceived ease of use as easy or just right. The first subscale of the TAM questionnaire consists of statements regarding perceived ease of use, which scored on average 5.60 (SD=1.36; min: 2, max: 7; reliability alpha=.84) on the 7-point Likert scale, which indicated that the exergames were found to be easy to use with the current set-up.

The final element, social interaction, appeared also to be one of the main findings in this study. During the observations it was noticed that the games themselves do not provide social interaction because the user has to do the exercise alone. However, the exergames were set up in communal rooms at the support housing facilities that made social interaction with other people possible before and after doing the exergames. The group size varied from 1 participant to up to 7 participants taking part in an exergame session. The participants played the exergames individually but were observed by the other attending participants. During the interviews and observations, it was clear that the social interaction encouraged the older participants to undertake the exergames, for example, it created competition between people that resulted in further motivation to improve. Another participant mentioned that it created opportunities to learn from and interact with each other. Seven older people were doubtful if they would do the exergames alone at their apartment, since they felt motivated by the group to do the exergames because others were doing them as well. Nevertheless, the findings also indicate that the social interaction might decrease someone's confidence because, for example, others might have higher scores. One participant with lower scores mentioned that others might start thinking something is wrong with her because she has lower scores. Furthermore, 2 participants mentioned they felt watched or judged by other people who were also in the room, which resulted in an uncomfortable feeling. These feelings might decrease the motivation to do the exergames. However, the older participants who mentioned these negative influences of the social interaction preferred in the end the set-up with social interaction. It appeared that the participants were not aware of their surroundings after undertaking a few exergame sessions.

During the observations, it appeared that not only was social interaction with other older people important, but also social interaction with the instructors of the exergames. The conversations with the instructors seemed to have a positive influence on the older participants because during informal conversations the older participants regularly thanked the instructors for being present and said they enjoyed their company. This observation was also confirmed by one of the participants during the interview.

Confidence

During the interviews and observations it appeared that besides enjoyment, confidence was also an important factor that influenced the intrinsic motivation of older people to use the exergames. This confidence was related to physical strength, mental capacity, and the social setting. The confidence in having physical strength appeared to be related to fear of falling. Older people reported that they became more confident in their physical function after doing the exergames, which might have also reduced their fear of falling. Older people could also be assumed to have gained confidence in relation to their cognition because they were able to do something new and develop new skills. There was also a confidence noted in the social interaction. Additionally, 2 older people did not feel comfortable

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doing the exergames in front of others; however, this changed after undertaking a few sessions in the social setting. This indicates that confidence related to social interaction may increase by undertaking the exergames in a social setting. The physiotherapist and the warden also confirmed that they saw an increase in confidence in relation to the social setting.

The instructors also appeared to have a large influence on the confidence of their clients. It was observed that the instructors made a lot of positive comments toward the older people. The instructors said things like “you can do it,” “well done,” “good job,” “you are really improving,” and “I am impressed.” These positive comments may have boosted the confidence of residents. Nevertheless, it should be considered that a coach is an extrinsic motivator who strengthens the intrinsic motivation. Coaching is mentioned as an intrinsic motivator in this study because it has a strong influence on the intrinsic motivation of the resident and does not influence the desired outcome of the participants for doing the exergames.

Discussion

Principal Findings

This study investigated the factors that may influence the intrinsic motivation of older people to use MIRA -exergames [9] to improve their physical function and reduce fall risk. The findings of this study show that most of the older participants enjoyed playing the exergames. Previous qualitative studies on exergames confirm that exergames in general are enjoyable [22-25]. These previous studies and this study demonstrate that exergames may be promising tools to enable physical exercises to be more enjoyable. However, it should be taken into account that not everyone may be interested or willing to use exergames to exercise and improve their physical function.

In general, all 8 elements, which define enjoyment according to the game flow model of Sweetser and Wyeth [16], were fulfilled for the older participants who enjoyed playing the exergames in this study. The systematic review by Boyle et al [26] regarding engagement in computer games describes elements for game enjoyment: “Flow, the best known term for describing the enjoyable subjective experiences of playing games, has a strong focus on cognitive features relating to the task such as challenge, concentration, goals and feedback.” The study of Boyle et al [26] confirms the importance of concentration, challenge, clear goals, and feedback in games to make enjoyment possible, which are also the first 4 elements discussed above of the game flow model of Sweetser and Wyeth [16]. Furthermore, the older people in this study experienced the exergames as challenging. The importance of challenge in games is also acknowledged by Jackson and Csikszentmihalyi [27], who described game flow as a balance between the skills of the player and challenges in the game. Jackson and Csikszentmihalyi [27] define this balance as “the golden rule of flow” in games.

During the exergame program, feedback was provided by scores and during or post game screen feedback such as “congratulations” and “well done.” Additional feedback was provided by the instructors of the exergames. The findings indicate that an individual approach is required during which the coaching of the instructors is an important factor to increase intrinsic motivation. Positive comments of the exergame instructors toward the older users appear to improve the intrinsic motivation. Furthermore, tailored coaching that corresponds with the individual needs and wishes of the older person is essential. The importance of coaching regarding motivation was also acknowledged by Pelletier et al [28], who stated “those providing feedback of competence and a clear structure or rationale for doing an activity, foster self-determined forms of motivation .”

Immersion was experienced by most of the older people because playing the exergames was experienced as an escape from reality and/or problems. These experiences are also acknowledged by Jennett et al [29], who describe that games provide the possibility to “lose” one self in the world of the game. Jennett et al [29] state that “ Immersion is often viewed as critical to game enjoyment, immersion being the outcome of a good gaming experience.”

The importance of social interaction is one of the main findings in this study. Brox et al [30] also investigated the importance of social interaction in exergames. They acknowledged that older people tend to be more homebound, and many of them suffer from loneliness and a lack of physical exercise. Therefore, Brox et al [30] recommend that persuasive Web-based social-exergames should be investigated further to increase the social interaction and exercise among older people. This study also acknowledges the importance of social interaction during the exergames. Therefore, this study also recommends a set-up of the exergames which makes social interaction with other people and instructors possible.

Besides enjoyment, another important intrinsic motivator raised during the interviews was the confidence of the participants. It appeared that the confidence of the participants increased after undertaking the exergames. The confidence of the residents who played the exergames was related to their perceptions of improved physical strength and mental capacity, and social interaction. Schutzer and Graves [31] investigated the barriers and motivations of older people to undertake exercise. They mention “self-efficacy is consistently identified as an important determinant of exercise behavior in various populations and in many types of behavioral learning throughout the scientific literature.” The concept “confidence” in this study can be correlated to self-efficacy. Schutzer and Graves [31] state that “The stronger one’ self-efficacy expectations and outcomes, the more likely the individual will initiate and persist with a specific behavior. Barring health factors, self-efficacy exerts a consistently powerful influence on the exercise behavior of older adults . ” The findings of Schutzer and Graves [16] confirm the influence and importance of confidence in the motivation of older people to use MIRA-exergames [9].

Strengths and Limitations

The use of mixed methods increases the validity of the findings in this study. The interviews, questionnaires, and 81 h of observations in general were in agreement and confirmed the findings. Nevertheless, a limitation of this study is that not all the 19 older people who joined the exergames program

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participated in this study. Of these, 7 older people declined to participate in this study because of various reasons (too onerous, too busy, or unwell). This might indicate some selection bias in this study. This selection bias might indicate overestimation of the motivation of older people toward exergames because most of the participants in this study adhered to the exergame program for a longer period of time.

Further Research

Several older people believed the MIRA-exergames [9] helped them to stay mentally active. However, further research is needed to investigate whether the exergames also stimulate cognitive function, and if so, whether exergames can reduce the risk of cognitive decline.

The findings of this study showed that social interaction appeared to be an important factor for the motivation of older people to do the exergames, which was also confirmed by the study of Brox et al [30]. Further research is recommended that investigates the effects of a social set-up of MIRA-exergames [9] on the mental and physical well-being and loneliness of older people. This way, the exergames could have different objectives to reach besides fall prevention.

Conclusions

In conclusion, MIRA-exergames [9] appear to be a promising tool to improve the physical functions of older people and reduce their fall risk because older people may be intrinsically motivated to use them for a longer period of time. The implementation of the falls prevention exergames in the daily lives of older people may reduce health care costs related to falls among older people. Furthermore, wider uptake and increased adherence to exergames, and thus, increased physical activity might also reduce the risk of other diseases such as vascular disease and osteoporosis, which could lead to further reduced health care costs and improve the well-being and quality of life among older people. Larger studies are required to investigate these hypotheses.

Acknowledgments

The authors wish to thank Trafford Housing Association and Trafford Falls Prevention Team, in particular Kelly Hagan, Debra Maloney, Angela Easdon, and Dr Jay Chillala for their support and help during this study **.** This study was supported by funding from the Small Business Research Initiative (SBRI) Health care Scheme, an NHS England initiative.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Example of exergames for a falls prevention rehabilitation schedule (supervising physiotherapist prescribes easy, moderate, or hard levels; duration; and rest periods according to assessed level of ability).

[PDF File (Adobe PDF File), 290KB - jmir_v19i7e238_app1.pdf]

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Edited by G Eysenbach; submitted 18.10.16; peer-reviewed by E Brox, YY Chao; comments to author 15.01.17; revised version received 20.02.17; accepted 07.03.17; published 06.07.17.

Please cite as:
Meekes W, Stanmore EK
Motivational Determinants of Exergame Participation for Older People in Assisted Living Facilities: Mixed-Methods Study
J Med Internet Res 2017;19(7):e238
URL: http://www.jmir.org/2017/7/e238/
doi:10.2196/jmir.6841
PMID:28684385

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Original Paper

My Team of Care Study: A Pilot Randomized Controlled Trial of a Web-Based Communication Tool for Collaborative Care in Patients With Advanced Cancer

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Abstract

Background: The management of patients with complex care needs requires the expertise of health care providers from multiple settings and specialties. As such, there is a need for cross-setting, cross-disciplinary solutions that address deficits in communication and continuity of care. We have developed a Web-based tool for clinical collaboration, called Loop, which assembles the patient and care team in a virtual space for the purpose of facilitating communication around care management.

Objective: The objectives of this pilot study were to evaluate the feasibility of integrating a tool like Loop into current care practices and to capture preliminary measures of the effect of Loop on continuity of care, quality of care, symptom distress, and health care utilization.

Methods: We conducted an open-label pilot cluster randomized controlled trial allocating patients with advanced cancer (defined as stage III or IV disease) with ≥3 months prognosis, their participating health care team and caregivers to receive either the Loop intervention or usual care. Outcome data were collected from patients on a monthly basis for 3 months. Trial feasibility was measured with rate of uptake, as well as recruitment and system usage. The Picker Continuity of Care subscale, Palliative care Outcomes Scale, Edmonton Symptom Assessment Scale, and Ambulatory and Home Care Record were patient self-reported measures of continuity of care, quality of care, symptom distress, and health services utilization, respectively. We conducted a content analysis of messages posted on Loop to understand how the system was used.

Results: Nineteen physicians (oncologists or palliative care physicians) were randomized to the intervention or control arms. One hundred twenty-seven of their patients with advanced cancer were approached and 48 patients enrolled. Of 24 patients in the intervention arm, 20 (83.3%) registered onto Loop. In the intervention and control arms, 12 and 11 patients completed three months of follow-up, respectively. A mean of 1.2 (range: 0 to 4) additional healthcare providers with an average total of 3

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healthcare providers participated per team. An unadjusted between-arm increase of +11.4 was observed on the Picker scale in favor of the intervention arm. Other measures showed negligible changes. Loop was primarily used for medical care management, symptom reporting, and appointment coordination.

Conclusions: The results of this study show that implementation of Loop was feasible. It provides useful information for planning future studies further examining effectiveness and team collaboration. Numerically higher scores were observed for the Loop arm relative to the control arm with respect to continuity of care. Future work is required to understand the incentives and barriers to participation so that the implementation of tools like Loop can be optimized.

Trial Registration: ClinicalTrials.gov NCT02372994; https://clinicaltrials.gov/ct2/show/NCT02372994 (Archived by WebCite at http://www.webcitation.org/6r00L4Skb).

(J Med Internet Res 2017;19(7):e219) doi:10.2196/jmir.7421

KEYWORDS

MeSH: Internet; professional-patient relations; interdisciplinary communication; neoplasms; adult; chronic disease; continuity of patient care; patient care team; communication; outcome assessment (health care)

Introduction

With advances in medical care enabling people to live longer, patients with chronic diseases and their families have increasingly complex care needs requiring the expertise of many health care providers from multiple settings and more frequent use of the health care system [1-3]. Important contextual information is not consistently exchanged between health care providers, and coordinated delivery of patient care as a team is lacking [4-7]. As such, there is a need for solutions that are cross-organizational, cross-setting, and that improve continuity of care, defined as the extent to which delivery of care by different providers is coherent, connected, and timely [8].

Organizations such as the Institute of Medicine and the Agency for Healthcare Research and Quality have called for solutions that build on the growing momentum of health information technology to address the deficits in continuity of care and coordinated delivery of care [9-13]. With over 80% of the populations of Canada and the United States having access to the Internet and mobile phones [14], Web and mobile-based communication are ideally positioned to improve the sharing of knowledge, expertise, and decision making between providers (ie, collaboration) [15], to involve patients and, by extension, improve continuity of care [16,17]. Solutions have generally been limited to one-to-one secure messaging or email, possibly as additions to information systems such as patient health records [18].

Reviews on the impact of tools for patient-physician communication have shown promising evidence of improvement on such outcomes as patient self-efficacy, satisfaction with care, and on clinical/psychosocial outcomes [19,20]. However, few tools exist with the express intent of facilitating secure *team*-based communication, which can enable sharing of information between different providers, across health events and settings, and promote collaborative care [21]. Previous studies examining tools that enable patients to communicate with their health care team have been observational in design and focused their examination on implementation in the pediatric [22], general primary care [23], elderly [24], and cerebral palsy [25] populations. These studies did not consider such outcomes as continuity of care, which is particularly pertinent to the patient population with complex care needs.

In this study, we evaluated a Web-based tool for clinical collaboration, called Loop. The purpose of Loop is to assemble care teams that include patients and caregivers in order to facilitate communication and collaboration [26]. We conducted a pilot randomized controlled trial in a population of patients with advanced cancer, as prototypical of a population with complex care needs [27,28]. Our objective was to evaluate the feasibility of integrating a tool like Loop into current care processes and to capture preliminary measures of the effect of Loop on continuity of care, quality of care, symptom distress, and health care utilization.

Methods

Trial Design

We conducted a 15-month multicentered, nonblinded, pragmatic pilot cluster-randomized controlled trial (cRCT), called the My Team of Care study, allocating participants to receive access to Loop as the intervention arm or to usual care as the control arm. The unit of randomization was at the level of the physician, and the unit of analysis was at the level of the individual patient.

See Multimedia Appendix 1 for the CONSORT EHEALTH checklist [29].

Setting and Participants

The study took place at the Temmy Latner Center for Palliative Care at Mount Sinai Hospital and Princess Margaret Cancer Center in Toronto, Ontario, Canada, from January 2015 to April 2016. The Temmy Latner Center is the largest home-based palliative care program in Canada, consisting of 23 palliative care physicians. The Princess Margaret Cancer Center is a University of Toronto affiliated research hospital with 46 medical oncologists and 42 radiation oncologists. At both study sites, patients generally access their physician through visits and telephone messages; some health care providers are contactable via email.

Participants consisted of eligible patients plus their principal cancer physician (oncologist or palliative care physician), and if interested, their family caregiver (informal, unpaid). For the

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intervention arm, additional health care providers as identified by the patient were also invited to participate as members of the circle of care to use Loop.

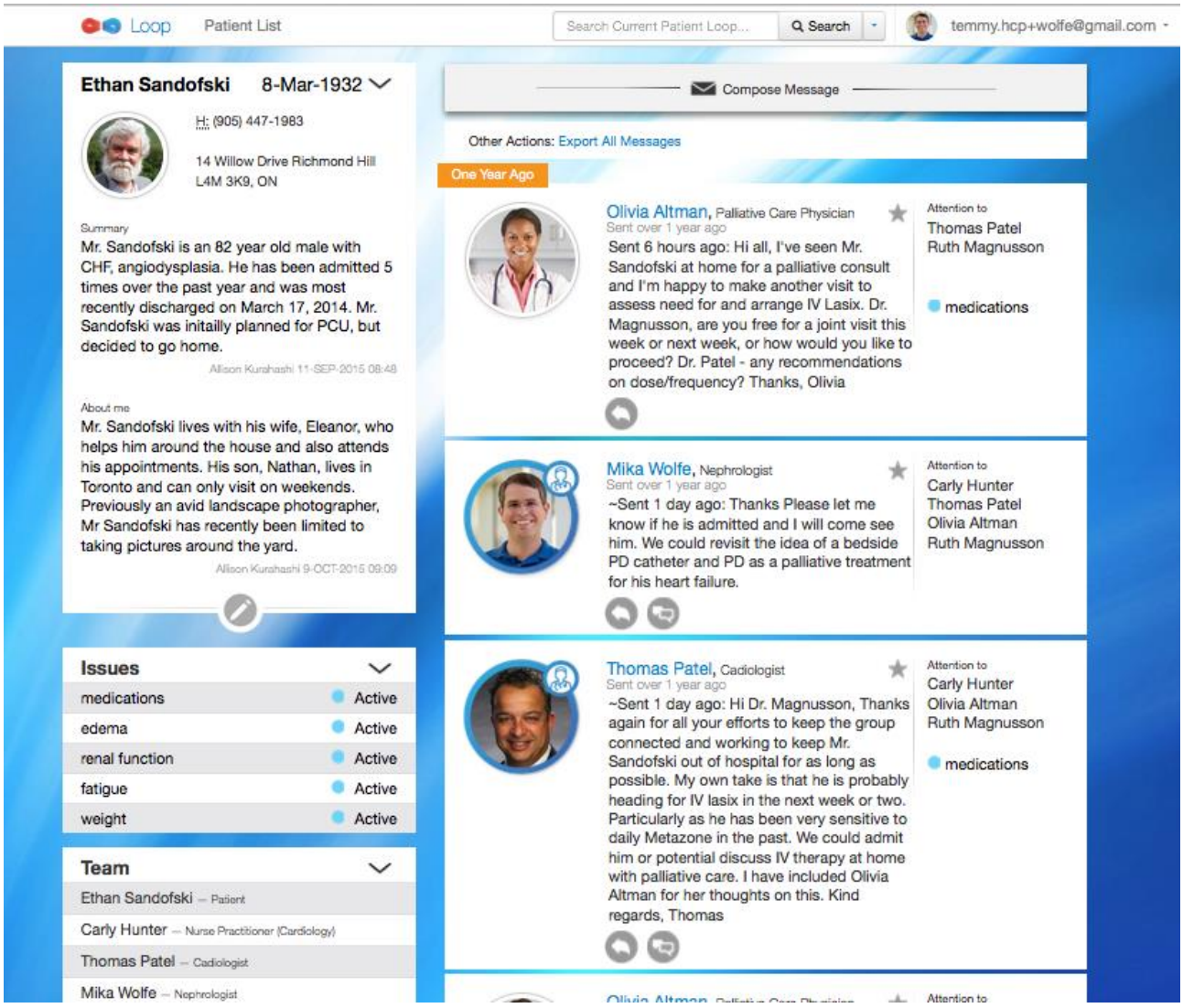
Eligible patients were aged 18 or older; had stage IV cancer or stage III cancer with poor prognosis as determined by their oncologist (a survival prognosis of 3 months but 2 years); Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2, as assessed by their oncologist or palliative care physician at time of enrollment; English literacy and language competency to provide informed consent and complete questionnaires; and patients or caregivers had access to a computer and Internet. Exclusion criteria were currently receiving or a candidate for hormone therapy for breast or prostate cancer (given the impact on prognosis); impaired mental status assessed with the Bedside Confusion Scale [30] (score of ≥2 suggesting cognitive impairment); or participation in another study precluding participation in this study.

Intervention

Participants randomly allocated to the intervention arm received access to Loop. Loop is a secure online communication tool for team-based clinical collaboration that enables patients and caregivers to communicate asynchronously with multiple members of the health care team involved in providing their direct care (ie, not individuals hired for the purpose of research), as well as for health care providers including physicians, nurses, and allied health professionals to communicate with each other.

The development of Loop followed a user-centered design approach [31] with substantial end-user and stakeholder involvement (including caregivers, health care providers from several specialties, and patients with different conditions). As described by Kurahashi et al [26], this process included initial needs assessments, ethnographic observational studies, and affinity diagramming leading to the development of a prototype. This was followed by simulation activities, usability testing in laboratory and real-world settings (ie, home, clinics, hospitals, offices), and piloting with patients and clinical teams.

Figure 1. Screenshot of the Loop interface on desktop computer.



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Figure 2. Screenshot of the Loop interface on mobile phone.



Loop was developed with an intuitive interface to allow for use ideally without prior training. A patient profile and space are created that can be viewed by the patient, health care providers, and caregivers on a computer or mobile phone after logging in with an email address and password (Figures 1 and 2). Each patient's Loop is a secure space partitioned from other Loops and can be joined only if involved in the patient's care and authenticated by a study administrator. Health care providers may be a part of multiple patients' Loops, but patients cannot access the Loops of other patients. On the main page, individuals can write and post text-based messages. All messages posted by any member of a patient Loop can be read and responded to by members of that given Loop. All entries remain on the patient space, allowing for previous posts to be viewed. The messages are threaded in conversations and can be searched using various filters. In addition to posting messages, users may label posts with user-defined "tags" and an "Attention To" feature that specifies individuals to be alerted to a post by a generic email. No updates to the system were made during the trial.

Recruitment and Study Procedures

In order to ensure that there would be at least one health care provider on each team, medical/radiation oncologists or palliative care physicians were recruited first ("initiating physician"), randomized, and patients from their practices were then approached in clinic prior to appointments or over the phone. Physicians at the two study sites were notified of the study through announcements at educational rounds, and physicians who expressed interest in participating were followed up with directly.

All participants provided consent and were asked to complete a baseline demographics form and an internally developed 11-item survey on participants' access, comfort, and usage of computers and Internet [32]. Initiating physicians and patients in the intervention arm were then invited to register on Loop. Registration involved completion of a form requesting participant name, address, and, in the case of health care providers, professional license number. Once registered on the tool, an intervention patient was considered active in the study. Through the tool, patients could invite family caregivers and additional health care providers to join their Loop. Study administrators contacted, explained the study, obtained consent from all additional members of a patient Loop prior to registration, and posted an introductory message welcoming participants. Study administrators were part of patient Loops only for the purpose of providing assistance during registration and with using the tool, as requested. When a patient was no longer part of the study, Loops remained open for 2 weeks to allow for message exchange records to be exported and saved.

Use of the tool and the type of communication that could occur on the tool were not prescribed. The intervention protocol did

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not specify intent to replace existing care practices or methods of communication; the intervention was additive. As Loop was not meant to be used for urgent communication, this was reinforced during the consent process and in the Loop terms of use.

Recruitment of initiating physicians and their patients was conducted similarly in the control arm.

Usage of Loop

Usage of the intervention was evaluated from message exchange transcripts and audit data from Loop. Data included time to registration on Loop from consent date, number of participants who registered on Loop, number of messages exchanged, number of times additional features (Attention To, Tagging) were used, and number of views and posts by participants.

We conducted a content analysis of Loop messages to summarize the content of messages on patient Loops. Two coders independently reviewed messages exchanged in each patient Loop and assigned categories thematically that emerged from the data (see Multimedia Appendix 2 for coding framework and definitions) [33]. Categories were assigned to messages and any responses or follow-up posts. Categories were assigned only once per Loop and not quantified. If multiple categories were perceived in a single post, then each was included once as a category identified in that particular Loop. Messages posted by administrators to welcome team members were excluded.

Outcomes

The primary feasibility outcomes were participant recruitment rate and implementation fidelity defined as the proportion of participants who were randomized, completed the baseline demographics and computer usage questionnaire, and if in the intervention arm, registered on Loop, with ≥70% completion indicating feasibility success. This threshold was selected as an adequate threshold to justify further study and has been suggested previously in the literature [34].

Secondary outcomes were measured using standardized instruments to assess the impact of Loop. Mean difference over the course of the study (from baseline to months 1, 2, and 3) for each instrument was calculated. Patient-reported continuity and coordination of care was measured with the 8-item Picker Ambulatory Cancer Care Survey (Picker) Continuity and Coordination subscale questionnaire. The Picker scale is scored by summing absolute positive responses, divided by the total number of responses (scores range from 0-100, with higher scores being better), and a minimal clinically important difference of 10 points has been previously found to be significant [35,36]. The Palliative care Outcomes Scale (POS) was used to assess patient-reported quality of care and well-being. The POS is a 12-item self-administered questionnaire (total scores range from 0-40, with higher scores being worse); a difference of one point on each item is considered clinically meaningful [37-39]. The Edmonton Symptom Assessment Scale (ESAS) is a 9-item, patient-reported questionnaire of symptom intensity (pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, well-being, shortness of breath) with each item rated from 0 (worst) to 10 (best). Individual symptoms are summed for the Total Symptom Distress score (ranging from 0-90, with higher scores indicating worse symptom distress) [40]. Health care utilization was measured as number of visits to the emergency department and number of hospitalizations and was self-reported at each monthly assessment using the Ambulatory and Home Care Record [41].

Data were collected monthly for 3 months from baseline (four time points). Questionnaires were distributed electronically using online surveys emailed to study participants via Research Electronic Data Capture version 6.16.7 [42], a data management system hosted at the Applied Health Research Center of St. Michael's Hospital, Toronto, Ontario. Patients who did not respond within 1 week were followed up via a reminder email or telephone call and were considered lost to follow-up if not reachable after four contacts. We piloted outcome assessments and survey administration prior to the study. We also collected qualitative interview data at assessments, which will be reported separately.

Randomization and Blinding

This study was designed as a cRCT with initiating physicians recruited first and randomized in order to minimize contamination between study arms. Participating patients were allocated to the study arm to which their initiating physician had been randomized. Randomization was done by a statistical team independent of the study using a computer-generated randomization sequence consisting of permuted blocks of varying size, and assigned initiating physicians in a 1:1 ratio to the intervention and control arms. It was not possible to blind patients completely to study arm, but control patients provided consent without being informed of the existence of another arm. This was done to minimize bias of control patients basing their decision to participate on study arm assignment. Control patients were informed that they were taking part in a study on patient-physician communication to improve health care delivery and care management. Investigators and initiating physicians were aware of study arm assignment.

Sample Size and Statistical Analysis

A formal sample size calculation was not computed, as this was a pilot study with primary feasibility outcomes. We set a target sample size of 20-25 patients per study arm, which has been previously justified as sufficient for pilot evaluations [34,43]

The primary analysis was intention-to-treat with available cases. We did not make adjustments for missing data but secondarily report comparison of data for complete cases (participants who completed outcome assessments at all time points). Descriptive statistics were used to describe each study arm. Analysis compared mean change scores and unadjusted differences in mean change scores on the preliminary effectiveness outcomes between study arms. Statistical tests of difference were not conducted since the study was not powered to undertake hypothesis testing.

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Table 1. Baseline patient and family caregiver characteristics by treatment arm.

Characteristics	Intervention arm (n=21)	Control arm (n=21)
Patients		
Age in years, mean (SD)	60 (12.8)	59.5 (13.8)
Female sex, n (%)	13 (61.9)	16 (76.2)
Primary cancer site, n (%)		
Breast	1 (4.8)	10 (47.6)
Colorectal	2 (9.5)	1 (4.8)
Lung	3 (14.3)	6 (28.6)
Prostate	2 (9.5)	0
Ovarian	0	1 (4.8)
Thyroid	2 (9.5)	0
Lymphoma	6 (28.6)	0
Melanoma	0	1 (4.8)
Brain	1 (4.8)	0
Other	4 (19.0)	2 (9.5)
Annual household income in CDN$, n (%)		
$0-$21,999	2 (9.5)	4 (19.1)
$22,000-$49,999	2 (9.5)	2 (9.5)
$50,000-$89,999	7 (33.3)	4 (19.1)
>$90,000	4 (19.1)	5 (20.8)
Prefer not to disclose	6 (28.6)	6 (28.6)
Primary language, n (%)		
English	20 (95.2)	20 (95.2)
Other	1 (4.8)	1 (4.8)
Age-adjusted Charlson Comorbidity Index, mean (SD)[a]	5.2 (2.5)	5.8 (1.9)
Caregiver, n (%)		
Yes	4 (19.1)	6 (28.6)
No	17 (81.0)	15 (71.4)
Highest education attained, n (%)		
Primary school		
High school	4 (19.1)	6 (28.6)
College/University	8 (38.1)	8 (38.1)
Professional/Graduate degree	9 (42.9)	7 (33.3)
ECOG score, median (interquartile range)[b]	1.5 (1-2)	1 (1-2)
Outcome measures (n=39)		
POS, mean (SD)[c]	9.3 (6.8)	9.8 (5.4)
Picker Continuity and Coordination subscale, mean (SD)[d]	47.9 (28.5)	62.5 (25.3)
ESAS (Total Symptom Distress Score), mean (SD)[e]	21.2 (17.1)	23.4 (12.9)
Family caregivers of consented patient participants	**(n=18)**	**(n=8)**
Age in years, mean (SD)	57 (15.9)	54 (14.6)
Female sex, n (%)	9 (60.0)	6 (33.3)
Missing, n (%)	3 (16.7)	

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Characteristics	Intervention arm (n=21)	Control arm (n=21)
Relationship to patient, n (%)		
Spouse	7 (38.9)	4 (22.2)
Immediate family	5 (27.8)	8 (44.4)
Other	3 (16.7)	
Missing data	3 (16.7)	

[a]Age-adjusted Charlson Comorbidity Index is a measure of comorbidity based on risk of mortality. The score is weighted by age, increasing for each decade over age 40 [44].

[b]ECOG scale is scored from 1-5 with 1 being well and 4 indicating complete disability. A value of 5 indicates death.

[c]Mean summed scores are presented for POS with a maximum score of 40. Higher scores indicate worse quality of care.

[d]The Picker Continuity and Coordination subscale is a proportion of total number of positive responses to total number of responses. Higher scores indicate the higher perceived continuity of care.

[e]Mean summed scores are presented for the ESAS with a maximum score of 90. Higher scores indicate higher symptom distress.

Ethics

All participants provided written, informed consent to participate. Research Ethics Boards of the University Health Network, Mount Sinai Hospital, University of Toronto, and the Community Care Access Centers of Toronto, Ontario, approved the study.

Results

We recruited 10 palliative care physicians and 9 medical oncologists and sequentially randomized 10 to the intervention arm and 9 to the control arm. We assessed 127 patients for eligibility of whom 94 were eligible. We recruited 24 patients each to the intervention and control arms. Figure 3 shows the randomization of clusters (initiating physicians), reasons patients declined to participate in the study, and patient follow-up. In each arm, the baseline questionnaire was completed by 21 patients. In the intervention arm, 18 family caregivers participated and in the control arm, 8 family caregivers participated. There were two instances of initiating physicians from the intervention arm serving as additional health care providers on other intervention patient Loops.

Between arms, there was minimal difference between patients on demographic characteristics, with some modest discrepancies resulting from small sample size (Table 1). There was differential distribution of patients' primary cancer diagnoses by arm reflecting differences in clinical subspecialty of the participating physicians: lymphoma (6 in intervention vs 0 in control), breast (1 in intervention vs 10 in control) and lung (3 in intervention vs 6 in control). There was minimal difference at baseline in comorbidity and performance status as measured with the ECOG score. Participants were comfortable with using computers and less so Internet-enabled devices (tablets and mobile phones), as described in Multimedia Appendix 2. Initiating physicians in both arms showed similar demographic and practice characteristics (Table 2). All were from academic settings, and most had an alternative payment plan fee structure.

Regarding team assembly in the intervention arm, an average of 3 health care providers, including the initiating health care provider, participated per patient Loop. Patients suggested between 1 to 5 additional health care team members to participate on Loop; 43% (22/51) consented to participate in the study (mean 1.2 per patient [range 0-4]), and 65% (13/20) of patient Loops had an additional health care provider register on the tool (Table 2).

Usage of Loop

In the intervention arm, 83% (20/24) of patients who consented, registered on Loop (Table 3). In terms of health care provider load, the mean number of patient Loops per initiating physician was 1.6 (range 0-7). Registration on Loop required that the baseline questionnaire be completed beforehand. The time from consent to registration on Loop varied considerably, with the mean time to registration being 39 days. Some patients experienced disease worsening between consent and registration, and one patient delayed taking the step to register for 156 days due to personal circumstances. Over the study period, the majority (85%, 17/20) of Loops had message exchanges, with 45% (13/20) having more than six messages exchanged. During the study, there were 358 logins by all participants: 43 on the mobile version and 315 on the desktop version. Patients viewed their Loops more often relative to their number of posts (a difference of 14.3) compared to initiating physicians viewing and posting to their patients' Loops (a difference of 3.9).

Content analysis of messages revealed that of Loops with messages exchanged, messages regarding medical care management, reporting of symptoms, and appointment coordination predominated (these categories were identified in 50%, 45%, and 45% of the 20 patient Loops, respectively), while only 10% of the Loops had messages that were prescription-related queries (see Figure 4). No urgent messages were exchanged during the study.

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Table 2. Baseline health care provider demographics.

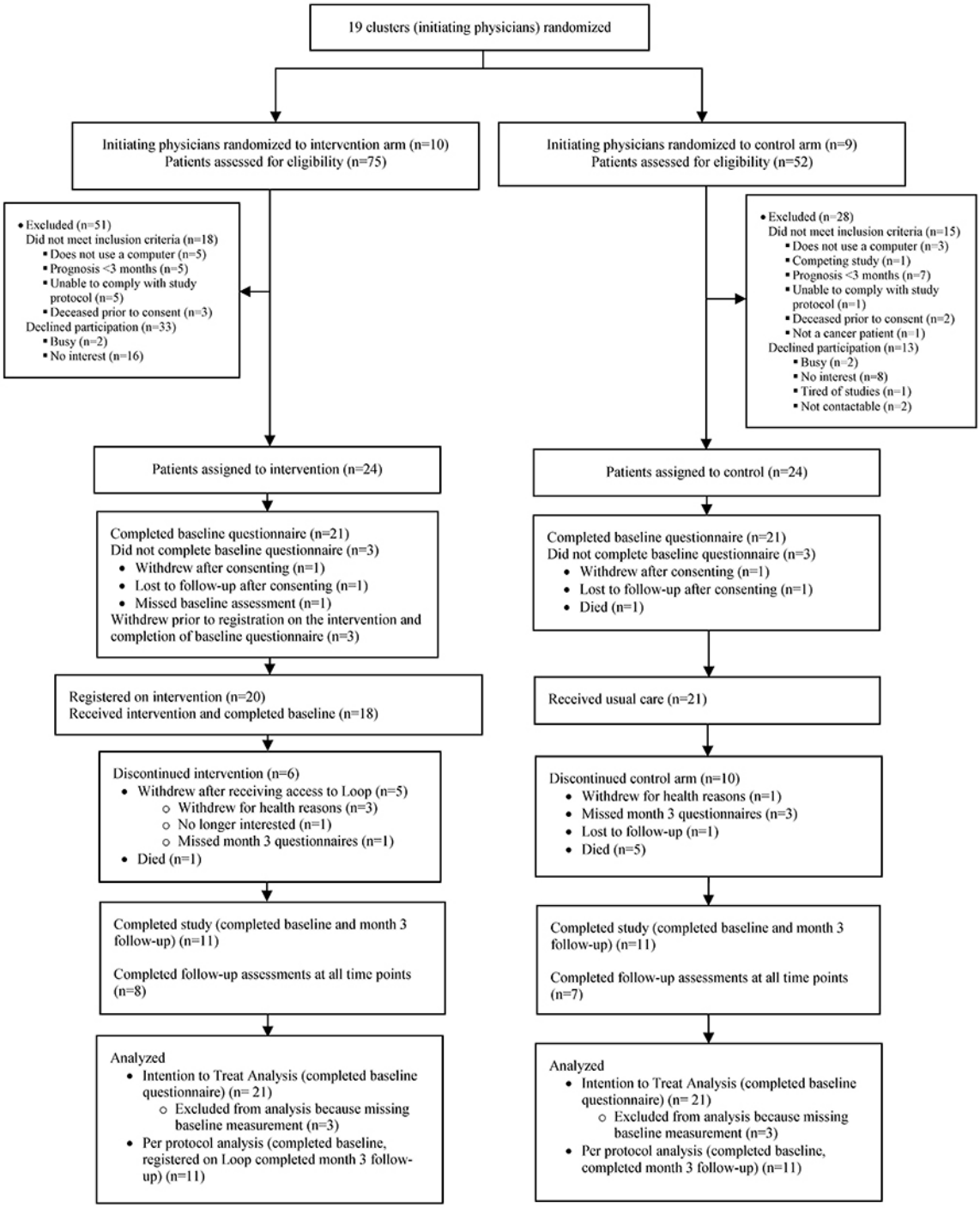
Characteristics	Intervention arm (n=10)	Control arm (n=9)
Initiating physicians		
Age in years, mean (SD)	44 (7.9)	43 (6.1)
Female sex, n (%)	5 (50.0)	3 (33.3)
Years in health care, mean (SD)	16 (8.8)	15 (6.5)
Initiating physician profession, n (%)		
Medical oncologist	4 (40.0)	2 (22.2)
Radiation oncologist	1 (10.0)	2 (22.2)
Palliative care physician	5 (50.0)	5 (55.6)
Primary practice setting, n (%)		
Hospital-based	6 (60.0)	4 (44.4)
Home-based care	4 (40.0)	5 (55.6)
Other		
Type of practice, n (%)		
Community setting		
Academic setting	10 (100)	9 (100)
Practice fee structure, n (%)		
Fee-for-service		
Alternate payment plan	8 (80.0)	7 (77.8)
Salaried	1 (10.0)	1 (11.1)
Other	1 (10.0)	1 (11.1)
Provides after-hours care, n (%)		
Telehealth		
Phone support	2 (20.0)	4 (44.4)
Phone support with visit when needed	6 (60.0)	5 (55.6)
Other		
None	2 (20.0)	
Additional health care providers identified, N	51	
Additional health care providers[a] (n=22)		
Profession, n (%)		
Family physician	1 (4.5)	
Nurse	4 (18.2)	
Case manager	1 (4.5)	
Palliative care physician	4 (18.2)	
Medical oncologist	5 (22.7)	
Naturopath	1 (4.5)	
Oncology nurse	1 (4.5)	
Otolaryngologist	1 (4.5)	
Personal support worker	1 (4.5)	
Psychiatrist	1 (4.5)	
Pharmacist	1 (4.5)	
Physiotherapist	1 (4.5)	
Additional health care providers who consented and registered on Loop, n (%)	16 (72.7)	

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Characteristics	Intervention arm (n=10)	Control arm (n=9)
Additional health care providers identified per patient, mean (range)	2.4 (1-5)	

[a]Recruited as part of the intervention arm and who provided consent.

Figure 3. Participant Flow Diagram.



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Table 3. Usage of Loop (intervention arm participants, n=24).

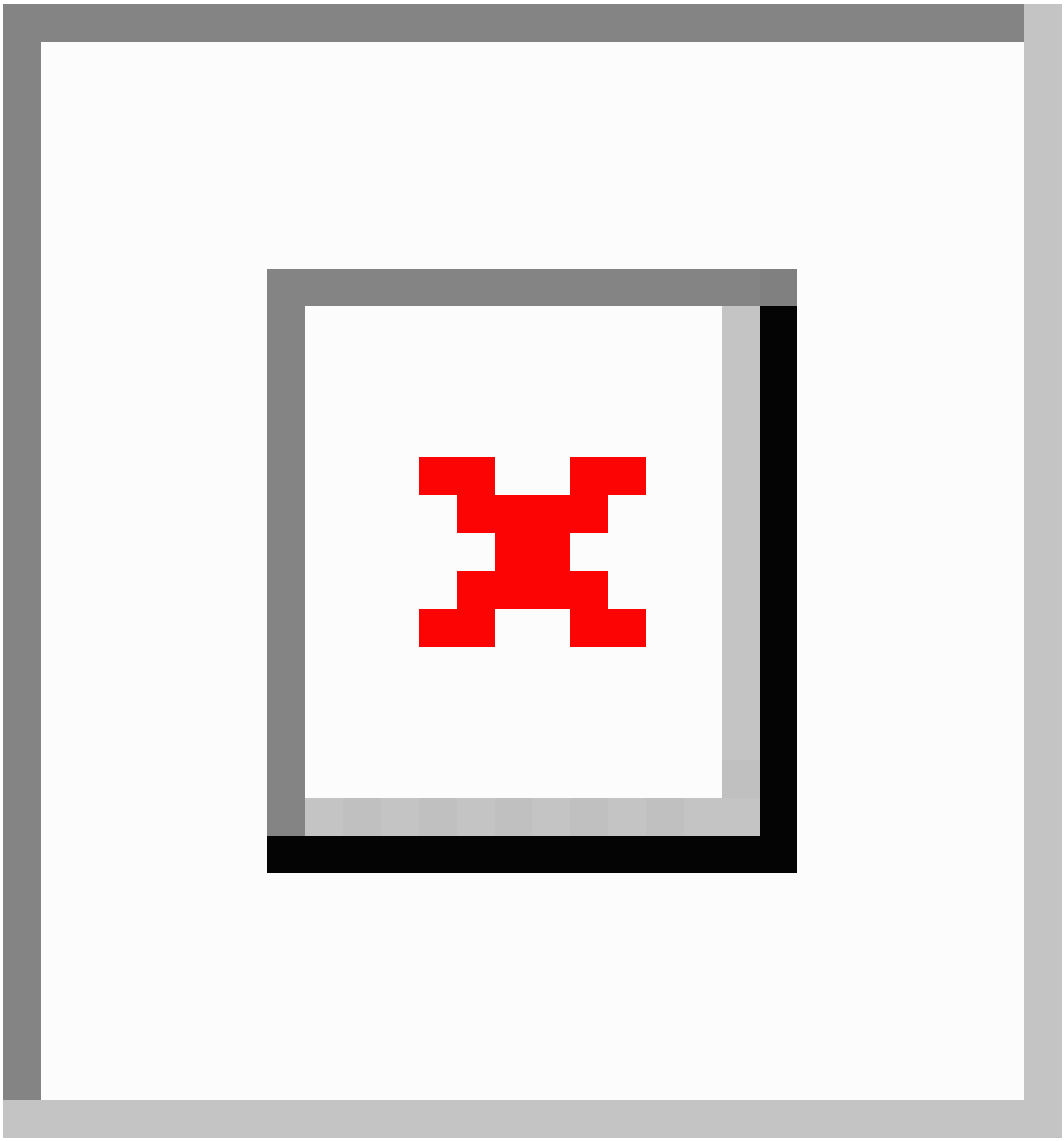
Loop usage	Mean (range) or n (%)
Loop composition[a]	
Patients who registered on Loop (regardless of baseline questionnaire completion), n (%)	20 (83)
Initiating physicians (intervention arm, n=10) who, n (%):	
Registered on Loop	9 (90)
Used the tool (posted at least 1 message or viewed a patient Loop)	7 (70)
Health care providers (including initiating physician) per patient Loop, mean (range)	3 (0-5)
Additional health care providers suggested by each patient, mean (range)	2.4 (1-5)
Additional health care providers per patient Loop, mean (range)	1.25 (0-4)
Patient Loops health care provider is a part of, mean (range)	1.6 (0-7)
Family caregivers per patient Loop, mean (range)	0.5 (0-1)
Frequency of use of the tool, n	Loops, n
Messages exchanged per Loop by registered participants (n=20)	
0	3
1-2	5
3-5	3
6-10	6
>10	3
Views of a patient' s own Loop by the patient or caregiver (n=20)	
0	0
1-2	3
3-5	4
6-10	5
>10	8
Posts to a patient' s own Loop by the patient or caregiver (n=20)	
0	6
1-2	5
3-5	3
6-10	4
>10	2
Views of a patient Loop by an initiating physician (n=9)	
0	2
1-2	1
3-5	2
6-10	4
>10	0
Posts to all their patient Loops by an initiating physician (n=9)	
0	3
1-2	5
3-5	1
6-10	0
>10	0
Use of additional features	

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Loop usage	Mean (range) or n (%)
Time from consent to registration on Loop (days), mean (range)	39 (2-156)
Times an issue was tagged, mean (range)	1 (1)
Times Attention To feature was used by a patient or caregiver, mean (range)	3 (0-14)
Times Attention To feature was used by a health care provider per Loop, mean (range)	0.6 (0-3)

[a]A "Loop" is an aggregation of a patient and/or caregiver and at least the initiating physician allocated to the intervention arm, and registered on the intervention tool.

Figure 4. Categories of messages on Loops with messages exchanged.



Outcomes

For the primary outcomes, the mean number of patients recruited per initiating physician was similar between study arms (in intervention arm 2.4 [range 0-7] in intervention vs control arm 2.7 [range 0-7]) (Table 4). With respect to implementation fidelity, 88% (21/24) of control patients who consented completed the baseline questionnaire and 75% (18/24) of

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intervention patients who consented completed the baseline questionnaire, along with registering on the tool. Regarding patient retention, in the intervention arm, 3 patients withdrew due to declining health, 1 patient withdrew because they were no longer interested, and 1 patient died. In the control arm, 1 patient withdrew due to declining health, and 5 patients died. Instrument and item completion were approximately proportional to patient retention. Of patients completing the baseline outcome assessment, 52% (11/21) in the intervention arm and 52% (11/21) in the control arm completed Month 3 outcome assessments.

Results described are based on available cases. Mean change scores and unadjusted difference in change scores between study arms for preliminary effectiveness outcomes are presented in Table 5. At Month 3, there was an increase in Picker scale scores (in intervention arm +10.2 [SD 31.5] vs control arm -1.1 [SD 30.3]), a negligible change in POS (in intervention arm +0.8 [SD 4.4] vs control arm +0.5 [SD 5.4]), and an increase in ESAS Total Symptom Distress score (in intervention arm +2.3 [SD 10.7] vs control arm +3.4 [SD 8.7]). The number of patients with emergency room visits self-reported at baseline was 3 in the intervention arm and 1 in the control arm. At the third month, no visits were reported in the intervention arm and 3 were reported in the control arm. Similar numbers were observed for number of patients with hospitalizations. On complete case analysis, the Picker scale showed a between-arm difference of +18.5 [47.4] in favor of the intervention arm (Table 6).

Table 4. Feasibility outcomes by treatment arm.

	Intervention arm (n=24)	Control arm (n=24)
Patients from oncology practices, n	18	13
Patients from palliative care practices, n	6	11
Initiating physicians, n	10	9
Consenting initiating physicians approached who provided at least one patient, n	9	7
Patients who completed baseline and, if in the intervention arm, registered on Loop, n (%)	18 (75)	21 (87.5)
Patients recruited per initiating physician, mean (SD)	2.4 (2.2)	2.7 (2.6)
Patients with a family caregiver who participated in study, n	18	8
Teams with an additional health care provider, n	13	

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Table 5. Preliminary measures of effectiveness by treatment arm, available case analysis.

	Score at each month in the intervention arm	Score at each month in the control arm	Mean observed change from baseline (SD) in the intervention arm	Mean observed change from baseline (SD) in the control arm	Unadjusted difference between change scores (SD)
Picker Continuity and Coordination subscale, mean (SD)[a]					
1 month	58.7 (23.0)	64.4 (23.3)	-3.4 (29.6)	-6.7 (11.0)	3.3 (31.6)
2 months	66.7 (27.4)	69.8 (24.7)	9.1 (25.1)	4.2 (22.8)	4.9 (33.9)
3 months	63.5 (25.8)	60.2 (24.9)	10.2 (31.5)	-1.1 (30.3)	11.4 (43.8)
POS, mean (SD)[b]					
1 month	7.5 (5.1)	8.3 (5.3)	-1.3 (4.0)	-1.0 (3.4)	-0.3 (5.2)
2 months	7.2 (4.5)	9.2 (6.0)	0.0 (3.2)	-0.6 (4.0)	0.6 (5.1)
3 months	8.2 (4.8)	10.3 (6.5)	0.8 (4.4)	0.5 (5.4)	0.4 (7.0)
ESAS (Total Symptom Distress Score), mean (SD)[c]					
1 month	14.6 (11.8)	24.7 (15.2)	-3.0 (9.0)	1.4 (12.2)	-4.4 (15.2)
2 months	15.2 (12.1)	21.1 (11.7)	-1.6 (9.4)	1.1 (8.0)	-2.7 (12.4)
3 months	19.2 (9.3)	23.3 (17.0)	2.3 (10.7)	3.4 (8.7)	-1.1 (13.8)
Patients with an emergency room visit in previous 4 weeks, n					
Baseline	3	1			
1 month	1	2			
2 months	0	2			
3 months	0	3			
Patients with a hospitalization in previous 4 weeks, n					
Baseline	3	0			
1 month	1	1			
2 months	0	0			
3 months	0	3			

[a]The Picker Continuity and Coordination subscale is a proportion of total number of positive responses to total number of responses. Higher scores indicate the higher perceived continuity of care.

[b]Mean summed scores are presented for the POS with a maximum score of 40. Higher scores indicate worse quality of care.

[c]Mean summed scores are presented for the ESAS with a maximum score of 90. Higher scores indicate higher symptom distress.

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Table 6. Complete case analysis preliminary measures of effectiveness by treatment arm.

	Score at each month in the intervention arm	Score at each month in the control arm	Mean observed change from baseline (SD) in the intervention arm	Mean observed change from baseline (SD) in the control arm	Unadjusted difference between change scores (SD)
Picker Continuity and Coordination subscale, mean (SD)[a]					
Baseline	57.8 (27.5)	76.8 (21.0)			
1 month	51.6 (20.5)	73.2 (28.3)	-6.3 (34.7)	-3.6 (11.9)	-2.7 (36.7)
2 months	62.5 (25.0)	76.8 (24.4)	4.7 (26.7)	0.0 (21.7)	4.7 (34.4)
3 months	65.6 (60.0)	66.1 (29.5)	7.8 (36.6)	-10.7 (30.1)	18.5 (47.4)
POS, mean (SD)[b]					
Baseline	8.0 (6.0)	8.0 (6.2)			
1 month	6.5 (3.7)	6.0 (5.9)	-1.5 (4.4)	-2.0 (3.0)	0.5 (5.3)
2 months	8.3 (3.5)	7.1 (5.1)	0.3 (3.8)	-0.9 (2.0)	1.1 (4.3)
3 months	8.3 (3.1)	8.4 (7.6)	0.3 (4.7)	0.4 (6.0)	-0.2 (7.6)
ESAS (Total Symptom Distress Score), mean (SD)[c]					
Baseline	16.8 (10.3)	16.8 (12.8)			
1 month	11.7 (8.0)	19.4 (13.2)	-5.1 (9.7)	2.5 (7.4)	-7.7 (12.2)
2 months	14.3 (8.3)	20.3 (13.6)	-2.5 (11.0)	3.5 (7.4)	-6.8 (13.3)
3 months	18.9 (8.4)	21.3 (21.4)	2.1 (11.6)	4.4 (10.3)	-2.4 (15.5)
Patients with an emergency room visit in previous 4 weeks, n					
Baseline	2	1			
1 month	1	1			
2 months	0	0			
3 months	0	2			
Patients with a hospitalization in previous 4 weeks, n					
Baseline	2	0			
1 month	1	0			
2 months	0	0			
3 months	0	3			

[a]The Picker Continuity and Coordination subscale is a proportion of total number of positive responses to total number of responses. Higher scores indicate the higher perceived continuity of care.

[b]Mean summed scores are presented for the POS with a maximum score of 40. Higher scores indicate worse quality of care.

[c]Mean summed scores are presented for the ESAS with a maximum score of 90. Higher scores indicate higher symptom distress.

Discussion

Principal Findings

In this pilot cRCT evaluating an online communication tool for clinical collaboration, trial feasibility conditions and implementation goals were met. The study was not powered to observe changes in outcomes between study arms, but we did observe an increase in continuity of care scores in the intervention arm at last follow-up, which was maintained on complete case analysis. Regarding the assembly of teams, though each patient identified at least one additional health care provider, only 65% of patient Loops had an additional health care provider register on the tool. Loop was primarily used for medical care management, symptom-related discussions, and appointment coordination.

Interpretation

As a population with complex care needs [45], the advanced cancer population served as an exemplar patient population in which to evaluate Loop but also proved challenging from a participation standpoint. Although the proportion of eligible patients who consented in this study was slightly higher than two previous studies conducted at the same institution with the same population (38% here vs 10%) [36,46], a number of patients withdrew due to ill health or died over the course of the study. This was expected given the uncertainty in prognosis in this population. Instrument completion rates reflected patient retention rates, indicating that questionnaire administration was feasible despite the nature of the patient population.

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Loop was designed to connect patients and caregivers to their team of health care providers in a virtual space where communication might be facilitated outside of appointments and across care settings [26]. While we did not assess differences in measures of effect for statistical significance, preliminary Picker scale results appear to support potential for this tool to improve continuity of care in future studies of adequate statistical power. Contextualized with the content of messages, the findings of this study may suggest that there were important needs that could be dealt with between appointments by using the tool, contributing to increased perceptions of continuity of care.

The care of patients with complex needs requires a redefining of the relationship between health care providers and patients to a team-based model of care that engages the patient [47]. These patients often have interdependent issues and thus require collaborative approaches to care (negotiated decision making between individuals in a synergistic manner around shared goals) over coordination between providers (alignment of functioning among independent individuals to address common needs) [48]. Here, the greater number of posts by patients over health care providers and the patient-driven content of messages (eg, Updates, Appointment Coordination) are suggestive that in this study, coordination tasks were addressed to some extent but collaboration did not occur. Given these results, we recognize that Loop in isolation did not produce collaboration, and further consideration into building relationships among these teams is required [49].

We further found that assembling the team was difficult in this study, with few health care providers from outside academic practices, who were identified by the patient, agreeing to join. Other studies have found that barriers to health care provider participation and uptake of studies of eHealth tools include lack of provider compensation and perceived worry about the burden of patient overuse [50]. Although this increased burden has not been observed thus far [51], better strategies to improve integration into clinical workflow need to be examined, especially for physicians with large patient rosters. Implementation of incentive schemes, akin to what has been done in the province of Ontario, Canada, for electronic consultations [52] may also improve uptake of eHealth tools, like Loop, into practice.

In this study, Loop was intentionally provided to teams without training. We observed that participants were able to understand and use the core functionality of Loop, that is, to post and read messages. We further observed that patients viewed their Loop more often than they posted compared to health care providers, who posted nearly as often as they viewed a Loop. This could be interpreted as showing that patients were more proactive tool users, while health care providers are more likely to wait for notifications before logging in.

Comparison With Previous Studies

While many tools for patient-physician communication exist (frequently as secure email or part of patient portals) [19,53], few have considered the potential value of team-based communication, which is crucial for complex care scenarios or situations requiring ongoing care. At least four studies have evaluated variations of tools connecting patients and caregivers with multiple health care providers. Gulmans et al [25] found that patient groups who used their tool more often tended to have a larger care network (number of professionals registered per patient). Furthermore, Ralston et al [23], in evaluating secure messaging as part of a portal, found that messaging increased proportionally with patient morbidity, which reinforces the suggestion that messaging is of more value in complex care. While our study was too small to examine such associations, these findings support the increased value that eHealth communication tools may have as complexity of team and illness increase.

In a study by Hsiao et al [22], as has been noted elsewhere [54,55], participants felt that text-based communication may diminish the therapeutic relationship gained from in-person visits or unstructured voice-based contact (such as telephone). This suggests that such forms of communication should supplement, but not replace, appointments or calls.

The ZWIP tool, by Robben et al [24], allows for patient-provider and between-provider communication. Evaluation in frail elderly patients found that use by both patients and providers depended on provider use of the tool. Health care providers considered implementation strategies (such as training to use the tool) “very necessary” to make the most use of ZWIP. This finding may reflect the need for guided implementation to facilitate integration into clinical workflow and to improve the use of Loop.

Limitations

The results of this study should be interpreted within the context of the study’s strengths and limitations. As a pilot study, we aimed for a sample size that was adequate to determine feasibility of implementation. However, this sample size limited the ability to test the effectiveness of the intervention. All health care providers described themselves as very comfortable with computers and worked in fully computerized practices; however, this may not be true of every medical practice, limiting study generalizability. Similarly, the complexity of clinical cases and nature of physician practice may be different elsewhere. While patients with advanced cancer are a prototypical population of patients with complex care needs and have involvement of multiple providers, similar results may not be reflected in other populations. The cRCT design, involving recruitment and randomization of initiating physicians (clusters) sequentially, and their patients prospectively, may have led to selection bias because of differential recruitment rates by provider and differences in their clinical subspecialty. We also observed that more patients died in the control arm than in the intervention arm possibly indicating unmeasured confounding. As use of the tool was voluntary, there is also a risk of confounding by indication, with patients who have more issues needing to use the tool more often, or functionally limited patients using the tool less often.

Future Research

The results of this study will inform the next phase of research, which aims to (1) understand the conditions that affect tool adoption and assembly of teams, (2) understand the relationship

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between use and outcomes such as continuity and quality of care, and (3) examine the contexts and target populations where the benefits of a tool like Loop may be best realized and where the effort to assemble the care team is justified. We anticipate that by making adjustments to the implementation approach [56] through use of site champions, consideration of strategies to foster team collaboration as a co-intervention with Loop, and considering an initiating physician (the "index provider") from those additional provider disciplines that were less represented, we may address issues with team assembly and optimize collaboration on Loop. We also expect that with a longer duration of follow-up, as could be done in other patient populations, participants' comfort with using Loop may improve, and the content of communication may become more oriented towards care planning and decision making, over coordination.

Conclusion

In this study, we found that it was feasible to implement Loop in clinical practice and that the tool may have the potential to improve continuity of care. We observed that Loop messages reflected message categories of medical care management, symptom reporting, and appointment coordination, among others. Usage of the tool suggests that some coordination tasks were improved but further strategies to build collaboration among team members may be needed. As an ongoing goal of eHealth development, the integration of the dynamic components of care (communication and collaboration) with the static repositories of medical records would enable a more seamless provision of health care. However challenging this may be in the current environment of multiple electronic health records across organizations, studying collaborative tools like Loop advances this goal.

Acknowledgments

The My Team of Care study would like to acknowledge the Loop Team, consisting of Alyssa Bertam, Joe Cafazzo, Eyal Cohen, Peter Weinstein, Adam Rapoport, Jennifer Stinson, Andrea Bezjak, Wayne Ho, Renee Desjardins, and Russell Goldman as well as Melanie Powis, Jodheme Goldhar, Dipti Purbhoo, Vishal Kukreti, Carol Sawka, Denise Guerriere, Rick Skinner, Ken Sutcliffe, Lydia Lee, Daniela Crivianu-Gaita, Andrew Szende, and Camilla Zimmermann for their contributions to making this study possible.

TV is supported by a Canadian Institutes for Health Research MD/PhD studentship and McLaughlin Foundation fellowship. EG is supported by a clinician-scientist award from the Ontario Institute for Cancer Research and the Giblon Professorship at the Department of Family and Community Medicine.

This research was funded by a grant from the Academic Health Science Centre AFP Innovation Fund- Mount Sinai Hospital/University Health Network Academic Medical Organization and the Temmy Latner Centre for Palliative Care.

Authors' Contributions

TV, EG, TJ, AK, BL, MK, MM, and AH were involved in study conception. TV, EG, AK, BL, MK, MM, RM, and AH were involved in study design. TV, AK, and BL were involved in acquisition of data. TV and RM were involved in analysis. TV drafted the manuscript, and all authors contributed to revisions.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [29].

[PDF File (Adobe PDF File), 6MB - jmir_v19i7e219_app1.pdf]

Multimedia Appendix 2

Coding framework for Loop usage.

[PDF File (Adobe PDF File), 357KB - jmir_v19i7e219_app2.pdf]

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Abbreviations

cRCT: Cluster Randomized Controlled Trial
ECOG: Eastern Cooperative Oncology Group scale
ESAS: Edmonton Symptom Assessment Scale
POS: Palliative care Outcomes Scale

Edited by G Eysenbach; submitted 27.01.17; peer-reviewed by C Kuziemsky, B Crotty, M Henton, L Rixon, A Mostaghimi; comments to author 26.03.17; revised version received 05.05.17; accepted 26.05.17; published 18.07.17.

Please cite as:
Voruganti T, Grunfeld E, Jamieson T, Kurahashi AM, Lokuge B, Krzyzanowska MK, Mamdani M, Moineddin R, Husain A
My Team of Care Study: A Pilot Randomized Controlled Trial of a Web-Based Communication Tool for Collaborative Care in Patients With Advanced Cancer
J Med Internet Res 2017;19(7):e219
URL: http://www.jmir.org/2017/7/e219/
doi:10.2196/jmir.7421
PMID:28720558

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Original Paper

Preliminary Evidence for the Emergence of a Health Care Online Community of Practice: Using a Netnographic Framework for Twitter Hashtag Analytics

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Abstract

Background: Online communities of practice (oCoPs) may emerge from interactions on social media. These communities offer an open digital space and flat role hierarchy for information sharing and provide a strong group identity, rapid flow of information, content curation, and knowledge translation. To date, there is only a small body of evidence in medicine or health care to verify the existence of an oCoP.

Objective: We aimed to examine the emergence of an oCoP through the study of social media interactions of the free open access medical education (FOAM) movement.

Methods: We examined social media activity in Twitter by analyzing the network centrality metrics of tweets with the #FOAMed hashtag and compared them with previously validated criteria of a community of practice (CoP).

Results: The centrality analytics of the FOAM community showed concordance with aspects of a general CoP (in terms of community, domain, and practice), as well as some specific traits of a health care community, including social control, common purpose, flat hierarchy, and network-based and concrete achievement.

Conclusions: This study demonstrated preliminary evidence of an oCoP focused on education and based on social media interactions. Further examination of the topology of the network is needed to definitely prove the existence of an oCoP. Given that these communities result in significant knowledge translation and practice change, further research in this area appears warranted.

(J Med Internet Res 2017;19(7):e252) doi:10.2196/jmir.7072

KEYWORDS

social media; network; community networks; community of practice; #FOAMed; Twitter

Introduction

Creation, dissemination, and management of knowledge are cornerstones of safe and effective health care, but achieving these goals in functional and successful large care systems remains enormously challenging. Within this construct of health systems [1], the concept of a network is vital for improving patient care by fostering collaboration, stimulating engagement and knowledge acquisition and management, and promoting learning [2]. Recently, social media-based platforms have been

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proffered as educational tools [3,4], based on the critical assumption that activity in online networks can lead to the emergence of personal learning networks [5] and communities of practice (CoPs) [6].

CoPs are an anthropological concept, defined as a group of people who organize around a specific component of knowledge (eg, a profession or particular task). They create, organize, and share information and not only develop specific domains but also foster development of individual members [6]. These communities are organized around a domain, community, and practice, where the domain is a realm of knowledge that the members of the group have interest in and value as important; the community is the coalescence of interactions and negotiations between members around the domain; and practice is the results of the cooperation leading to the creation of tangible resources affecting their practice of the knowledge. The presumed natural evolution of organically organized online communities [7] is the description and identification of an online CoP (oCoP) [8]. This construct offers an enormous potential for the creation, dissemination, and management of knowledge and people using a relatively minimal amount of resources and appearing as an ideal framework for information-oriented teams. These have arisen from the Internet in general and particularly in social media platforms [9] because of their ability to efficiently connect and engage groups, provide peer-based education [10], and manage meaningful knowledge [8].

The concept of CoP has been thoroughly described in health care [11], and the critical components of an appropriate network were refined and expanded by Aveling et al in 2012 [12]. A health care CoP is defined by 8 core characteristics (described below) that are themselves derived from Wenger's [6] pivotal components of community, domain, and practice.

Although CoPs are not a new phenomenon, social media platforms have enabled them to form rapidly and across international boundaries, with nonlinearity and on a large scale [13]. These new oCoPs create discrete and quantifiable data flow among users (nodes) of the network. Knowledge and relationships develop by these interactions (links), with functional communities arising as information transfer increases. These communities of online learning and practice offer an open digital space for information sharing, with a flat role hierarchy, strong group identity, high engagement, and rapid flow of information, content curation, and knowledge translation. In many ways, their topology represents the structure of scale-free networks [14,15]. The use of social media platforms as an educational medium is dependent on these oCoPs providing reliable and manageable information for their participants [16].

Despite the recognition of several possible candidates for CoPs and their derivatives in online platforms [8], particularly in the health care sector [11] and for peer-to-peer patient interactions [17], medical learning and practice oCoPs have been rarely described in the medical literature to date. An international movement that began within the past 5 years now aims to collaborate to create, curate, and disseminate medical knowledge with the intention of changing patterns of care; an explicit aim is to reduce the knowledge translation gap [2,15]. This movement describes the concept as "free open access medical education" (FOAM) [18,19] and organizes around the Twitter hashtag #FOAMed; the group name is synonymous with and represents its core philosophy.

The strength of oCoPs can be established if these communities are identified and their relationships described; social media education could then be validated as a viable paradigm for knowledge translation [16] that affects health care practice. The aim of this study was to show preliminary evidence of the emergence of a health care oCoP focused on knowledge translation and organized as a network architecture around the Twitter hashtag #FOAMed. By using data extracted from our #FOAMed hashtag analysis, we aimed to demonstrate that the FOAM community fulfills the core characteristics of a CoP, as described by Wenger [6] and expanded by Aveling et al [12], and is a community of individuals with different roles who belong to different organizations and places, who organize themselves around a concrete domain and specific goal, and who function to support and promote each other's development to achieve change.

We hypothesized that the FOAM community, defined by the explicit interactions that include the #FOAMed hashtag, constitutes an oCoP. To confirm this, we believed it should be possible to recognize the emergence of the community, domain, and practice of the network, while describing information flowing between nodes and the semantic relationships between the members. Describing the structure of the network, as well as the influences of nodes outside the network (eg, spambots), requires a robust intrinsic familiarity with the community; therefore, we approached the analysis using a netnographic methodology [20,21] based on our personal participation in the FOAM movement.

Methods

The challenge of analyzing billions of interactions in social media [22,23] is a relatively recent area of activity that requires a high level of expertise and computational power. We created a Symplur Signals database (Symplur LLC, Upland, CA, USA) around the Twitter hashtag #FOAMed and interrogated it from March 1, 2013, through August 31, 2015; this dataset contained almost all data available for the hashtag because the accepted inception time for #FOAMed was March 2013 and the activity occurred explicitly around the hashtag [18]. The computational tools implemented by Symplur Signals have been validated previously for the analysis of Tweet chats [24]. There is a large amount of FOAM community activity, such as blogs, podcasts, and conference proceedings, that is not directly related to the #FOAMed hashtag or Twitter; however, these products are typically references in community activity and it is highly unlikely that such activity outside of Twitter would nullify the existence of the oCoP.

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Table 1. Aveling's core components of clinical communities of practice and their relationship with Wenger's classic definition.

Composite postulate notation	Aveling core components of clinical communities[a]	#FOAMed proof	Wenger definition[b]
A1C	Consists of interdependent groups and individuals	The #FOAMed hashtag connects individuals who demonstrate interactions with each other. Over time, influencers increase in number and become divergent rather than convergent.	Community
A2C	Consists of members who may cross clinical and organizational boundaries	#FOAMed hashtag is used by a variety of individuals and organizations. Over time, geographic area of use increases.	Community
A3D	Consists of members united by a common purpose of bridging the gap between best scientific evidence and current clinical practice	Content of #FOAMed remains around health care-related themes, centered on creation and access to content.	Domain
A4CDP	Consists of members who come together not only to learn or share knowledge but to achieve those aims	Discussion around #FOAMed results in positive attributions regarding content.	Community, domain, practice
A5DCP	Exploits the networks' inherent potential for effective and low-cost knowledge generation and diffusion	#FOAMed generates subnetworks around individuals or content nodes (such as specific websites).	Domain, community, practice
A6C	Operates through both vertical and lateral structures	The network expands through increasing individuals who influence others across increasingly wide geographic areas.	Community
A7CP	Deploys peer influence and uses primarily informal, social control mechanisms to achieve change	Key nodes exert influence, but this changes through time.	Community, practice
A8P	Harnesses the power of the community and its collective wisdom when seeking solutions to problems; includes contextual factors and local solutions	Interactions (measured through mentions) expand rather than contract over time.	Practice

[a]Adapted from Aveling et al [12]. Used with permission.

[b]Data from Wenger [6].

To reduce potential bias in the analysis, we submitted a protocol to the Symplur Signals team defining the a priori analytic strategy. Within this protocol, we proposed several proofs to demonstrate concordance with the Aveling-Wenger postulate for a CoP. Table 1 lists these proofs, matched to the 8 distinct core characteristics. For example, evidence of interdependent groups and individuals (A1C) would be demonstrated by showing that the #FOAMed hashtag was used by individuals who had interactions with each other and that, over time, influencers increased in number, becoming divergent rather than convergent. To do this, we would therefore need to describe #FOAMed hashtag use quantitatively. Conceptually, we aimed to analyze #FOAMed hashtag activity as a network. The hashtag [25] constitutes the core scaffold in which the identified social activity occurs. The network consists of Twitter users (nodes), and interactions (links) with specific metrics of interactions such as retweets, favorites, and engagements, which constitute the connections and distribution by which networks are typically constructed [26,27].

Given the social nature of the Twitter platform, we used the social network analysis component of the netnographic framework for analysis, as described by Kozinets [20]; this method is particularly effective at identifying external influences that are not meaningful to the community (eg, spambots, large commercial interests), as well identifying digital artefacts that are created by mistake or are otherwise inappropriate (eg, links to unrelated events associated with the hashtag but used by a completely different community). From a netnographic perspective, it is difficult to appreciate the metrics of centrality without a personal understanding of the symbolism, meaning, and consumer patterns of the groups [28]; however, as members of the community of study, we had an immersive and descriptive understanding of the FOAM movement. Our intimate understanding allowed us to determine (via a consensus view of the authors) the relevance of the top 100 shared links identified in the ethnographic analysis of the FOAM community We generally excluded broken links, links to landing pages of websites or home pages, and any other links that did not point to a webpage with a publicly visible forum for comments and feedback or had no comments posted. This study was deemed exempt from ethics board review by the English National Health Service Health Research Authority.

Results

During the study period, we identified 49,459 active users who issued 429,606 tweets and created 1,258,692,900 impressions (ie, the number of times a user is served a Tweet in their timeline or search results); this translated to more than 8 tweets and 25,000 impressions per user involved in the conversation (Table 2). The user and hashtag activity, expressed as number of daily tweets, increased during the study period (from ~250 to ~700 tweets/day) (Figure 1). User participation increased substantially during the same time frame, rising from around 1000 users to more than 45,000; an additional 1000 users per month have participated since March 2014 (Figure 2). Multimedia Appendix 1 shows the top influencers. In terms of engagement, 27,635

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users (55.71%) participated with 1 tweet (representing 6.43% of all tweets), while 2603 users (5.25%) tweeted more than 20 times and were responsible for 72.45% of all tweets (Table 3).

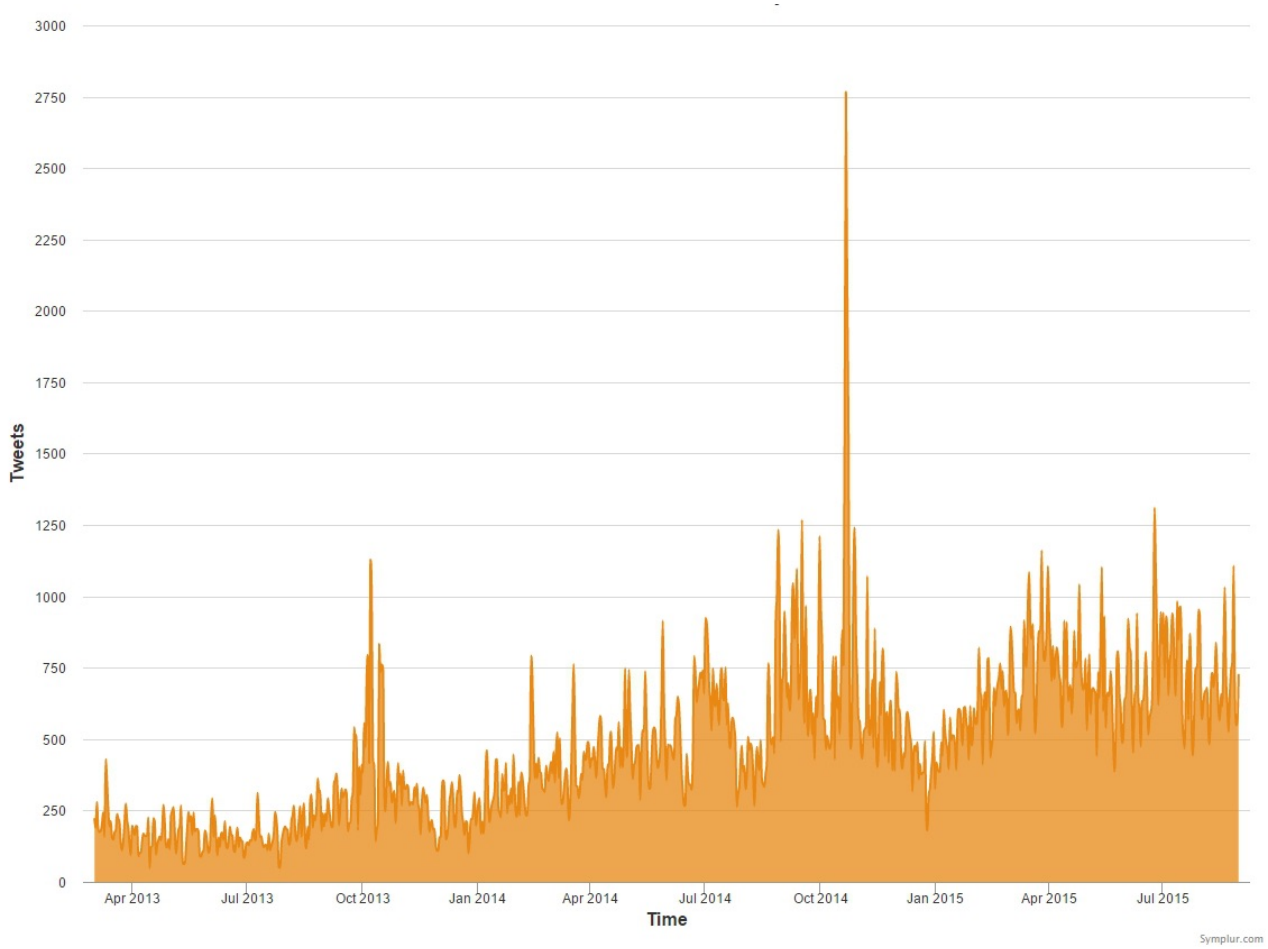
From a network distribution perspective, the top 200 users created 148,185 tweets, representing 34.49% of all tweets of the community. The Symplur Signals analytics algorithm created a centrality map by considering nodes (users) and their interactions (links) to assign weight and used the metrics of mentions, authority, and hub to assign the weight of centrality [29,30]. The 100 users with the highest weights also tended to have high authority and edge scores (Multimedia Appendix 2), and from a netnographic perspective, they were recognizable as community leaders. Figure 3 outlines their status in relation to the number of interactions with other participants in a graphical representation, where the size of the node represents its network centrality (relative influence) and the links depict the strength and directions of the interactions between members (nodes) of the network. Also, Figure 4 depicts a perspective of the communication between nodes on a conversation matrix showing the frequency and strength of interactions among the most active community members.

Table 2. Metrics of the Twitter hashtag #FOAMed[a].

Metric	Total	No. per month	No. per week	No. per day	No. per hour
Tweets	429,606	14,132	3298	471	20
Users who tweeted	49,459	1627	380	54	2
Tweets per user	8.69	0.29	0.07	9.52×10^{-3}	3.97×10^{-4}
Impressions	1.26×10^{9}	4.14×10^{7}	9.66×10^{6}	1.38×10^{6}	5.75×10^{4}
Impressions per user	25,447	837	195	28	1

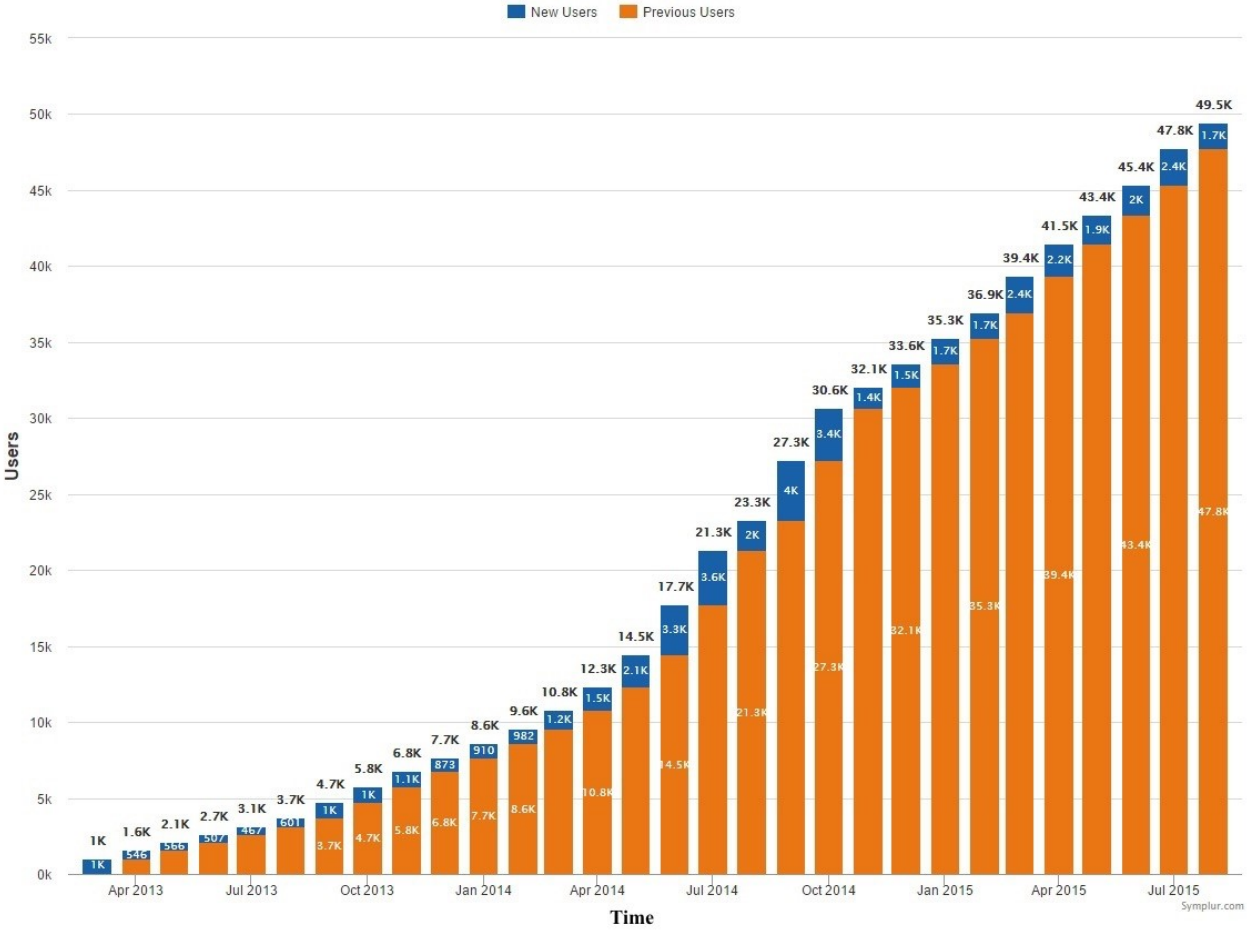
[a]Hashtag activity was monitored from March 1, 2013, through August 31, 2015.

Figure 1. Tweet activity (number of tweets per day) using the #FOAMed hashtag from March 1, 2013, through August 31, 2015.



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Figure 2. Cumulative number of users participating in the #FOAMed community.



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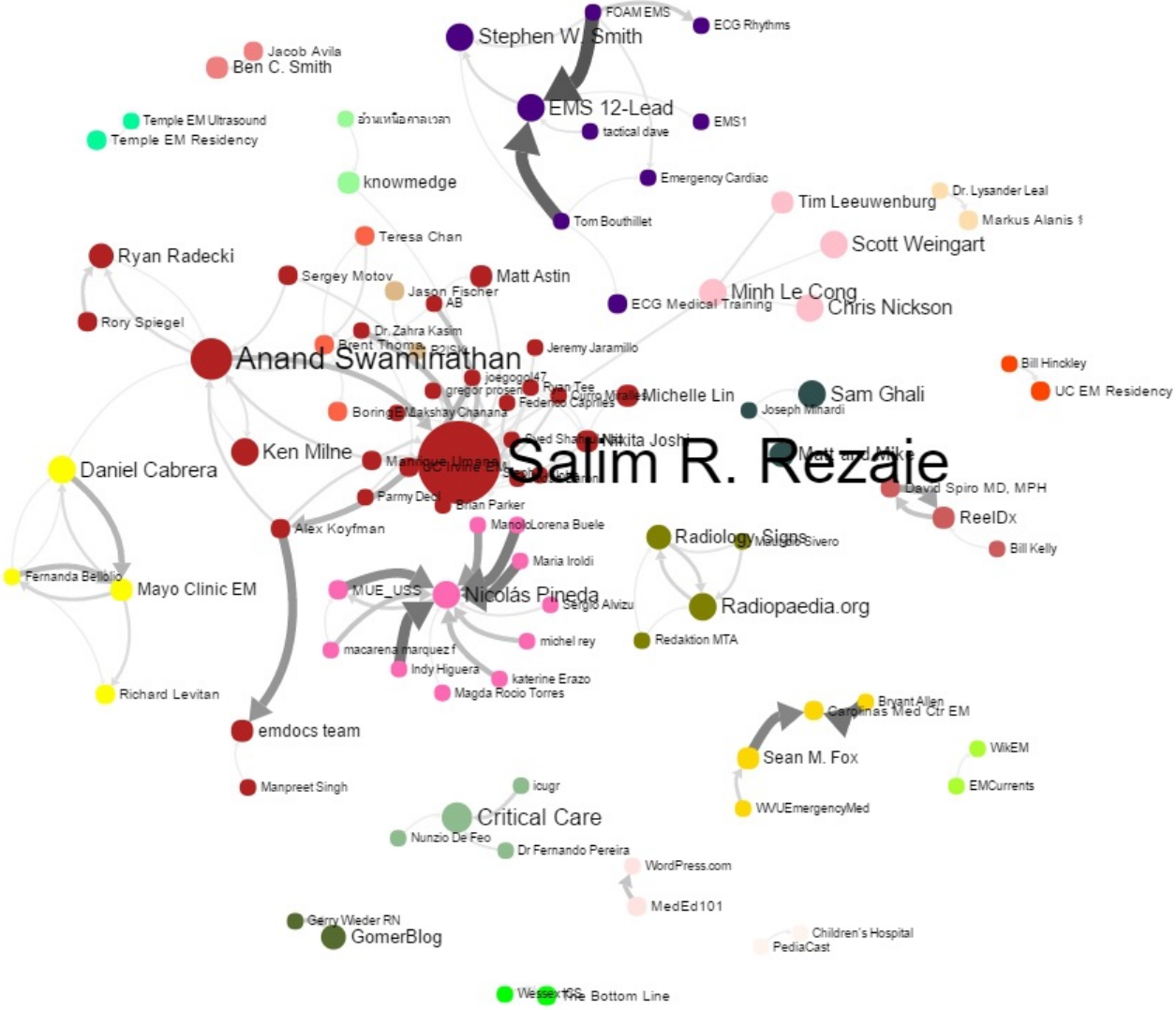
Table 3. Twitter engagement metrics for the #FOAMed hashtag[a].

User activity by no. of tweets	Total users, n (%)	Proportion of all tweets, %
1	27,635 (55.71)	6.43
2	7078 (14.27)	3.30
3	3703 (7.46)	2.59
4	2103 (4.24)	1.96
5	1366 (2.75)	1.59
6	1011 (2.04)	1.41
7	698 (1.41)	1.14
8	602 (1.21)	1.12
9	454 (0.92)	0.95
10	382 (0.77)	0.89
11	326 (0.66)	0.83
12	269 (0.54)	0.75
13	229 (0.46)	0.69
14	182 (0.37)	0.59
15	164 (0.33)	0.57
16	164 (0.33)	0.61
17	145 (0.29)	0.57
18	122 (0.25)	0.51
19	118 (0.24)	0.52
20	110 (0.22)	0.51
>20	2603 (5.25)	72.45

[a]Total tweets, 429,606; total number of users who tweeted, 49,459.

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Figure 3. Partial graphic depiction of the centrality metrics of the top 100 #FOAMed users based on weight (defined by mentions, hub, and authority quotients).



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Figure 4. Conversation identifier depicting frequency and strength of interaction among top members of the #FOAMed community.



Table 4. Geographic location of #FOAMed community members (n=9502)[a].

Country	n (%)
United States	4137 (43.5)
United Kingdom	1926 (20.3)
Australia	820 (8.6)
Canada	797 (8.4)
Spain	434 (4.6)
Russia	384 (4.0)
Brazil	270 (2.8)
Mexico	270 (2.8)
India	264 (2.8)
Saudi Arabia	200 (2.1)

[a]Not all users self-identified their locations.

In terms of geographic distribution, the community members generally lived in anglophone Western countries, although some of them were located in Latin American and Asian countries (Table 4). However, the analytic tool was unable to consider

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the geographic location of more than 50% of users because they did not provide self-identified geolocation information.

Multimedia Appendix 3 details the top 150 conversations (defined by Symplur in terms of level of engagement) generated in the community during the study period. The users involved were those with the highest network weight and hub index. The conversations showed a relatively low level of branching, with most having 2 or 3 levels of interactions (replies). An automatic sentiment analysis [31] showed a 0.367 positive sentiment embedded in the tweets. In terms of knowledge sharing, an analysis of the top 100 links (Multimedia Appendix 4) shared by the group shows a mix of self-created content (blogs), referral to social platforms (eg, YouTube, Vine), and referral to traditional media (eg, website for the *New England Journal of Medicine*). We analyzed a total of 26 blogs (Multimedia Appendix 5) to explore the contextual meaning of the #FOAMed community. Ethnographic examination showed forums of discussion by way of blog comments, with commenters also being members of the #FOAMed Twitter community.

Discussion

Principal Findings

Analysis of the data revealed evidence of a community organized around a scale-free topology network built on the hashtag #FOAMed, with an increasing number of users (nodes) and connections (links) manifested as impressions. The community is organized around members with a high degree of influence (centrality) that functions as a major hub for communication and knowledge management. In terms of content, knowledge appears to have a similar architecture, with relatively small pieces (blog posts or videos) concentrating most of the interactions and functioning also as hubs with high centrality [32,33].

The outcomes of the #FOAMed hashtag database analysis can be matched against the composite Aveling-Wenger [6,12] postulate for a health care CoP (Table 1). Thus, there is preliminary evidence suggesting the #FOAMed community possesses many of the characteristics of an oCoP and may contribute to recent literature describing learning and practice oCoPs [34].

In terms of the formation of interdependent groups and individuals (A1C) and the crossing of clinical and organizational boundaries (A2C), the data support the existence of a diverse group of people, organized around content and users hubs (Tables 1 and 2); the community includes health care providers in different roles (physicians, nurses, paramedics, etc), as well as health care and educational organizations; and there is robust interaction between users (nodes) of different background, trainings, and specialties. At the time of analysis, community members were mostly located in Western anglophone countries, with fewer members in Asia and Latin America (Multimedia Appendix 4). However, while it is possible to describe the volume of the dependencies, it is more challenging to demonstrate their meaning. It must be acknowledged that, due to the size of the community, it is difficult to completely verify the relationships and interactions that prove the interdependencies suggested by the Aveling-Wenger postulate. The analysis of an oCoP focuses on the members of the community and their interactions around pieces of the domain in order to construct a practice and is essentially different from a network analysis. This approach, although very relevant, would not have been appropriate for this work, given the lack of focus on content. Clearly, community members are engaged in the dissemination and sharing of medical knowledge, as demonstrated by the type and frequency of link sharing and the efforts of the community to increase the reach of the information through retweets (Multimedia Appendix 4). It is key to describe that all of the content analyzed was quite concentrated on medical knowledge, there were no links to nonbiomedical content, and the discussions were in a high degree quite focused on dissemination and critique; in other words, there was very minimal noise in the discussions among the members of the community (Multimedia Appendix 3). These actions embody the core of the common purpose postulate (A3D) and the exploitation of inherent networks (A5DCP). However, the nature of those networks is not clear and diffusion of knowledge cannot be encapsulated using this whole-system review approach, which is a limitation of a digital-based analysis of knowledge translation.

The most powerful characteristic of the #FOAMed network [27] is the robustness and richness of the interactions between the users (nodes) through strong relations (links); this activity resulted in more than a billion relations (retweets or links) [30], with a clear delineation of network synergy (Figures 3 and 4; Table 4), which support achievement as well as learning and sharing knowledge (A4CDP) and vertical and lateral structure operation (A6C). The centrality maps show a classic scale-free topology, with clear hubs for content and users arranged in a mesh topology, illustrating a vertical and horizontal arrangement in the Aveling construct.

The measures of weight based on hub and authority showed evidence of peer influence and online social mechanisms that influence peers and community members and create subcommunities (Figures 3 and 4); this suggests social control mechanisms (postulate A7CP) and, combined with the activity related to link and knowledge, suggests evidence of harnessing the power and collective wisdom of the community (A8P) as shown in the netnographic analysis in Multimedia Appendix 3. This describes the top 150 conversation threads and demonstrates the branching structure, each with up to 15 different users and as many as 8 branches. A very small number of conversations with very few participants would have challenged the postulate that users all have a contribution to make. We acknowledge our analysis of the #FOAMed community appears to show centralization around a few clusters of influence and not a completely distributed architecture. This appears to be related to coalescence of users around sources of knowledge and does imply that there are core users of the network as well as those at the periphery.

The primary aim of this research was to show preliminary evidence of the emergence of an oCoP from the FOAM movement represented by Twitter interactions that included the #FOAMed hashtag. The concept of CoP was introduced by Wenger [6] and describes the appearance of networks of people

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who interact explicitly, create and negotiate knowledge, and are able to translate this knowledge into a praxis. Our analysis indicates the possible emergence of a community, as evidenced by the large number of users, with a clear level of engagement and persistent participation across time. There was an exchange of information and ideas primarily through a microblogging format but nimbly cross-linking to platforms with more knowledge depth, such as blogs and media hubs (eg, YouTube and Vimeo). The community shows a topology similar to other mesh-organized networks, in particular high centrality hubs or users and content.

The main challenge of a digital community of people with little interaction in real life is translating the information, knowledge, and innovation into practice change [35]. However, the #FOAMed community is able to generate content, refine its applicability, and identify tailored and meaningful adaptations based on the information negotiated. This is evidenced in the sentiment analysis of the content, as well as the organization around specific links. It appears that some members of the group serve as knowledge gatekeepers without forcing the community's focus (demonstrated by the significance of the links and by the concentrated domains where information is stored and appraised). In terms of evidence of real-world application of the knowledge created, analysis of the content of the information suggests they are actionable concepts; however, a proof of application in real practice is difficult to obtain using an online analysis and is a limitation of this study. The conversations held in the forum of the comments sections of the most commonly shared blogs showed the social construct of testing, challenging, and contextualizing new knowledge, and they challenged assumptions of the different clinical practice areas of the contributors. These interactions ranged from affirmations agreeing that the new knowledge was practice changing, to instances of reflection that changes had been made with positive results. We observed a process of affirmation, contextualization to current or changed practice, and presentation of further evidence by way of linking to other primary or secondary literature on the discussed topic.

Limitations

A major limitation of our study is that the fine detail interlinking community practice has not been confirmed. This will require a different methodological approach, which is not possible in the scope of this study. Given the clear matching of the dataset to the a priori postulate, further more detailed work seems worthwhile.

Further limitations to this work include the inability to confirm alterations in day-to-day patient clinical outcomes by network participants. However, the size of the network and its continued expansion and evolution suggest engagement through an evidence hierarchy that reaches beyond perceived or reported benefit. We believe the main implication of this preliminary evidence of an oCoP is the possible adoption of this structure (ie, a decentralized, distributed, self-regulated, diverse, nonhierarchical network of users and knowledge) as a suitable, relatively cheap and powerful method for knowledge management in health care teams and institutions.

The emergence of an oCoP oriented toward collaboration and the creation, curation, appraisal, and dissemination of knowledge would be a paradigm change in medical education. The concept of education based on a CoP have been described previously [11], but its existence with regard to medical education has never been shown before, although theoretical benefits have been considered and anxiously anticipated [9,36], with some authors arguing that social learning may replace formal training [9].

Conclusion

The advent of a network devoted to knowledge translation constitutes a new frontier for health care education and knowledge management, with consequences that we are just beginning to understand. Our work shows that social media have been innovative in progressing medical education and that identification of oCoPs within social media may well be possible. This new framework of knowledge organization may appear as a new model for the management of information and users in a network-based health care system.

Acknowledgments

We received an unrestricted grant from Symplur (California, USA) for the use of the Symplur Signals [37] analytic engine. The grant was awarded as part of a research challenge sponsored by the Stanford Medicine X conference [38]. The sponsors had no role in the review or approval of the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Top 100 influencers in the #FOAMed community.

[PDF File (Adobe PDF File), 44KB - jmir_v19i7e252_app1.pdf]

Multimedia Appendix 2

Weighted network centrality metrics, based on mentions, hub, and authority quotients.

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[PDF File (Adobe PDF File), 25KB - jmir_v19i7e252_app2.pdf]

Multimedia Appendix 3

Top 150 conversations generated by the #FOAMed community.

[PDF File (Adobe PDF File), 169KB - jmir_v19i7e252_app3.pdf]

Multimedia Appendix 4

Top 100 links shared by the #FOAMed community.

[PDF File (Adobe PDF File), 26KB - jmir_v19i7e252_app4.pdf]

Multimedia Appendix 5

Netnographic evaluation of digital products from #FOAMed conversations.

[PDF File (Adobe PDF File), 27KB - jmir_v19i7e252_app5.pdf]

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Abbreviations

CoP: community of practice
FOAM: free open access medical education
oCoP: online community of practice

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Edited by A Keepanasseril; submitted 29.11.16; peer-reviewed by G Petrič, S Aggarwal; comments to author 24.01.17; revised version received 06.03.17; accepted 14.06.17; published 14.07.17.

Please cite as:
Roland D, Spurr J, Cabrera D
Preliminary Evidence for the Emergence of a Health Care Online Community of Practice: Using a Netnographic Framework for Twitter Hashtag Analytics
J Med Internet Res 2017;19(7):e252
URL: http://www.jmir.org/2017/7/e252/
doi:10.2196/jmir.7072
PMID:28710054

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Original Paper

Do Physicians Respond to Web-Based Patient Ratings? An Analysis of Physicians' Responses to More Than One Million Web-Based Ratings Over a Six-Year Period

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Abstract

Background: Physician-rating websites (PRWs) may lead to quality improvements in case they enable and establish a peer-to-peer communication between patients and physicians. Yet, we know little about whether and how physicians respond on the Web to patient ratings.

Objective: The objective of this study was to describe trends in physicians' Web-based responses to patient ratings over time, to identify what physician characteristics influence Web-based responses, and to examine the topics physicians are likely to respond to.

Methods: We analyzed physician responses to more than 1 million patient ratings displayed on the German PRW, jameda, from 2010 to 2015. Quantitative analysis contained chi-square analyses and the Mann-Whitney *U* test. Quantitative content techniques were applied to determine the topics physicians respond to based on a randomly selected sample of 600 Web-based ratings and corresponding physician responses.

Results: Overall, physicians responded to 1.58% (16,640/1,052,347) of all Web-based ratings, with an increasing trend over time from 0.70% (157/22,355) in 2010 to 1.88% (6377/339,919) in 2015. Web-based ratings that were responded to had significantly worse rating results than ratings that were not responded to (2.15 vs 1.74, $P<.001$). Physicians who respond on the Web to patient ratings differ significantly from nonresponders regarding several characteristics such as gender and patient recommendation results ($P<.001$ each). Regarding scaled-survey rating elements, physicians were most likely to respond to the waiting time within the practice (19.4%, 99/509) and the time spent with the patient (18.3%, 110/600). Almost one-third of topics in narrative comments were answered by the physicians (30.66%, 382/1246).

Conclusions: So far, only a minority of physicians have taken the chance to respond on the Web to patient ratings. This is likely because of (1) the low awareness of PRWs among physicians, (2) the fact that only a few PRWs enable physicians to respond on the Web to patient ratings, and (3) the lack of an active moderator to establish peer-to-peer communication. PRW providers should foster more frequent communication between the patient and the physician and encourage physicians to respond on the Web to patient ratings. Further research is needed to learn more about the motivation of physicians to respond or not respond to Web-based patient ratings.

(J Med Internet Res 2017;19(7):e275) doi:10.2196/jmir.7538

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KEYWORDS

Internet; online ratings; doctor-patient communication; public reporting; transparency

Introduction

Over the last decade, physician-rating websites (PRWs) have become a popular tool to create more transparency about the quality of doctors in the United States, Germany, England, the Netherlands, Australia, Norway, Canada, and other industrialized countries [1-5]. PRWs are designed similarly to websites in other areas such as travel (eg, TripAdvisor and HRS), shopping (eg, Amazon), and restaurants (eg, Zagat). Besides the possibility of searching on the Web for physicians, patients can scan other patients' reviews and also rate the received treatment. On PRWs, patients usually obtain structural information about a doctor's office and results from Web-based patient satisfaction surveys [6]. Regarding the popularity of PRWs, a recently published article reported that 65% of US consumers are aware of PRWs, and 36% have gone on the Web to seek ratings or reviews about physicians [7]. These numbers are similar to those from Germany [8,9] and exceed those from other countries such as England [3]. Further surveys have shown that 1 out of 20 Internet users in the United States, and 1 out of 9 Internet users in Germany, have already rated a physician on the Web [7,9].

Much of what is known about PRWs is related to the level of awareness and usage among patients [3,7,9,10], the number and distribution of available Web-based ratings [5,11-13], ethical principles [14], underlying satisfaction survey instruments [15], the content of narrative review comments about physicians [16-18], the type of publicly reported quality information [6], pros and cons of PRWs in general [19], the association of Web-based ratings with clinical measurements of care [1,5,20-23], as well as the impact of Web-based ratings on patient care [4,24]. So far, less research has focused on the perspective of doctors who are being rated on PRWs [25]. What we have learned so far is that general practitioners in the United Kingdom had reservations and concerns about being rated on the Web. They mostly question the validity, usability, and transparency of Web-based ratings, as well as the resulting impact of Web-based ratings on them, their professional practice, and their relationship with their patients [25]. Besides, a study from Germany has demonstrated that Web-based patient ratings have an impact on the behavior of physicians and may have the potential to improve patient care. Here, more than half of the physicians surveyed (54.66%) used Web-based ratings to determine measures to improve patient care [4]. The most widely implemented quality measures were related to communication with patients (28.77%), the appointment scheduling process (23.60%), and office workflow (21.23%). However, we know little about whether and how physicians respond on the Web to patient ratings on PRWs. Learning more about those physicians who respond on the Web to patient ratings might also be beneficial if we want to further increase the usage of PRWs [25].

It thus seems important to gain a scientific understanding of whether and how physicians respond on the Web to patient ratings on PRWs and about the characteristics of those physicians who respond on the Web to patient ratings. In this context, this paper adds to the literature by presenting an analysis of all physician responses to Web-based patient ratings on the most popular German PRW, jameda, from 2010 to 2015. The following paper is divided into two parts. Part I contains results of quantitative analysis (1) to describe trends in physicians' Web-based responses to patient ratings over time, and (2) to compare physicians who respond on the Web to patient ratings with nonresponders. In the second part (Part II), we used quantitative content analysis to evaluate a randomly selected sample of 600 Web-based ratings and corresponding physician responses from 2015 in detail. Based on those findings, we determined physician responses according to the topic and result of the Web-based patient rating.

Methods

Design and Data Source

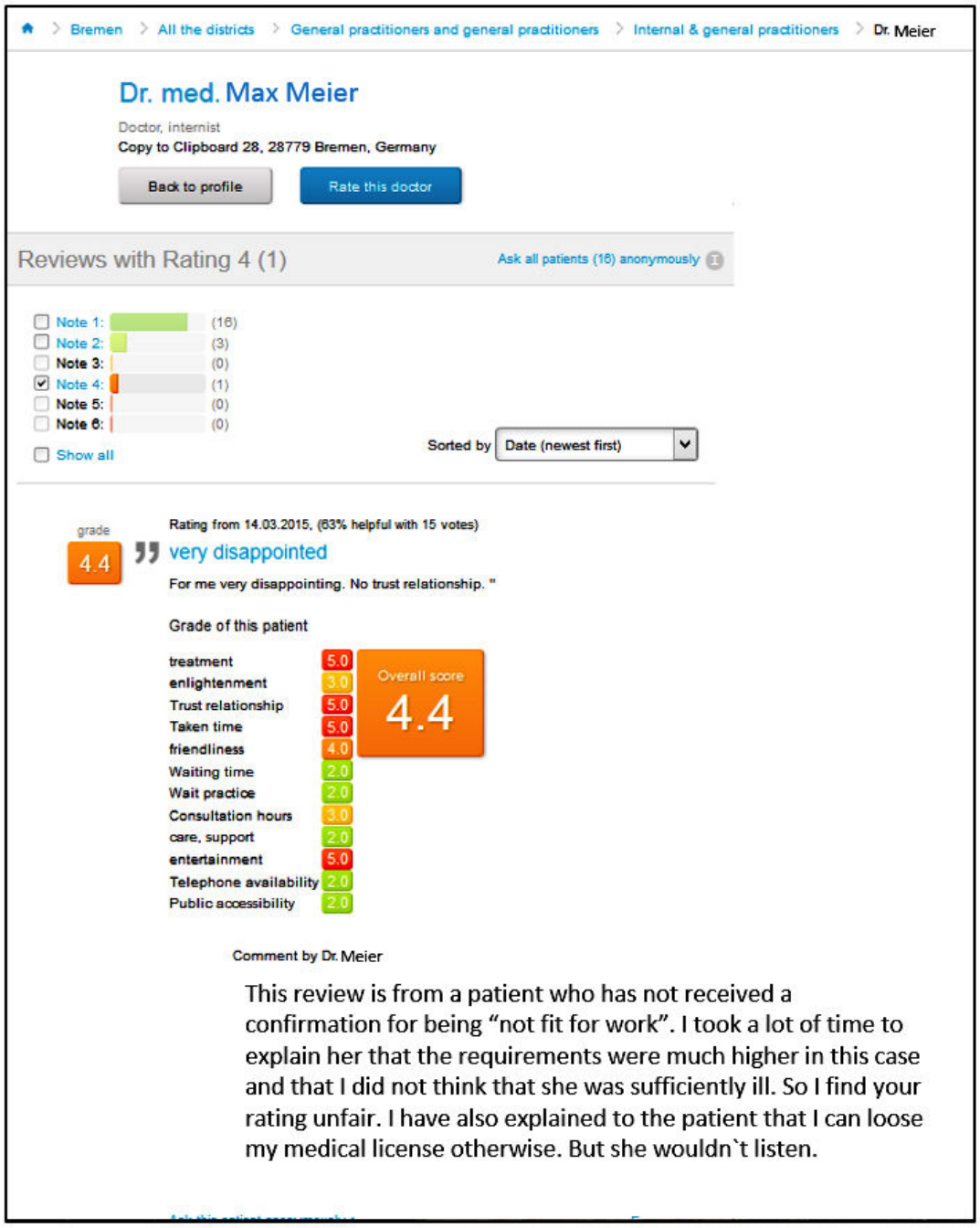
This paper presents an analysis of both patient ratings and physician responses, as well as physician responder characteristics displayed on the most popular German PRW, jameda, from 2010 to 2015. The mandatory rating system on jameda consists of 5 questions that have to be rated according to the grading system in German schools on a 1-6 scale (1=very good, 2=good, 3=satisfactory, 4=fair, 5=deficient, and 6=insufficient) [13]. These relate to (Q1) satisfaction with the treatment offered by the physician, (Q2) education about the illness and treatment, (Q3) the relationship of trust with the physician, (Q4) the time the physician spent on the patient's concerns, and (Q5) the friendliness of the physician. A mean score ("overall performance") is calculated afterwards, based on the results of these 5 questions. Beyond that, a narrative commentary must be given, and several optional questions are available for answering. Figure 1 displays an example of one physician response to a Web-based rating of a less-satisfied patient.

Data from the German PRW, jameda, from 2010 to 2015 were analyzed and contained slightly more than 1 million Web-based ratings and corresponding physician responses. The information included age, gender, and health insurance status of the patient, as well as the results of the physician ratings. Regarding the physician-related available data, the information included medical specialty and gender of the physician, the narrative response to the Web-based rating, the physicians' overall rating, the membership status (ie, whether any service products are booked that contain different tools; eg, to modify or highlight a physicians' profile [4]), the number of likes and site visits, as well as the percentage of how many patients would recommend the physician.

In our study, we analyzed both quantitative as well as qualitative data [26].

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Figure 1. An example of a physician response to Web-based rating of a less-satisfied patient on jameda.



Part I: Quantitative Analysis of Physicians' Web-Based Responses

Regarding quantitative analysis, we performed comparisons between two groups by using a chi-square test (two-sided) for categorical variables and a Mann-Whitney *U* test for continuous nonparametric variables. (The Shapiro-Wilk test was applied to examine the normality of the data distribution.) In addition, we used the Phi coefficient to calculate the effect size for categorical variables and the formula by Fritz et al [27] for continuous nonparametric variables. All statistical analyses were conducted using SPSS version 22.0 (IBM Corp). Interrater agreement between the 2 raters was assessed using Cohen kappa coefficient (weighted). Differences were considered to be significant if $P<.05$ and highly significant if $P<.001$.

Part II: Quantitative Content Analysis to Evaluate Physician Responses According to the Topic and Result of the Web-Based Patient Rating

Besides this, we used quantitative content analysis to determine the topics discussed in narrative patient comments [28] and topics physicians are most likely to respond to [29,30] based on previous evidence [16]. For this purpose, we analyzed a randomly selected sample of 600 Web-based ratings and corresponding physician responses from 2015. To assess differences between the 6 rating scores, we stratified the sample by rating score and collected 100 Web-based ratings and

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corresponding responses of each rating score. We applied an iterative process of both deductive and inductive steps for developing an all-embracing and disjunctive categorization framework that enabled us to capture the topics mentioned within the narrative comments and the physician responses. As a starting point, we used the categorization framework developed by Emmert and colleagues that distinguished between three main categories (ie, physician, office staff, and practice) and 50 subcategories (eg, patient involvement, communication, friendliness and caring attitude, information, and advice) [16]. This framework was extended in an iterative process; that is, new categories were added until a saturation of topics had been reached [31]. The final framework was pretested for 25 randomly selected pairs of narrative comments. Two of the authors independently carried out the assessment (n=450 for both coders, interrater agreement: 0.799; 95% CI 0.772-0.825).

Results

Part I: Quantitative Analysis of Physicians' Web-Based Responses

In the following, we (1) describe trends in physicians' Web-based responses to patient ratings over time and (2) compare physicians who respond on the Web to patient ratings with nonresponders. Table 1 shows the number of patient ratings and Web-based physician responses on the German PRW, jameda, from 2010 to 2015. Over the 6-year study period, slightly more than 1 million Web-based ratings were left for 142,948 rated physicians. The mean number of Web-based ratings per rated physician was calculated to be 7.36 (standard deviation [SD]=11.87; range 461) with a mean rating of 1.75 (SD=1.45; range 5). In total, 16,640 Web-based physician responses were left by 4187 physicians; in other words, physicians responded to 1.58% (16,640/1,052,347) of all Web-based ratings. Thereby, the percentage of Web-based ratings being responded to increased constantly over time from 0.70% (157/22,355) in 2010 to 1.88% (6377/339,919) in 2015. When regarding only those physicians who respond on the Web to patients' reviews, the mean number of Web-based responses was 3.97 responses per physician (SD=9.64; range 241). The mean rating of responded Web-based ratings was 2.15 (SD 1.66) and significantly worse than of nonresponded Web-based ratings (mean rating=1.74, SD=1.45; $P<.001$). In absolute terms, most responses were given to answer to more favorable ratings; that is, 69.53% (11,571/16,640) of all responses were related to favorable comments, 14.34% (2387/16,640) to neutral comments, and 16.12% (2682/16,640) to negative comments, respectively. In relative terms, most responses were related to ratings in the middle range of the rating scale (3.54%, 962/27,167 for satisfactory and 3.57%, 1425/39,875 for fair overall ratings, respectively) but not to the most or least favorable ratings.

Table 1. An overview of the number of patient ratings and physician responses on jameda from 2010 to 2015.

Overview of patient ratings and physician responses	Year	Overall rating result[a]						Overall
		1	2	3	4	5	6	
Web-based ratings, n								
	2010	16,939	1817	619	877	1339	764	22,355
	2011	39,591	3715	1455	1962	2890	1654	51,267
	2012	103,342	9582	3405	4841	7294	5725	134,189
	2013	159,250	15,212	5913	8426	13,367	11,058	213,226
	2014	218,520	20,160	7660	11,465	18,643	14,943	291,391
	2015	259,032	22,079	8115	12,304	20,702	17,687	339,919
	Total	796,674	72,565	27,167	39,875	64,235	51,831	1,052,347
Physician responses, n (%)								
	2010	87 (0.51)	10 (0.55)	17 (2.75)	14 (1.60)	21 (1.57)	8 (1.05)	157 (0.70)
	2011	200 (0.51)	23 (0.62)	49 (3.37)	40 (2.04)	43 (1.49)	23 (1.39)	378 (0.74)
	2012	809 (0.78)	83 (0.87)	80 (2.35)	110 (2.27)	166 (2.28)	77 (1.34)	1325 (0.99)
	2013	1979 (1.24)	193 (1.27)	217 (3.67)	311 (3.69)	376 (2.81)	202 (1.83)	3278 (1.54)
	2014	3327 (1.52)	294 (1.46)	276 (3.60)	434 (3.79)	526 (2.82)	268 (1.79)	5125 (1.76)
	2015	4176 (1.61)	390 (1.77)	323 (3.98)	516 (4.19)	645 (3.12)	327 (1.85)	6377 (1.88)
	Total	10,578 (1.33)	993 (1.37)	962 (3.54)	1425 (3.57)	1777 (2.77)	905 (1.75)	16,640 (1.58)

[a]German school-based rating system (1=very good, 2=good, 3=satisfactory, 4=fair, 5=deficient, and 6=insufficient).

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Table 2. A comparison of the responders and nonresponders of Web-based ratings on physician-rating websites (PRWs).

Characteristics	Responder (N=4187)	Nonresponder (N=138,761)	*P*-value[a,b]	Effect size
Gender (% female)	1035 (24.72)	51,615 (37.20)	<.001[a]	0.0431
Booked service package (% premium member)[c]	1652 (39.46)	5408 (3.90)	<.001[b]	0.2735
Web-based encounter scheduling tool (in %)[d]	332 (7.93)	853 (0.61)	<.001[a]	0.1325
Number of likes, mean (SD[e])	98.8 (261.3)	25.5 (46.9)	<001[b]	0.1850
Site visits (Web-based profile on jameda), mean (SD)	17,789.1 (28,979.7)	5297.1 (7,214.9)	<.001[b]	0.1699
Recommended by patients, mean (SD[e])	82.07 (17.10)	65.95 (34.97)	<.001[b]	0.0517
Overall Web-based rating (1-6 scale), mean (SD)	1.33 (0.47)	1.72 (0.98)	<.001[b]	0.0328

[a]Ch-square test (df=1 each).

[b]Mann-Whitney *U* test (Note: *P* values are adjusted for type 1 error by using the Holm-Bonferroni method).

[c]Service products contain different tools; for example to modify or highlight a physicians' profile [1]).

[d]Web-based encounter scheduling tools allow to book an appointment on the Web.

[e]SD: standard deviation.

As shown in Table 2, physicians who responded on the Web to patient ratings (2.93%, 4187/142,948) differ significantly from nonresponders (97.07%, 138,761/142,948) in several aspects; they could be shown to be less likely to be female (mean=24.72% vs mean=37.20%), are more likely to have booked both one premium package (mean=39.46% vs mean=3.90%) and a Web-based encounter scheduling tool on jameda (mean=7.93% vs mean=0.61%), have a higher number of likes (mean=98.8, SD=261.3 vs mean=25.5, SD=46.9) and site visits on jameda (mean=17,789, SD=28,980 vs mean=5297, SD=7215), as well as both better patient recommendation results (mean=82.07; SD=17.10 vs mean=65.95; SD=34.97) and overall Web-based ratings (mean=1.33, SD=0.47 vs mean=1.72, SD=0.98; *P*<.001 each). As presented, the effect size was small and ranged between 0.0328 and 0.2735, respectively.

Part II: Quantitative Content Analysis to Evaluate Physician Responses According to the Topic and Result of the Web-Based Patient Rating

Table 3 presents the number of patient ratings and physician responses to scaled-survey rating elements and narrative commentary, according to the topic and overall result of the patient rating, for a randomly selected sample of 600 Web-based ratings from 2015, which were equally distributed among the six overall rating result categories (ie, 100 ratings each). To leave a rating, patients had to rate numbers 1-5, whereas answering numbers 6-22 was optional. As shown for the scaled-survey mandatory rating topics (1-5), all 600 patients rated the friendliness and caring attitude of the physician. In addition, 268 patients described their experience of the friendliness and caring attitude of the physician in more detail using the narrative commentary. Here, every tenth physician (10.2%, 61/600) responded on the Web to this special aspect of the patient rating. The distribution of those 61 responses demonstrates that physicians were more likely to respond to lower patient ratings. For example, whereas approximately 20% of comments about the friendliness and caring attitude in negative ratings were responded to, this holds true only for 2% in very good ratings. In relative terms, most responses were given in answer to patient comments about the time spent with the patient (18.3%, 110/600). Again, physician responses were more likely for low ratings; for example, 28% of all 110 responses were given to ratings with an "insufficient" overall rating result.

With respect to the scaled-survey optional rating topics (6-22), the response rate varies between 0.4% (1/248) for patient ratings about additional treatment options and 19.4% for ratings concerning the waiting time within the practice (99/509). Regarding the latter, 498 patients used the scaled-survey rating system, and 142 patients provided additional information in the narrative commentary. As shown above, responses were more likely for lower ratings.

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Table 3. An overview of the number of patient ratings and physician responses on jameda according to the topic of the rating for a randomly selected sample of 600 Web-based ratings (2015), equally distributed among the six overall rating result categories (ie, 100 ratings each).

Rating elements	Category	Topic	Patient ratings overall (Scaled survey ratings or narrative comments)	Physician responses, n (%)	Physician response rate per overall rating result (%)					
					Very good	Good	Satisfactory	Fair	Deficient	Insufficient
Scaled-survey mandatory rating elements[a]										
1	Physician	Friendliness and caring attitude	600 (600/268)	61 (10.2)	2 (2.0)	4 (4.0)	12 (12.0)	5 (5.0)	17 (17.0)	21 (21.0)
2	Physician	Satisfaction with treatment	600 (600/224)	95 (15.8)	6 (6.0)	11 (11.0)	18 (18.0)	17 (17.0)	21 (21.0)	22 (22.0)
3	Physician	Time spent with the patient	600 (600/195)	110 (18.3)	9 (9.0)	19 (19.0)	20 (20.0)	13 (13.0)	21 (21.0)	28 (28.0)
4	Physician	Information and advice	600 (600/126)	73 (12.2)	6 (6.0)	6 (6.0)	15 (15.0)	8 (8.0)	17 (17.0)	21 (21.0)
5	Physician	Trust	600 (600/46)	31 (5.2)	4 (4.0)	4 (4.0)	3 (3.0)	10 (10.0)	6 (6.0)	4 (4.0)
Scaled-survey optional rating elements										
6	Physician	Availability (eg, by telephone and email)	418 (417/10)	5 (1.2)	1 (1.1)	1 (1.2)	1 (1.4)	1 (1.6)	1 (1.6)	0 (0.0)
7	Physician	Additional treatment options	275 (246/60)	39 (14.2)	2 (4.3)	6 (12.2)	12 (22.6)	4 (11.1)	8 (16.3)	7 (16.7)
8	Physician	Child-friendliness	207 (203/12)	8 (3.9)	0 (0.0)	2 (5.3)	0 (0.0)	2 (6.1)	2 (7.1)	2 (6.3)
9	Office staff	Service or assistance	466 (463/38)	8 (1.7)	3 (3.3)	1 (1.2)	2 (2.4)	0 (0.0)	1 (1.3)	1 (1.4)
10	Office staff	Availability (eg, by telephone and email)	417 (417/1)	2 (0.5)	1 (1.1)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
11	Office staff	Additional treatment options	248 (246/3)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.1)	0 (0.0)	0 (0.0)
12	Office staff	Child-friendliness	203 (203/3)	2 (1.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (3.6)	0 (0.0)
13	Practice	Waiting time within the practice	509 (498/142)	99 (19.4)	6 (6.5)	25 (27.5)	13 (15.1)	19 (22.9)	21 (25.9)	15 (19.7)
14	Practice	Waiting time to get an appointment	500 (490/86)	51 (10.2)	3 (3.2)	12 (13.3)	5 (5.8)	13 (15.9)	11 (14.3)	7 (10.0)
15	Practice	Consultation hours	447 (446/5)	10 (2.2)	1 (1.2)	3 (3.8)	1 (1.3)	0 (0.0)	2 (2.8)	3 (4.8)
16	Practice	Entertainment	423 (423/12)	15 (3.6)	1 (1.3)	7 (8.6)	2 (2.8)	2 (3.3)	3 (4.4)	0 (0.0)
17	Practice	Availability (eg, by telephone and email)	421 (417/16)	13 (3.1)	5 (5.6)	4 (4.9)	1 (1.3)	3 (4.9)	0 (0.0)	0 (0.0)
18	Practice	Practice equipment	407 (404/40)	14 (3.4)	3 (3.5)	1 (1.3)	2 (2.7)	2 (3.1)	3 (5.4)	3 (6.1)

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Rating elements	Category	Topic	Patient ratings overall (Scaled survey ratings or narrative comments)	Physician responses, n (%)	Physician response rate per overall rating result (%)					
					Very good	Good	Satisfactory	Fair	Deficient	Insufficient
19	Practice	Parking spaces	386 (386/7)	34 (8.8)	11 (14.1)	8 (11.6)	5 (6.8)	4 (7.5)	4 (7.1)	2 (3.6)
20	Practice	Accessibility by public transport	346 (346/0)	8 (2.3)	2 (3.2)	0 (0.0)	3 (5.3)	0 (0.0)	2 (3.8)	1 (2.0)
21	Practice	Barrier-free access	272 (272/4)	9 (3.3)	3 (5.1)	1 (1.9)	2 (4.0)	1 (2.8)	1 (2.7)	1 (2.8)
22	Practice	Child-friendly environment	203 (203/3)	6 (3.0)	1 (2.7)	1 (2.7)	2 (5.3)	2 (6.3)	0 (0.0)	0 (0.0)

[a]The rating system on jameda consists of 5 mandatory questions, rated according to the grading system in German schools on a 1-6 scale (1=very good, 2=good, 3=satisfactory, 4=fair, 5=deficient, and 6=insufficient). These relate to Nr. 1-5. A mean score ("overall rating") is calculated based on the results of these 5 questions. In addition, several optional questions are available for answering. Beyond that, a narrative commentary has to be given for every rating.

Table 4 presents the three categories (ie, physician, office staff, and practice) and all 29 corresponding topics that could be derived from the analysis of the 600 narrative comments, as well as from corresponding physician responses. The 600 narrative comments contained 1246 topics, of which most were related to physician (73.76%, 919/1246); in addition, 214 (17.17%, 214/1246) narrative comments contained information about the office staff, and 113 (9.07%, 113/1246) about the practice, respectively. Overall, almost one-third of commented topics were responded to by the physicians (30.66%, 382/1246). Thereby, the response rate varied between 20.6% (44/214) for office staff-related comments and 33.1% (304/919) for physician-related comments, respectively. As displayed, a recommendation for or against consulting a particular physician was given in slightly more than one-third of all narrative comments (35.2%, 211/600), which were answered by approximately every ninth physician (11.9%, 25/211). The second most frequently mentioned topic was an assessment of the professional competence of the physician (28.5%, 171/600). Here, approximately every fifth physician responded to those narrative comment elements (19.9%, 34/177). Higher response rates for more frequently mentioned topics were determined when patients wrote about their medical history; here, almost 4 out of 5 physicians (77.4%, 72/93) responded to the patients' narrative. Similarly, narrative comments that contained information about treatment costs were answered by 69.4% (29/43) of all physicians.

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Table 4. An overview of the content of narrative comments, ratings and physician responses on jameda for a randomly selected sample of 600 Web-based ratings (2015), equally distributed among the six overall rating result categories (ie, 100 ratings each).

Number	Category	Topic	Appearances in narrative comments, n (%)	Physician responses, n (%)	Physician response rate per overall rating result (%)					
					Very good	Good	Satisfactory	Fair	Deficient	Insufficient
1	Physician	Recommendation of the physician	211 (35.2)	25 (11.9)	1 (2.4)	2 (10.0)	5 (21.7)	5 (16.7)	6 (12.8)	6 (12.0)
2	Physician	Professional competence	171 (28.5)	34 (19.9)	4 (6.2)	5 (13.2)	7 (24.1)	3 (17.7)	8 (61.5)	7 (77.8)
3	Physician	Overall assessment	121 (20.2)	13 (10.7)	3 (10.3)	1 (4.0)	4 (15.4)	3 (21.4)	1 (6.7)	1 (8.3)
4	Physician	Patient history	93 (15.5)	72 (77.4)	2 (11.1)	5 (100.0)	12 (100.0)	21 (100.0)	19 (100.0)	13 (72.2)
5	Physician	Revenue orientation	73 (12.2)	32 (43.8)	0 (0.0)	3 (33.3)	4 (30.8)	12 (57.1)	4 (36.4)	9 (56.3)
6	Physician	Patient involvement	58 (9.7)	25 (43.1)	1 (10.0)	1 (9.1)	1 (50.0)	10 (83.3)	3 (27.3)	9 (75.0)
7	Physician	Atmosphere	50 (8.3)	20 (40.0)	7 (33.3)	2 (25.0)	2 (33.3)	3 (50.0)	5 (83.3)	1 (33.3)
8	Physician	Treatment cost	43 (7.2)	29 (67.4)	N/A	3 (60.0)	8 (61.5)	6 (54.6)	4 (66.7)	8 (100.0)
9	Physician	SHI[a]-PHI[b]-differentiation	41 (6.8)	25 (61.0)	4 (44.4)	7 (70.0)	1 (25.0)	5 (83.3)	3 (60.0)	5 (71.4)
10	Physician	Being taken seriously	30 (5.0)	5 (16.7)	0 (0.0)	0 (0.0)	2 (100.0)	2 (33.3)	0 (0.0)	1 (14.3)
11	Physician	Communication	16 (2.7)	14 (87.5)	N/A	4 (80.0)	3 (100.0)	1 (100.0)	4 (66.7)	2 (100.0)
12	Physician	Cooperation with medical specialists	7 (1.2)	5 (71.4)	2 (66.7)	0 (0.0)	N/A	2 (100.0)	N/A	1 (100.0)
13	Physician	Privacy	3 (0.5)	3 (100.0)	N/A	N/A	1 (100.0)	N/A	N/A	2 (100.0)
14	Physician	Additional information or advertisement	2 (0.3)	2 (100.0)	N/A	N/A	1 (100.0)	1 (100.0)	N/A	N/A
15	Office staff	Friendliness of the office staff	155 (25.8)	31 (20.0)	4 (10.3)	6 (14.0)	4 (18.2)	5 (27.8)	6 (35.3)	6 (37.5)
16	Office staff	Overall assessment	28 (4.7)	7 (25.0)	2 (33.3)	2 (33.3)	2 (25.0)	0 (0.0)	0 (0.0)	1 (50.0)
17	Office staff	Information and advice	9 (1.5)	2 (22.2)	1 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)
18	Office staff	Privacy	8 (1.3)	4 (50.0)	0 (0.0)	1 (100.0)	2 (50.0)	1 (100.0)	N/A	N/A
19	Office staff	Recommendation	5 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	N/A	N/A	N/A	N/A
20	Office staff	Atmosphere	4 (0.7)	0 (0.0)	0 (0.0)	N/A	N/A	N/A	N/A	N/A
21	Office staff	Time spent with the patient	4 (0.7)	0 (0.0)	N/A	0 (0.0)	0 (0.0)	N/A	N/A	N/A
22	Office staff	Trust	1 (0.2)	0 (0.0)	0 (0.0)	N/A	N/A	N/A	N/A	N/A
23	Practice	Office organization	38 (6.3)	27 (71.1)	2 (50.0)	7 (77.8)	5 (71.4)	4 (50.0)	4 (100.0)	5 (83.3)
24	Practice	Atmosphere	26 (4.3)	5 (19.2)	4 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3)
25	Practice	Overall assessment	26 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	N/A	0 (0.0)	0 (0.0)

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Number	Category	Topic	Appearances in narrative comments, n (%)	Physician responses, n (%)	Physician response rate per overall rating result (%)					
					Very good	Good	Satisfactory	Fair	Deficient	Insufficient
26	Practice	Recommendation	17 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	N/A	N/A	0 (0.0)
27	Practice	Privacy	4 (0.7)	1 (25.0)	N/A	1 (50.0)	N/A	0 (0.0)	N/A	0 (0.0)
28	Practice	SHI-PHI-differentiation in practice equipment	1 (0.2)	0 (0.0)	N/A	N/A	N/A	0 (0.0)	N/A	N/A
29	Practice	Connection to medical infrastructure	1 (0.2)	1 (100.0)	0 (0.0)	N/A	N/A	N/A	N/A	N/A

[a]SHI: statutory health insurance.

[b]PHI: private health insurance (eg, different waiting rooms and more service comfort for privately insured patients).

Discussion

Principal Findings

Physician-rating websites (PRWs) may lead to quality improvements in case they enable and establish a peer-to-peer communication between patients and physicians [19]. Whereas most research has addressed the perspective of rating patients (mentioned previously), less research has focused on the perspective of physicians who are being rated on PRWs [25]. So far, we know little about whether and how physicians respond on the Web to patient ratings. Therefore, the aim of this study was to describe trends in physicians' Web-based responses to patient ratings over time, to identify what physician characteristics influence Web-based responses, and to examine the topics physicians are likely to respond to. To the best of our knowledge, this is the first study adding knowledge in this regard by presenting the results of a comprehensive analysis based on patient ratings and physician responses displayed on the German PRW, jameda, from 2010 to 2015. As a result, we could show that physicians have responded to less than 2% of all Web-based ratings (1.58%, 16,640/1,052,347). Moreover, less than 3% of all rated physicians have responded on the Web to patient ratings (2.93%, 4187/142,948). Those numbers demonstrate that a Web-based peer-to-peer communication between patients and physicians on such platforms has not been reached [11]. In contrast, further steps seem to be necessary to both enable and further establish such a communication between patients and physicians.

Several requirements need to be satisfied in order to achieve a peer-to-peer communication system between patients and physicians on such websites [1,32-35]. To the best of our knowledge, no such requirements have been discussed in the literature. However, we discuss some requirements as an initial step in the following. First, PRWs must provide the infrastructure for such a dialogue among users [19,32-34]. The results presented in this paper were based on Web-based ratings and corresponding physician responses from the leading German PRW, jameda. However, it is important to mention that jameda is currently the only PRW on which physicians communicate on the Web with patients in a more or less significant manner (ie, in 2015, physicians still responded to less than 2% of all Web-based ratings). To get a more in-depth understanding of the opportunity and current numbers of physician responses to Web-based ratings, we analyzed the 12 most important PRWs in Germany (not presented here in detail). On 5 of those, physicians do not even have the opportunity to respond on the Web to patient ratings. The remaining 6 PRWs have incorporated this option, but we did not find a single physician response here for a randomly selected sample of 400 orthopedic doctors across Germany on any PRW. This additional analysis demonstrates the need to enhance the options for physicians to comment on their patient ratings by providing the relevant infrastructure on those rating websites.

It also seems important that physicians are made aware of the existence of PRWs and make good use of them [4,19]. As shown recently for a sample of 828 physicians affiliated with one of four hospitals in a large accountable care organization in eastern Massachusetts, 53% of those surveyed reported visiting a PRW at least once. Here, a decreasing age, having ambulatory clinical time, and practicing in a surgical specialty or obstetrics or gynecology was associated with visiting a website [36]. Another study from Germany has demonstrated that 67.08% of a survey sample of 2360 outpatient physicians has stated that they use PRWs at least once per month. Only a minority of those who are aware of PRWs stated that they never use them (5.81%, 137/2360) [4]. Even though those numbers appear to confirm the awareness of PRWs among physicians, they are likely to overestimate the real level awareness of physicians in the outpatient sector in both countries. For example, the German sample comprised of health care providers who have either subscribed to a monthly newsletter on jameda or booked a jameda service product. This means that physicians who are less interested in Web-based topics (eg, those without a practice website), or PRWs in general, are less likely to be represented by those results [4]. Nevertheless, the numbers in general seem to indicate that not only patients [3,7,9] but also physicians have become more aware of the PRW movement.

Furthermore, it seems important to gain a better understanding of the purposes for which physicians use PRWs and respond to Web-based ratings [4,36]. So far, little research has addressed those questions. What we know from one German study is that the main reason for using PRWs is to read Web-based ratings

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for their own practice; here, almost 9 out of 10 physicians (87.08%, 2055/2360) confirmed this to be the main driver for using PRWs [4]. Other important reasons given were to read the ratings of other physicians because of interest (48.69%, 1149/2360) and for marketing purposes (33.26%, 785/2360). Only slightly more than every fourth physician stated they comment on their own ratings (27.80%, 656/2360), confirming the low numbers of Web-based responses to Web-based ratings from the study presented in this paper.

In this context, we could show that 142,948 physicians have been rated on jameda over the 6-year study period from 2010 to 2015. Compared with the overall number of physicians in the outpatient sector (N=157,720 [37]) and dentists (N=52,295 [38]) in Germany in 2015, this means that almost 7 out of 10 physicians have been rated so far (68.07%, 142,948/210,015). The result from this study, that is, that only 3% (4187/142,948) of all rated physicians have responded on the Web to their patient ratings and from our additional analysis for a randomly selected sample of 400 orthopedic doctors across Germany on 6 further German PRWs (see above), emphasizes the need to encourage more physicians to respond to Web-based ratings if we want to establish peer-to-peer communication among users on such platforms [11]. Therefore, PRW providers should take action to foster a more frequent communication process between the patient and the rated physician. This could be realized by the providers of PRWs by taking over a more active role as a moderator between the patient and the physician [19]. For example, PRWs providers should inform rated physicians on a regular basis (eg, monthly) about Web-based patient ratings and enable them to respond to those ratings in an easy manner. Only then could a feedback loop be generated between patients and providers that would create value for both patients and providers.

So far, we know little about why physicians respond or do not respond to Web-based patient ratings. Our analysis has demonstrated that most responses were related to ratings in the middle or lower range of the rating scale. One likely reason is that physicians try to express their point-of-view and explain what consequences the rating will have on the daily practice. For example, Hardey states one example of how a hospital responded to one patient who complained about the friendliness of one doctor and the incomprehensibility of another doctors' explanation. Referring to this comment, the hospital responded: "Thank you very much for your kind comments particularly regarding Brendan. We have forwarded your comments onto him. However, we were very sorry to read of your experience of the communication with some of our medical staff and we have raised this with the clinical lead of Orthopaedics and A&E to raise with the medical teams. We are glad however that your overall experience was good and the nursing staff supported you"[32]. Such a mechanism might increase the usefulness for both patients and physicians since it becomes possible to understand the concern and the reason for the positive or negative evaluation, as well as the perspective of the rated physician. However, physicians might try to learn from the patient comments in the first place so as to avoid negative patient reviews. In this regard, a comprehensive meta-analysis by de Matos and colleagues has shown that services providers (such as physicians and hospitals) should make every effort to provide services correctly on the first time, rather than permitting failures and then trying to respond with superior recovery [39]. Nevertheless, we still know very little about the motivation of physicians to respond or not respond to Web-based patient ratings. Future research should elaborate on this issue more in detail.

Limitations

There are some limitations that must be taken into account when interpreting the results of this investigation. First, we analyzed the frequency and content of patient ratings and corresponding physician responses from only one rating website. Although jameda has been shown to be the most frequently used German PRW [4], it is possible that the analysis of other PRWs would have resulted in other findings. However, as stated above, other PRWs are very likely to contain a far lower number of physician responses to Web-based ratings. Second, the quantitative content analysis contained 600 narrative comments that were equally distributed among the six overall rating result categories (ie, 100 ratings each). This means that those results are not likely to represent the real distribution of comments on PRWs. Finally, we did not discuss the level of disagreement between the patient rating and the physician response.

Conclusions

So far, only a minority of physicians have taken the chance to respond on the Web to patient ratings on the leading German PRW, jameda. This demonstrates that the goal of establishing a Web-based peer-to-peer communication between patients and physicians on such platforms has not been reached [11]. This is likely because of (1) the still-low awareness of physicians of PRWs, (2) the fact that only few PRWs provide the infrastructure for physicians to respond on the Web to patient ratings, and (3) the lack of an active moderator to foster peer-to-peer communication between the patient and the physician. If we want a feedback loop to be generated between patients and health care providers that creates value for both the patients and the providers, health policy makers should implement measures to encourage physicians to respond on the Web to patient ratings. Further research is needed to learn more about the motivation of physicians to respond or not respond to Web-based patient ratings.

Acknowledgments

The authors would like to thank the provider of the PRW, jameda, for the provision of the data. There was no funding reported for this study.

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Conflicts of Interest

None declared.

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Abbreviations

PRW: physician-rating website
SD: standard deviation

Edited by G Eysenbach; submitted 20.02.17; peer-reviewed by F Rothenfluh, S Bidmon; comments to author 09.03.17; revised version received 21.03.17; accepted 02.06.17; published 26.07.17.

Please cite as:
Emmert M, Sauter L, Jablonski L, Sander U, Taheri-Zadeh F
Do Physicians Respond to Web-Based Patient Ratings? An Analysis of Physicians' Responses to More Than One Million Web-Based Ratings Over a Six-Year Period
J Med Internet Res 2017;19(7):e275
URL: http://www.jmir.org/2017/7/e275/
doi:10.2196/jmir.7538
PMID:28747292

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Original Paper

Studying Scale-Up and Spread as Social Practice: Theoretical Introduction and Empirical Case Study

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Abstract

Background: Health and care technologies often succeed on a small scale but fail to achieve widespread use (scale-up) or become routine practice in other settings (spread). One reason for this is under-theorization of the process of scale-up and spread, for which a potentially fruitful theoretical approach is to consider the adoption and use of technologies as social practices.

Objective: This study aimed to use an in-depth case study of assisted living to explore the feasibility and usefulness of a social practice approach to explaining the scale-up of an assisted-living technology across a local system of health and social care.

Methods: This was an individual case study of the implementation of a Global Positioning System (GPS) "geo-fence" for a person living with dementia, nested in a much wider program of ethnographic research and organizational case study of technology implementation across health and social care (Studies in Co-creating Assisted Living Solutions [SCALS] in the United Kingdom). A layered sociological analysis included micro-level data on the index case, meso-level data on the organization, and macro-level data on the wider social, technological, economic, and political context. Data (interviews, ethnographic notes, and documents) were analyzed and synthesized using structuration theory.

Results: A social practice lens enabled the uptake of the GPS technology to be studied in the context of what human actors found salient, meaningful, ethical, legal, materially possible, and professionally or culturally appropriate in particular social situations. Data extracts were used to illustrate three exemplar findings. First, professional practice is (and probably always will be) oriented not to "implementing technologies" but to providing excellent, ethical care to sick and vulnerable individuals. Second, in order to "work," health and care technologies rely heavily on human relationships and situated knowledge. Third, such technologies do not just need to be adopted by individuals; they need to be incorporated into personal habits and collaborative routines (both lay and professional).

Conclusions: Health and care technologies need to be embedded within sociotechnical networks and made to work through situated knowledge, personal habits, and collaborative routines. A technology that "works" for one individual in a particular set of circumstances is unlikely to work in the same way for another in a different set of circumstances. We recommend the further study of social practices and the application of co-design principles. However, our findings suggest that even if this occurs, the scale-up and spread of many health and care technologies will be neither rapid nor smooth.

(J Med Internet Res 2017;19(7):e244) doi:10.2196/jmir.7482

KEYWORDS

sociology; medical; technological innovations; telemedicine; health policy; mHealth

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Introduction

Background

Increasing the uptake of digital health and care technologies is a policy priority around the world. For example, in the United States, the Agency for Healthcare Research and Quality is promoting an ongoing program of research grants intended to rapidly advance the spread and scale-up of health information technologies [1]. In the United Kingdom, a reimbursement program was announced in 2016 to support "medtech innovations" intended to "help cut the hassle experienced by clinicians and innovators in getting uptake and spread across the NHS" [2]. These new policy programs are based on the assumption that if a health technology has been demonstrated as effective and cost saving (sometimes merely on the anticipation of efficacy and efficiency), then its widespread adoption should be supported across the system as a whole. Such initiatives reflect a push to improve the spread and scale-up of service innovations in health and care systems more generally [3-6].

Theories of Social Practice: An Overview

Attempts to scale up (increase local usage) and spread (extend usage to new localities and settings) health technologies often prove more difficult than anticipated [7,8]. Previous systematic reviews by us [9,10] and others [11-16] have documented the multiple interacting influences that affect the diffusion and spread of innovations (including technologies) in health care and depicted these as operating at multiple levels in a complex system. In earlier field work, we developed a set of methodologies for combining detailed ethnographic studies of the intended technology user with an analysis of the meso (organizational) and macro (eg, policy) context to begin to theorize both the successes and failures of technology implementation efforts [17-23]. These previous studies by our own team, which covered remote booking services, electronic patient records, repeat prescribing systems, personal health organizers, and home-based assisted living, focused on the detailed study of human action in organizational and wider social contexts and prompted us to develop a new theoretical framework that drew on both structuration theory and actor-network theory [23]. Other researchers have used normalization process theory [6,8,24], actor-network theory [25,26], cultural-historical activity theory [27], technological sensemaking [28], technology structuration theory [29], socio-technical systems theory [30], or simply "practice theory" [31,32] to conduct similar studies of technology-related action in a health care context.

Table 1. Overview of theories of social practice.

Theory	Overview
(Cultural-historical) activity theory	It focuses on an object of activity, that is, the aim toward which people work collectively to meet an identified need. The notion of an object of activity encapsulates the mutual motivation around which people from different backgrounds come together in the workplace in more or less stable groupings. Knowledge is seen as intimately tied to practice rather than as a "commodity" to be "transferred."
Sociotechnical systems theory	It proposes that introducing technologies in an organization is a social process that depends on values, mindsets, and engagement. It is also an evolutionary process (sociotechnical systems are grown, not built), hence best achieved by early and active input of front-line workers into the design of redesign of work routines. Sociotechnical systems theory informed early work on human-computer interaction, workplace ergonomics, and human factors engineering.
Structuration theory	It brings together the notion of an external social reality (aspects of context that exist independently of individual actors, such as the economy, the law, and professional codes of conduct) and that of a subjective reality (individuals' interpretations and perceptions of reality); it views these as reciprocally linked and mutually reinforcing and is centrally interested in the dynamic between structure (external reality) and agency (individual action and judgment).
Actor-network theory	It considers networks of both people and technologies, known as "actor-networks." They are often highly dynamic and inherently unstable. They can be stabilized to some extent when people, technologies, roles, routines, training, incentives, and so on are aligned. This alignment is achieved (or at least, attempted) through "translation," which involves the four stages of problematization (defining a problem for which a particular technology is a solution), interessement (getting others to accept this problem-solution), enrolment (defining the key roles and practices in the network), and mobilization (engaging others in fulfilling the roles, undertaking the practices, and linking with others in the network).
Technological sensemaking	It proposes that that technologies introduced into organizations are open to different interpretations. Sense-making—in which members negotiate the meaning of the technology, how it should or might be used in particular contexts, and what benefits and hazards it could bring—is crucial for successful implementation.
Normalization process theory	It depicts the uptake and routinization of technology in health care organizations as generated through four mechanisms: coherence (users coming to understand and make sense of the technology), cognitive participation (users building a community of practice around the use of the technology), collective action (users collaboratively developing and embedding new work routines), and reflexive monitoring (users agreeing on and implementing measures to evaluate program success).

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Table 2. Origins of, and comparisons between, different theories of social practice.

Theory	Original publication	Country of origin	Disciplinary roots	Emphasis
Activity theory	Leont'ev 1904 (translated 1979) [38]	Russia	Social psychology	Relationship of workers to their shared activity (linked originally to Marxist philosophy of work)
Socio-technical systems theory	Cherns 1976 [36] (updated 1987) [37]	United Kingdom	Social psychology	Design of effective and efficient work processes with goal of non-stressed workers
Habitus and practice theory	Bourdieu 1977 [39]	France	Anthropology and sociology	Theoretical analysis of how human agents' dispositions and knowledge are reciprocally shaped by external social structures
Post-structural practice theory	Foucault (1979) [40]	France	History and philosophy	Role of discourses and their impact on the body; creation of individual subjects through discursive historical patterns of practice
Structuration theory	Giddens 1984 [41]	United Kingdom	Sociology	Theoretical analysis (drawing on Bourdieu) of the relationship between social structures and human agency
Actor-network theory	Callon & Latour 1986 [42]	France	Philosophy	Explaining how humans and technologies are linked in dynamic and often unstable networks, and what emerges from these networks
Technological sense-making	Weick 1990 [43]	United States	Organizational sociology	Explaining how workers make sense of technologies in the workplace and negotiate their (changing) meaning as they work to implement them
Technology structuration theory	Barley 1986 [44] and Orlikowski 1992 [45]	United States	Information systems	Explaining the contingency and unpredictability of technology implementation in organizations
Adaptive structuration theory	DeSanctis and Poole 1994 [46]	United States	Organizational sociology	Explaining the contingency and unpredictability of technology implementation in organizations
Contemporary practice theory	Schatzki 1996 [47], Shove 2012 [48]	United States and United Kingdom	Sociology and anthropology	Human experience within fields of practice; interaction between material and social elements of everyday life
Strong structuration theory	Stones 2005 [49]	United Kingdom	Sociology	Detailed empirical methodology for applying Giddens' structuration theory to study social change
Normalization process theory	May 2006 [50]	United Kingdom	Sociology	Explaining why technologies do or do not become routinized in the workplace
Strong structuration theory adapted for technology	Greenhalgh and Stones 2010 [23]	United Kingdom	Sociology	Explaining technology adoption (and non-adoption) by considering the situated actions of humans within wider sociotechnical networks

All these approaches are, broadly speaking, theories of social practice (Table 1). Whilst their specific emphasis differs (Table 2), they have in common a focus on individual actions and judgments in context. They hold that human agency (ie, what people do) is based on both their general prior knowledge and their situated local judgments about the meaning of particular technologies and particular actions, taking account of the contingent and material features of context. "Context" is differently defined by different scholars [8,10,33,34] but, broadly speaking, it includes both local and more distant social, political, economic, and technical influences, including "scripts" (patterns of how we might be expected to behave), professional and cultural norms (what is viewed as morally correct), as well as laws, regulations, and availability of resources. The purpose of this paper is to provide an overview of theories of social practice and to illustrate their value in understanding efforts to achieve spread and scale of health and care technologies through a single case example of the adoption of a Global Positioning System (GPS) tracking device for people living with dementia.

All theories of social practice view human agency and context as reciprocally interacting and evolving dynamically over time. Different theories have different disciplinary roots, emerged in different countries, and emphasize different aspects of human agency, context, technology, and the dynamic interaction between them (Table 2). There has been much cross-fertilization over the years. For example, the contemporary science of human factors design, which is largely based in the United States and led by engineers [35] draws heavily on earlier work from British organizational psychologists on socio-technical systems theory [36,37].

Despite the differences in theoretical emphasis (Table 2), this empirical work by ourselves and others on technology uptake from a social practice perspective has produced a striking common finding: sustained use of a technology in a healthcare environment appears to be critically dependent on the situated (that is, locally contingent) actions and judgments of technology end-users, and these actions and judgments are in turn directly influenced by local contextual factors and indirectly influenced by more distant ones.

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Theories of Social Practice in Health Care

The actions of human actors in a healthcare setting are not merely "behaviors" that can be analyzed in isolation from the context in which they occur. Rather, these actions have social meaning and (sometimes) moral significance. Furthermore, they are both shaped and constrained by the material affordances of technologies, which are influenced by such things as technical standards and the assumptions that have been built into technologies as scripts (for example the technology designer may assume that a doctor may give an instruction and a nurse carry it out—a naïve and outdated view of inter-professional teamwork but one that would be scripted into the technology) and access privileges (for example, that administrative staff need not have access to the clinical aspects of a patient's record). Similarly, *inaction* ("resistance" to technology use) may also be socially, morally and even politically significant and/or materially constrained in socially determined ways. In the study reported here, we applied a social practice lens to explore the different kinds of contextualized social practices on which the scale-up and spread of health technologies depends.

An example of a social practice contributing to technology uptake is the different ways in which people interact with their friends and families via social media apps on their mobile devices. This particular practice carries *meanings related to the evolving role of mobile devices* in our everyday lives, only exists within the *context of the growing penetration of mobile devices* in the global population, and *reproduces assumptions and patterns* of appropriate ways to interact with friends and family (and the appropriate use of these of mobile devices in public places). The rapid spread and scale-up of personal use of such technologies is made possible by the affordability of social media apps (many are free to download), their widespread interoperability with existing platforms, and the lack of legal or regulatory barriers.

By contrast, the use of mobile apps by health care professionals in the context of delivering care is heavily constrained by the prevailing legal and regulatory context and may require changes to the professional scope of practice and/or codes of conduct. The question of whether medical apps should be formally appraised, approved, and regulated for safety reasons has been much debated recently [51]. The United States Food and Drug Administration [52], European Commission, [53] and United Kingdom Medicines and Healthcare Devices Regulatory Agency [54] have attempted to do so (with partial success), but the field remains contested and progress in introducing apps into routine clinical practice remains extremely slow [55]. In short, the social practice of using an app *in the context of health care work* is influenced by a host of both local and more distant contextual issues.

The same can be said for other technologies. Empirical studies adopting a social practice perspective have focused largely on the proximal elements of context, that is, the immediate organizational and material factors that shape and constrain practice. However, these approaches have huge potential to also consider more distal and indirect social, technological, political, and regulatory influences on the practices upon which spread and scale-up of digital health and care technologies depend. Many of the identified barriers to technology uptake operate at what might be called the "macro" level of national policy, regulation, the economic value chain, arrangements for contracting and reimbursement, and other system-level structures [7].

It follows that instead of focusing solely or predominantly on individuals and groups within local organizations, researchers might better spend their time trying to understand the dimensions of entire "fields of practice" (eg, entire health systems) in which implementation initiatives are taking place. An empirical example of this is our study of why primary care clinicians "resisted" the introduction of an electronic booking service for outpatient referrals and were not amenable to crude behaviorist incentive schemes: their reluctance was traceable to deep-seated opposition to a policy of introducing overt competition between secondary care providers (which they considered to be at odds with their professional code of conduct) [22]. Arguably, it is these broader fields of practice that are most relevant for the scale-up and (especially) spread of health technologies, though the immediate local context is also often the key.

Objective and Research Questions

To illustrate how a social practice approach can allow analysis of both proximal and distal contextual influences on spread and scale-up, we describe an example of the implementation of a care technology—a Global Positioning System (GPS) "geo-fence" for people with dementia. Drawing on the real-life case of 76-year-old Rahim (pseudonym)—a Pakistani man living with dementia, we illustrate how a social practice approach can help us understand why and how implementation of GPS technology occurs. Whilst our own chosen analytic approach to this case uses a particular middle-range theory with which we are familiar, we believe that the potential for studies of social practice to reveal distal barriers to spread and scale-up applies to all the theoretical approaches listed in Tables 1 and 2. In other words, we take the view that the commonalities among the numerous approaches to studying technology use as social practice are more important than their differences.

Our research questions were as follows:

1. At an empirical level, and using detailed analysis of a single case, what explains the difficulties with spread and scale-up for a particular technology?
2. At a more abstract level, what kind of insights can a social practice approach provide that will inform the study of spread and scale-up for technological innovations in health and care more generally?

Methods

Study Design

This study was part of the Studies in Co-creating Assisted Living Solutions (SCALS) program based at the University of Oxford, United Kingdom, which is following six case studies of health and care organizations as they strive to improve the care of people with multimorbidity in their own homes with the help of assisted-living technologies. A detailed background and methodology for the SCALS program has been published elsewhere [33]; the study builds on previous work that explored

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the lived experience of assistive technologies using home-based ethnography [19,56], explored the use of co-design methodologies in customizing such technologies with input from industry and care organizations [57], and developed a set of quality standards for telehealth and telecare [58]. SCALS builds on these previous studies by focusing primarily on the "meso" (organizational) level, considering how the organizational roles, routines, and practices required to embed technologies into business as usual are developed and sustained. This meso-level work is supported with an action research component and informed by micro-level ethnographic case studies of individual patients and clients (the intended technology users), focusing in particular on the work practices of organizational members as they interact with these intended users and with one another. It is also informed by macro-level studies of the wider policy context and political-economic influences. Data sources include semistructured interviews, ethnographic field notes, documents (eg, business plans, correspondence, policies, and protocols) and analysis of the material features and affordances of the technologies being introduced.

The six case studies in SCALS are introducing a wide range of technologies in different settings across the United Kingdom from virtual wards to telehealth support and disease-specific self-management programs. Our theoretical perspective has been developed previously and is based mainly on Stones' empirical extension of Giddens' structuration theory [49], enhanced for the study of technology use by Greenhalgh and Stones using selected concepts and terminology from actor-network theory [23]. We return to this approach in the Discussion.

The case we present here addressed the implementation of a GPS tracking system intended to help people with cognitive impairment go out for walks unaccompanied. "Wandering" is depicted as one of the most challenging behaviors displayed by people living with dementia [59]. It is defined as involving "a tendency to move about in either a seemingly aimless or disorientated fashion or in pursuit of an indefinable or unobtainable goal" [60]. "Wandering" raises safety concerns, for which a potential technological solution involves the person wearing a GPS tracking device (eg, on a wrist band or belt) that alerts relevant caregivers (often a remote monitoring center in the first instance, who in turn contact a nominated caregiver) when the device leaves a pre-defined geographical area (a previously agreed upon "geo-fence"). GPS is envisaged as a future "scalable" technology for use with a wide range of people living with dementia and related disorders [61]. Yet, in the setting we were studying only 7 clients, where 30 individuals had been provided with the technology (within a larger regional population of approximately 1500 people living with dementia in the local region), and only around half of those who were provided the technology were actually using it.

The implementation of a GPS device to track the movements of a person with dementia might at first seem quite simple: just attach it to the person's wrist. But this neglects the substantial technological support, expert consultation, and commitment of local caregivers necessary to make the technology "work." Attaching a tracking device (whether overtly or covertly) to the body of someone whose ability to give informed consent may be impaired is a socially meaningful and morally-laden act [61]. One person's "safety technology" is another's infringement of autonomy. The contested social meaning and ethical implications of the GPS device are central, not marginal, to the success of the service.

To illustrate these issues in more detail, we use the example of Rahim, a 76-year old man, originally from Pakistan and currently living in a large city in England with his adult son and his son's family. Rahim has dementia, is hard of hearing, and does not speak English. His daughter-in-law, Shakila, is the primary caregiver but does not speak much English, either; Rahim's two granddaughters Bharti and Labani often translate for health and social care providers. The family is eager to help facilitate the use of the GPS technology because Rahim has been leaving the house for long periods of time, becomes aggressive if his family tries to stop him from leaving, and his behavior has been drawing attention from neighbors. Kate, an occupational therapist, is supporting Rahim and his family in introducing the technology.

Data Collection

To study the organization's attempts to assure Rahim's safety and reduce the stress experienced by his family through the implementation of a GPS device, one of us (JW) made a total of three visits to Rahim's home between October 2015 and March 2016. As well as interviewing Rahim and his family with the aid of an interpreter, JW made extensive ethnographic field notes both contemporaneously and as soon as was practicable after leaving. JW also conducted phone contact with family members between the home visits and three interviews with staff from the care organizations involved, including his occupational therapist and two telecare coordinators responsible for the provision of the technology. The data collection related to the case of Rahim was supported by wider fieldwork within the organization (and collaborators) involved in the provision and use of the GPS tracking technology. This included shadowing and "naturalistic" interviews with health and social care service providers (occupational therapists, telecare coordinators, and commissioners), monitoring center operators, and technology suppliers. Similar ethnographic data was collected on six other index cases. Finally, we made detailed analyses of the different GPS technologies being offered to support people with dementia, focusing on their material properties and affordances in the context of use (or reasons for non-use).

Analysis

The multi-modal dataset was stored on NVIVO software and converted into interim summaries of individual cases using narrative as a synthesizing device. Each individual case narrative was between four and five pages long and included extensive quotes and annotations; it presented a brief history of the person's medical details and social situation as well as a longitudinal account of how they came to be offered a GPS device and how their experiences with it unfolded. In all cases, the narrative included several specific situations in which the device was rejected, failed to work as expected, and/or generated unintended consequences. In a second stage of analysis we

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applied a set of questions to these small-scale social situations, asking (for example) "what assumptions have been built into this technology about who will take what action and how in this situation?" "What professional codes and standards may be driving the behavior of the staff member at this point in the narrative?" and "what does person A assume about person B's role or perspective?" In this way, we were able to use a sample of small-scale efforts as "troubleshooting" to surface a complex set of interacting influences, both proximal and distal, on the unfolding of social action.

Results

Overview

We chose to report Rahim's case in detail because it illustrates a number of more general findings from the 7 individual cases within the GPS tracking case study. In qualitative research, there is always a trade-off between depth and breadth, and the study of social practices requires in-depth analysis of small-scale social situations. Rahim's is largely but not entirely a case of "successful" implementation, and hence it offers an opportunity to analyze carefully the unique combination of people, circumstances, and technologies that account for such success. Below, we give three examples of empirical data on the social practices of care staff and family members that illuminate the context in which GPS technology for people with dementia is implemented and in determining the success (or otherwise) of any future scale-up initiative.

Professional Judgment and Technology Implementation

Our first data excerpt illustrates how professional practice is oriented not to "implementing a technology" but to delivering a personalized care solution that improves the individual's quality of life as well as safeguards the vulnerable. Sometimes, these two important goals are at odds with one another (it can seem impossible to achieve safety without burdening the individual with constraints), so creativity and compassion are needed to generate individual solutions.

Take the following observational note in which Kate demonstrates her professional reasoning when helping Rahim and his family use the GPS technology. The family had just finished explaining to Kate that Rahim (who used to work as a tailor and enjoys collecting buttons) has been venturing into the street when his family is unaware, and, while wandering, sometimes eating discarded, rotten food:

> *Kate is serious and concerned and takes out her A4 notebook to jot this all down. She does not think it is safe for him to be attempting to eat rotten food and is further concerned about his risk of falling or being hit by traffic when engaging in this activity. Her attention is drawn to ways of reducing Rahim's desire to find things on the street...She comes up with an idea for the family to place buttons and other interesting materials around the garden, which Rahim can then search for and collect. This may help occupy Rahim's time and allow him to do something he enjoys, without the risks associated with leaving the house. Both Shakila and Bharti [granddaughter] appear optimistic about the idea and say they will give it a go.*

In this example, Kate manages to find a possible way of providing Rahim with a meaningful activity that could *replace* his outdoor wandering behavior. If this plan were successful, the GPS technology would no longer be necessary in the same way it was when initially introduced to the family and actually might not be needed at all.

The key point here is that Kate's effort to implement the technology was not driven solely by her desire to see the technology used, but by a more holistic professional assessment of the individual in his family context. When Kate undertook her initial assessment of Rahim for the possible supply of a GPS device, she was influenced by (among other things) the United Kingdom Mental Capacity Act 2005 [62], including the principle of pursuing the least restrictive option when making decisions, and therefore not interfering with Rahim's freedom of action to leave his home. This legislative framework represents important elements and principles of the routine Kate is performing as she works to implement the technology.

Notwithstanding the policy goal of "scaling up" the GPS technology for the management of wandering, then, it is not only good professional practice but also a legal requirement to view this technology as desirable for *some but not all* individuals exhibiting wandering behavior. This should not be seen as a "barrier to scale-up," but as the provision of appropriate, family-centered care.

In a previous study of resistance to technology use by clinicians [20], we asked the question "what is excellence in professional practice?" We concluded (page 20) that:

> *Good clinical practice involves judgement and attention to the particularities of the patient and their situation (the 'existential patient') as well as up-to-date knowledge and incorporation of best scientific evidence (the 'objective patient'). It follows...that technologies which support the latter at the expense of the former are likely to be experienced by clinicians as interfering with excellent care.*" [20]

In the example above, Kate makes the (unconscious) professional judgment that the GPS tracking device is irrelevant to the optimal solution for Rahim. Indeed, it is likely that Kate would define her professional role as caring for Rahim, *not* implementing technology.

This example affirms previous studies that have emphasized the unpredictability of scale-up efforts [7,9,46], because it depends on case-by-case decisions about the appropriateness and relevance of the technology that are made iteratively as professionals interact with patients and their families. These decisions simply cannot be specified in a linear logic model at the outset of an implementation initiative, but depend on the unfolding of highly individualized contextual factors. More fundamentally, it is unlikely that professional staff will ever accede to the goal of "scaling up" the implementation of a technology at the expense of individual client needs.

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Personal and Professional Relationships

Our second data excerpt illustrates how, in order to "work," technologies rely heavily on human relationships and situated knowledge. Our ethnographic observations and interviews showed how Rahim's daughter-in-law Shakila and granddaughter Bharti spent a lot of time learning about and supporting the GPS technology. They had to be able to operate it and ensure that it was charged every night and switched on, and they had to persuade Rahim to put it on before going off on his walks. They also cared deeply about Rahim and had an intimate knowledge of what mattered to him and how he was likely to behave in particular situations. This allowed them to make judgments about what particular alerts from the technology meant in practice, and particularly, whether Rahim was likely to be "safe" or not, given his specific location.

It was also the case that the professionals involved developed a close knowledge of Rahim and his extended family, and provided what is sometimes known as "relationship-based care" to support their use of the GPS tracking device. In other words, the professionals' knowledge was not limited to how the technology worked in general; they learnt how Rahim and his family were using it, their individual and collective capabilities in relation to the technology, and their interactions with the wider health and care system. Furthermore, Kate had developed professional relationships with others involved in supporting the technology, such as Chris, the senior engineer responsible for troubleshooting technological issues. Decisions and recommendations about how to use the device drew on this knowledge (which was both explicit and tacit) of the circumstances, needs, and perceived obligations of others involved in Rahim's care. For example, understanding the family's close contact with Rahim and knowing Chris' willingness to modify the parameters around the technology for her clients, Kate was able to facilitate the family's request to de-activate the emergency button that was being inadvertently (accidentally) pushed throughout the day.

To the extent that the GPS technology "worked" for Rahim, it was due to Shakila and Bharti being available to respond whenever they received an alert that Rahim had crossed over the pre-defined geo-fence that had been programmed into the GPS device. Furthermore, in order to respond to the alert about Rahim's "objective" location (ie, the pinpoint on a map), these family members also factored in a substantial amount of tacit knowledge about what that location meant subjectively (ie, the relevance to Rahim, his everyday life, and memories) and in terms of Rahim's safety. Bharti explains in the following interview extract:

> *Like, if he has gone to the corner shop, [the call operator] will say he is out of his boundary, but we know he comes back [from there]. But, if he doesn't come back within ten minutes, we will look where he is...About three times a week [we get a call], and twice out of that three we know where he is. And then once we don't know. If they say three roads away or further, we know he is not familiar with the area. Someone will pick him up...Usually we get someone like my sister, auntie, someone who drives and they will be on the phone.*"

What Bharti references here are the underlying social networks and arrangements that support the GPS technology; it relies on one or more dedicated caregivers who can be contacted at any time, who own a phone, who can communicate in English, and who have transportation (in this case, a private car) available to search for Rahim. The success of the technology also relies further on a larger group of people within the social network who can help search for him, if necessary.

As noted above, technologies are designed based on particular assumptions about how and by whom those technologies will be used. This is not a criticism of technology designers (it could not be otherwise), but the assumptions made by designers about who will use it and what additional knowledge will be required to interpret its outputs have consequences for whether and how the technology will be used, adapted, or discarded (and hence for how easy it will be to scale up and spread its implementation). The GPS technology is *designed* to rely on stable arrangements and relationships, intimate knowledge of the client, and a high degree of commitment and availability, like those we observed in Rahim's family.

Rahim had the necessary social relationships to support the use of GPS technology within his family. However, this is not the case for all people with dementia who exhibit wandering behavior. This raises a crucial point when thinking about scaling up technology: instead of relying on background assumptions (eg, about the "typical" family, how they interact with one another, and how they seek out health and social care), we must acknowledge the variable social networks and accountability arrangements in which potential users of the technology are embedded. Only by understanding how a particular technology will or will not fit into the caregiving practices made possible by a particular family or other interpersonal relationships can a technology such as this be scaled up successfully.

Personal Habits and Collaborative Routines

Our third data extract illustrates the general point that adoption of a new technology by a client requires changes in the *practices* adopted by both professional and lay caregivers, and in particular, co-ordination and stabilization of shared practices and routines. Implementing technologies requires changing what people do. In many instances, it requires that people come to use, on a regular basis, some new piece of technology that they did not use before. However, changing what people do "on a regular basis" (ie, every time a certain routine is enacted) is not a simple task. At an individual level, peoples' actions are embedded in longstanding habits that are connected to their surroundings in important ways. At an organizational level, routines are what align the work of individuals into collaborative work patterns, thereby improving the efficiency and predictability of shared tasks; they are not easily changed, especially when they interact with other routines [63].

In Rahim's case, the "simple" GPS tracking technology required coordinated input from a number of people including Kate (the occupational therapist), the staff at the GPS call center, Shakila (Rahim's daughter-in-law and primary caregiver), Bharti (his

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granddaughter), other family members, and of course, Rahim. Each of these individuals had some accumulated knowledge and experience, and each made situated judgments based on what information they considered to be salient, meaningful, ethical, legal, and professionally or culturally appropriate. They also, to some extent at least, had to understand where the other people in the network were coming from and what contribution each could and would make to Rahim's support package.

This GPS device "worked" for this particular client, for example, because the family was sufficiently close-knit and well-organized to orchestrate a search in response to an alert, because they fully accepted their responsibility to contribute to the routine, and because either Bharti or her sister were usually available to translate between the English-speaking call center and members of her limited-English-speaking family when notified that Rahim had breached his geo-fence. Indeed, the routine worked so well in the case of this particular family that it is easy to take its elements for granted.

It is noteworthy that in Rahim's case, the collaborative family routine for keeping Rahim safe *before* the technology was introduced was considerably more challenging than the one the technology was able to support. Bharti described it thus:

> *When he didn't have [the GPS tracker] we were always looking for him. We had five different cars go out. It would be 2 to 3 hours. And we would find him in random places...This happened three times, and we were really worried. We were looking for him in different places, it was really hard.*"

Importantly, the "success" of the GPS tracking technology in Rahim's case is not that the technology, in and of itself, kept Rahim safe but that within the context of an existing pattern of caring, it made the collective task of keeping him safe when wandering considerably easier. However, the same technology introduced into a different family network may not support or enhance existing care routines (for example, if key caregivers are out at work all day) and may actually increase the workload on caregivers as it potentially "empowers" the individual to wander relatively safely and so may require caregivers to search and rescue more often.

Discussion

Summary

This paper has presented a key theoretical and methodological argument—that the study of social practices has great potential for informing the study of spread and scale-up (and the common problem of *lack* of spread and scale-up) of health and care technologies. We have illustrated this with a detailed worked example of a single case study of an elderly man and his family who were using a GPS tracking device, more or less successfully, to increase his freedom to safely wander in his neighborhood. Data extracts were used to illustrate three exemplar findings. First, professional practice is (and probably always will be) oriented not to "implementing technologies" but to providing excellent, ethical care. Second, in order to "work," health and care technologies rely heavily on networks of human relationships and the situated knowledge of individuals. Third, such technologies do not just need to be adopted by individuals; they need to be incorporated into personal habits and collaborative routines (both lay and professional).

Implications for Scale-Up and Spread of Health and Care Technologies

Following Giddens [41], we conceptualized the people involved in Rahim's case as "social actors" who were, to a greater or lesser extent, knowledgeable and reflexive. They contemplated their actions by taking account of social structures such as norms (in Giddens' terminology, "structures of legitimation," ie, what they saw as reasonable and ethical, such as assumptions about the nature of excellence that underpins professional practice), meaning-systems ("structures of signification"—the symbolic meanings and significance that they attached to people, experiences, and artifacts), and rules and regulations ("structures of domination," ie, what they saw as following protocol or obeying external authority).

Giddens himself did not offer a theorization of technology as part of structuration theory, but as we and others have shown previously in relation to a range of technologies, social structures are typically inscribed (sometimes unwittingly) in the software or other design features of technologies [21,23,44-46,64]. In other words, technologies *assume* that particular social practices will be being followed in particular ways as the technology is used, and when these inbuilt assumptions clash with the actual social practices of real actors, the technology may not be adopted at all or it will be rapidly abandoned.

The literature on non-adoption of health and care technologies is dominated by behaviorist terminology and by proposed solutions (such as "incentives" or "levers") that do not engage meaningfully with the social structures described above [20]. Our findings suggest that unless we deepen our understanding of the complex and situated nature of technology use, the policymakers' vision of rapid scale-up of new technologies will not be realized.

As we demonstrated previously in the empirically derived ARCHIE standards for assisted-living solutions, it is critically important to work *with* professional and lay intended users to co-design solutions that align with what matters to people and that are achievable and sustainable in practice (ARCHIE: technologies should be Anchored in shared understanding, Realistic about illness, Co-creative, Human, Integrated, and Evaluated) [58]. This study reinforces that message but also sounds a note of caution: even when co-design methodologies are used, we may never achieve the policymakers' vision (implied in the opening paragraph in this paper) of high levels of scale-up and spread of technological innovations for health and care, achieved through "mass customization" and systematic implementation strategies. At the very least, we must build in considerably more flexibility and nuance to the menu of technological options available and also work to maximize flexibility and scope for professional judgment in the service models that support their use.

We believe that this study provides important insights into the study of the scale-up and spread of health and care technologies

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through a social practice lens. The use of a single in-depth example allowed us to illustrate themes that emerged consistently across a larger sample of cases in the GPS tracking study and which are also evident in other technologies being studied in the SCALS program.

Limitations

This study has limitations. The examples illustrate the general principle that external social structures of various kinds profoundly influence the situated action of human actors, but we did not have space here to explore any of these examples in close theoretical detail (this will be addressed in a future paper to be published in the social science literature). The use of a single "successful" case example raises the question of what additional insights we would glean from the study of "failures." Even with the other 6 individual case examples, the overall sample size for the GPS tracking study was small. That study was in a single locality, hence it did not offer scope to study *spread* to new settings (though we have recently added a second GPS tracking site in a new locality and will be addressing this issue through further empirical work).

We have included a range of theories under the banner of theories of social practice. Each addresses the relationship between some understanding of "the collective" (eg, social structure) and the individual's propensity to act in particular ways (eg, agency). Sorting out these constructs and their relationships are open questions across social science disciplines. We acknowledge the ongoing debates on this but suggest that these theories collectively offer instructive guidance for studies like ours.

Conclusions

Whilst we have tabled one example of how a social practice lens might be used to research the enormous policy challenge of the scale-up and spread of new technologies, we have not produced a definitive methodology for addressing all aspects of this challenge. The task before us is to draw on the data generated by research, combined with real-world experience, to establish and examine scale-up strategies that balance the needs of context-sensitivity with the realities of producing technologies that have potential for mass application.

To begin what we hope will be a productive discussion, we suggest that future social practice research studies might throw light on which elements of health and care technologies will need to be customized to every individual user (and her or his context) and which can be produced in a more standardized way. There is also scope for using prospective implementation studies to research how health and social care professionals manage the tension between the policy pressure to implement technologies "at scale" and the professional need to provide appropriate personalized solutions, whether technological or not. We invite others to suggest additional applications of social practice approaches to the important questions of spread and scale-up.

Acknowledgments

The SCALS program's main funding is from a Senior Investigator Award and Public Engagement Award to TG from the Wellcome Trust in its Society and Ethics Programme (WT104830MA). Additional funding for the GPS case study was provided by the National Institute for Health Research (Programme Development Grant RP-DG-1213-10003 and Health Services and Delivery Research Grant 13/59/26), on which Rob Procter was co-investigator. We are grateful to the participants in all the empirical studies funded by these grants, and in particular to Rahim and his family, whose case is reported in the paper and the health and care professionals involved in the GPS tracking study. The study is registered on the Wellcome Trust's Society and Ethics research portfolio.

Conflicts of Interest

None declared.

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Abbreviations

ARCHIE: technologies should be Anchored in shared understanding, Realistic about illness, Co-creative, Human, Integrated, and Evaluated
GPS: global positioning system
SCALS: studies in co-creating assisted living solutions

Edited by C Gibbons; submitted 10.02.17; peer-reviewed by S Levy, J McMurray, J Sturt, M Sujan, J Boger, J Apolinário-Hagen, TR Soron; comments to author 08.04.17; revised version received 24.04.17; accepted 08.05.17; published 07.07.17.

Please cite as:
Shaw J, Shaw S, Wherton J, Hughes G, Greenhalgh T
Studying Scale-Up and Spread as Social Practice: Theoretical Introduction and Empirical Case Study
J Med Internet Res 2017;19(7):e244
URL: http://www.jmir.org/2017/7/e244/
doi:10.2196/jmir.7482
PMID:28687532

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Original Paper

Using Digital Technologies in Clinical HIV Research: Real-World Applications and Considerations for Future Work

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Abstract

Background: Digital technologies, especially if used in novel ways, provide a number of potential advantages to clinical research in trials related to human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) and may greatly facilitate operations as well as data collection and analysis. These technologies may even allow answering questions that are not answerable with older technologies. However, they come with a variety of potential concerns for both the participants and the trial sponsors. The exact challenges and means for alleviation depend on the technology and on the population in which it is deployed, and the rapidly changing landscape of digital technologies presents a challenge for creating future-proof guidelines for technology application.

Objective: The aim of this study was to identify and summarize some common themes that are frequently encountered by researchers in this context and highlight those that should be carefully considered before making a decision to include these technologies in their research.

Methods: In April 2016, the Global HIV Vaccine Enterprise surveyed the field for research groups with recent experience in novel applications of digital technologies in HIV clinical research and convened these groups for a 1-day meeting. Real-world uses of various technologies were presented and discussed by 46 attendees, most of whom were researchers involved in the design and conduct of clinical trials of biomedical HIV prevention and treatment approaches. After the meeting, a small group of organizers reviewed the presentations and feedback obtained during the meeting and categorized various lessons-learned to identify common themes. A group of 9 experts developed a draft summary of the findings that was circulated via email to all 46 attendees for review. Taking into account the feedback received, the group finalized the considerations that are presented here.

Results: Meeting presenters and attendees discussed the many successful applications of digital technologies to improve research outcomes, such as those for recruitment and enrollment, participant identification, informed consent, data collection, data quality, and protocol or treatment adherence. These discussions also revealed unintended consequence of technology usage, including risks to study participants and risks to study integrity.

Conclusions: Key lessons learned from these discussions included the need to thoroughly evaluate systems to be used, the idea that early success may not be sustained throughout the study, that some failures will occur, and considerations for study-provided

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devices. Additionally, taking these key lessons into account, the group generated recommendations on how to move forward with the use of technology in HIV vaccine and biomedical prevention trials.

(J Med Internet Res 2017;19(7):e274) doi:10.2196/jmir.7513

KEYWORDS

clinical trial; HIV; mobile phone; text messaging; biometric identification; observational study privacy; data collection

Introduction

Those who sponsor, conduct, and analyze data from clinical trials actively seek new digital tools and technologies that could reduce costs or timelines; potentially improve clinical operational efficiencies; facilitate recruitment and retention of volunteers; and improve data collection, quality, and analysis [1]. However, deployment of such tools is not always straightforward and may have implications for regulatory approval, ethics reviews, statistical analysis, study design, and other aspects of clinical trial conduct. Moreover, practical experience with a given technology often uncovers benefits and pitfalls that were not anticipated at the planning stage. The use of such technologies in trials related to human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) poses unique challenges due to stigmatization of HIV in many communities [2], which may decrease participants' willingness to share information with study staff. Therefore, it is critical to review past experiences and to discuss innovative uses of digital technologies that could be adopted in future clinical trials.

Methods

In April 2016, the Global HIV Vaccine Enterprise surveyed the field for research groups with recent experience in novel applications of digital technologies in HIV clinical research and convened these groups for a 1-day meeting. Real-world uses of various technologies were presented and discussed by 46 attendees, most of whom were researchers involved in the design and conduct of clinical trials of biomedical HIV prevention and treatment approaches. After the meeting, a small group of organizers reviewed the presentations and feedback obtained during the meeting and categorized various lessons-learned to identify common themes. A group of 9 experts developed a draft summary of the findings that was circulated via email to all 46 attendees for review. Taking into account the feedback received, the group finalized the considerations that are presented here.

Many of the listed considerations are not specific to HIV and AIDS research but potentially can be applied to clinical studies of other diseases. However, due to the group's focus on HIV and AIDS, we aimed to highlight unique aspects of dealing with this disease and did not fully evaluate the relevance of these considerations to other diseases.

The rapidly changing landscape of digital technologies presents a challenge for creating future-proof guidelines for technology application. To address this concern, the group included experts with many years of experience in applying digital technologies to clinical research, who were able to point to long-term trends in the industry and identify concerns, summarized below, that are likely to persist in the foreseeable future.

Results

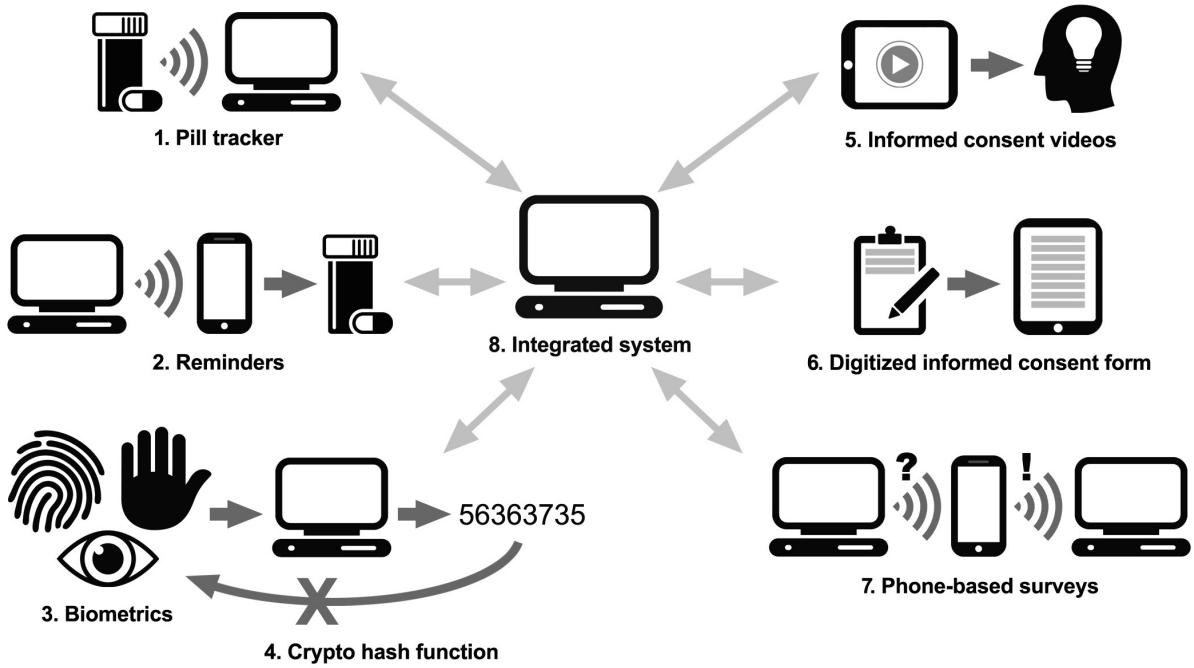
Successful Applications of Digital Technologies to Improve Research Outcomes

Recruitment and Enrollment

When conducting HIV-related research, it is critical to be able to recruit from populations that have been previously underrepresented in research. The advent of digital technologies offers new opportunities for the recruitment and enrollment of these populations. Technologies necessary for research surveillance and other forms of data collection are increasingly becoming common in low- and middle-income settings [3,4] and have facilitated recruitment and enrollment of diverse populations in the United States [5]. For example, use of mobile devices such as tablets and phones for data collection within and outside the clinic increases the convenience of participation in research studies and positively influences participant response rates [6]. Using algorithms to tailor recruitment messages to individuals (eg, by sending personalized letters, emails, or text messages [short message service, SMS]) also increases response rates [7]. Figure 1 shows examples of these digital technologies, including: (1) electronic systems embedded in pill bottles which allow recording of every instance of bottle opening, providing researchers with a verifiable record of adherence; (2) messages sent via cell phones, which can be used to improve adherence to drugs, encourage specific behaviors, or remind about appointments; (3) various biometric measures (fingerprints, palm prints, and iris scans being the most common) which can be used to identify participants; (4) cryptographic hash functions that allow for one-way matching of participants, protecting their privacy in situations when trial records may be compromised; (5) videos or interactive forms that can be used to improve participants' understanding by providing more visual information by allowing self-pacing, or by ensuring comprehension before allowing progress to following sections; (6) scanning and electronic storage of documents such as informed consent forms to improve record keeping; (7) cell phones, which can be used to reduce the need for in-person visits or to gather information from participants in real time, reducing recall bias; and (8) some systems which integrate two or more of the digital technologies allowing more efficient project management and better data integration.

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Figure 1. Examples of digital technologies.



Participant Identification

Devices such as electronic fingerprinting technologies, retinal scans, or palm identification can be used to identify participant coenrollment in different trials within or across trial sites, as well as "fraudulent" participation (occurring when a nonenrolled individual appears for a trial visit, presumably to receive trial incentives)[8,9]. In the context of community-, clinic-, or other cluster-randomized trials, they can help identify and possibly prevent intervention contamination, which occurs when participants in one group or cluster migrate into another group and "share" the intervention in a control group. For example, in a community-randomized trial of safe sex messaging when people interact with members of a control community, they may share the messages they have heard. This would result in moving the evaluation measures of the two communities closer and masking the true effect size [10].

Assessing participant identification in a longitudinal fashion can be used to prevent such issues, which not only compromise study and data integrity but also may harm patients (eg, if coenrolled patients receive double doses of a vaccine or other experimental product or if noneligible participants receive a vaccine or other experimental product)[8,9,11]. When these issues cannot be prevented, biometric identification used in longitudinal fashion can help measure the magnitude of such contamination and mitigate this effect during analysis [12-14].

Several studies indicate that the use of biometric devices is feasible in an array of resource settings and acceptable among both research study staff and participants [15-17]; in the case of some stigmatized populations, there is even data suggesting that biometric identifiers may be preferred over providing one's name or other identification during study visits [18].

Biometric tools, if integrated into the study with strong cryptography, can provide a means of protecting participant identity while providing even greater levels of identity assurance than the traditional tools [19]. For example, systems that use retina scans convert the unique image of the participant's eye into digital information using a cryptographic hash (an algorithm that links data to a string of symbols that cannot be used to identify the original image). That key is only available to operators of the study making identification of a participant with only the image of their eye virtually impossible. This approach significantly reduces the potential for release of data to the wrong participant or if there is a compromise of the study data that would breach confidentiality. In addition, assurance of identity also reduces the risk that the participant is misidentified and therefore receives an incorrect regimen.

Informed Consent

Videos and interactive electronic systems can provide alternatives to traditional informed consent procedures. Whereas data are mixed on whether video-based informed consent offers improvement over the traditional paper documentation of informed consent, there are indications that people may experience greater comprehension of the research process with video-based consent [20]. This may be especially helpful in populations where literacy rates are a concern. Additionally, interactive programs or websites can offer user-centered approaches to informed consent that include simpler layouts and opportunities for self-pacing that can help to ensure participants comprehend study processes [20].

Data Collection

Digital technologies have made study conduct more efficient as well. Systems such as the Research Electronic Data Capture (RedCap) [15,16], Open Data Kit [17], and MagPi [21] offer researchers the capacity to streamline the workflow and collect data more efficiently. These systems combine storage of participant information, validation of informed consent, and in some cases reminder recalls and communication with participants in a single program, which simplifies project

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management and removes the need for posthoc integration of information from multiple sources [16,22]. This technology in turn improves the workflow so that research coordinators, and data collectors can use a single system to understand who has enrolled, who needs to complete informed consent, and who needs to complete assessments or return for follow up.

Data Quality

Digital data collection for psychosocial characteristics of participants offers important advantages. Automated skip patterns, also known as conditional branch logic, present the participant with questions that are customized based on their responses to previous questions. For example, if a participant indicates sexual encounters in the past week, more questions appear to gather additional details about those encounters, but these questions are omitted if the participant answers that there was no sexual activity [6,22]. Forced item response (when participants are required to answer a question before they can move to the next question)—offering a "don't want to answer" option to avoid coercion—helps reduce or eliminate missing data, substantially contributing to data quality [6,23,24]. Advances in technologies for measurement of biomedical variables can help improve integration of biomedical measures with psychosocial measures in a single dataset [25].

Protocol or Treatment Adherence

Clinical trials are typically designed to determine the efficacy of a medication or other biomedical intervention. True biologic efficacy, however, can only be determined in the setting of high adherence [26]. Incomplete adherence reduces the trial's power to determine if suboptimal efficacy is due to the intervention or to participants' behavior. The importance of this relationship between adherence and efficacy has been highlighted in the recent clinical trials assessing pre-exposure prophylaxis (PrEP) against HIV infection [27].

Numerous methods exist for measuring adherence, including self-report, pill or product counts, pharmacy refill records, drug levels, and electronic adherence monitoring (eg, pill or product bottles that record openings). Each method has its pros and cons, and none is considered a gold standard [28]. For example, self-reported adherence is often an overestimate because of social desirability bias (ie, wanting to report high adherence to please a clinician or researcher regardless of the true adherence behavior) and recall bias (ie, not accurately remembering forgotten doses). Digital technologies can be used to help optimize these measures in several ways.

Cellular Phone–Based Adherence Support

Given the near ubiquity of cellular phones, even in low-income countries, multiple studies have explored the use of short message service (SMS) and interactive voice response to potentially improve upon self-reported data [29,30]. Some data suggest that the relative anonymity of a cellular phone (compared with an in-person interview) leads to reduced social desirability bias [31]. Moreover, the convenience of cellular-based data collection allows for more frequent data collection, thus reducing recall time. However, validation of cellular phone-based reporting is limited [32], and further research into this measurement approach is needed.

Real-Time Adherence Monitoring Devices

Electronic adherence monitors provide a day-to-day assessment of pill or product container openings, which can be a highly informative, objective measure of adherence behavior. Whereas this technology has existed for many years, wireless versions have become available in recent years, enabling the use of this type of adherence data in real-time in both resource-rich and resource-limited regions [33,34]. Real-time electronic monitoring devices can be used both for measurement and for intervention at the precise time when nonadherence is occurring. Three recent trials assessing real-time adherence linked to SMS reminders revealed improvements in adherence, although the extent of the impact was variable [35-37]. Real-time adherence monitoring has yet to be used in a large-scale HIV clinical trial but has great potential to improve adherence and increase the discrimination between biological and behavioral aspects of efficacy.

Unintended Consequences of the Use of Technology

Risks to Study Participants

Data Security as a Risk to Study Participants

For clinical trial participants, the data security practices of the researchers and their sponsors are critically important. For participants in HIV research trials, these practices are even more critical as breaches of confidentiality may negatively impact participants' lives [38,39]. These negative impacts could include concerns around physical safety due to breach of location information or could result in social stigma of assumed infection status for participants and their family members.

Digital technologies used in clinical research offer opportunities to improve the data security whereas also introducing vulnerabilities for the breach of that data. Some examples of how the new technologies offer improvements for the security of the participant data include encryption for data within storage systems, encryption of the data transmission stream from one system to another, and the ability to use identity assurance tools such as biometrics that verify the participants' identity without maintaining personally identifiable information in the study management systems [40].

Simultaneously, new technologies are providing unexpected ways that the data security can be breached. Location services on mobile phones record the location and use of apps and connected devices such as accelerometers and biosensors, which are already used in clinical protocols [41]. These location data can be shared inadvertently by other applications, in metadata of other files, or by the phone itself. Updates to applications or the phone operating system can change the way location data or storage is handled by the device without the knowledge of data managers or study managers.

Additionally, the use of wearable technologies, which often include new data gathering and transmission tools, presents new opportunities for unexpected data release [42]. Many of these systems are consumer- and vendor-optimized and not designed for use in clinical studies. Commercial companies often have an interest in collecting and monetizing personal information, not protecting it.

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Social Impacts to Study Participants

As noted above, cellular technology and electronic adherence monitors have great potential for adherence measurement and intervention; however, ethical concerns may arise in using this technology, primarily around privacy [43].

Participants may be able to utilize mobile phones to capture sensitive behavioral data in real time and in a confidential manner; however, the use of a study-provided phone may pose a risk to those participants who do not disclose study participation to their partner, family members, or roommates. As participants may be requested to keep a study-provided phone with them at all times in order to submit the daily survey records, participants may inadvertently disclose their study participation. Moreover, the participant may be accused of cheating on a partner or hiding a secret if he or she is discovered to be using a secret "second" mobile phone.

Risks are also present when participants use their own phones for study communication. Cellular phones in developing countries are commonly shared by multiple people [44], and an SMS sent to a trial participant may be seen by others, disclosing HIV status or trial participation. Protections against such situations include the use of nondescript messages that only the intended recipient will recognize, a personal identification number (PIN) to trigger an SMS with trial-specific content, and flash SMS or unstructured supplementary service data (USSD) protocols (ie, the messages disappear once read). Although such protections may not be needed in all contexts and some individuals may prefer direct messages [45], privacy should be considered when designing the use of SMS in any clinical research.

Electronic adherence monitors may attract attention in some settings such as rural villages or in stigmatized populations such as injection drug users. This attention may lead to unintended disclosure of HIV status or trial participation. The degree of concern expressed by participants in research studies has ranged from low to moderate [46,47]. To protect against this situation, users of electronic adherence monitors should plan to store, carry, and use them in an inconspicuous manner. Device manufactures can make alerts for missed doses (eg, lights or audible notifications) optional. In the future, use of these devices in clinical care may reduce concerns about privacy; however, they are currently limited to the research context.

Implementation of these and other technologies requires a careful understanding of the specific population(s) using them and the concerns they may have. Participant counseling may also be used to reduce concerns of inadvertent information release (eg, encouraging HIV status disclosure when it is safe to do so). Interestingly, at least one study found that an electronic adherence monitor was used to start discussions of disclosure [48].

Risks to Study Integrity

Introduction of Bias

The use of skip patterns may have unintended consequences for data collection [49]. Bias in responses to digital questionnaires can occur because of the length of mobile or Web-based surveys conducted at specific time points in a study. For example, a recent study of adolescent male sexual behaviors used mobile phone daily diaries that varied in length based on the number of partners reported by the respondents [49]. Participants reporting no sexual partners answered a total of 38 questions, whereas those reporting the maximum of 5 partners could see a total of 748 items. As a result, there was a tendency among participants to report fewer partners than they actually had in order to reduce the amount of time spent completing the daily diaries.

One way to address this is to limit the number of highly detailed follow-up items triggered by a "yes" response to sexual behavior and to add alternative, general information items to "no" responses so that the entire diary has a smaller number of questions and that gaming the system by responding "no" does not shorten the length of the diary.

Participation Fatigue

As with any traditional data collection method, participation fatigue can occur with electronic data capture methods such as daily diaries or periodic surveys. Participants with children and a very busy working and school schedule may find it especially difficult to complete study procedures daily as part of their busy day schedules. Therefore, if daily participation is required, then a shorter duration of study participation is recommended. If the study duration is longer, then active engagement of participants would be recommended to sustain motivation, such as lotteries [50,51]. Alternatively, study procedures could be completed based on particular events or on an ad hoc basis to maintain the novelty of study participation.

The issue of participation fatigue presents a particular concern given the power of electronic and Web-based data capture. Investigators now have the capacity to collect nearly limitless amounts of highly specific and often sensitive data using these tools. This desire to "measure everything" needs to be mitigated with the understanding that patient fatigue issues have not been alleviated as compared with traditional data collection methods. Therefore, investigators need to be thoughtful about the questionnaire design including effective skip patterns and innovative incentives and thoroughly pilot test new instruments before final implementation. As with any type of behavioral data collection, the key is to focus on the necessary variables that aid accomplishment of the protocol objectives and not gather more data than one can or will analyze.

Discussion

Key Lessons Learned From Early Technology Implementations

Systems Need to Be Thoroughly Evaluated

Staff Training

Thought and care need to be put into the setup and maintenance of the system to be used, including assessment of the need for training of site staff. For example, biometric identification technologies often require training to ensure high-quality capture of biometric measures, especially in limited resource settings [11]. This can be addressed by developing didactic and practical

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trainings, job aids, error logs, and scheduling intermittent refresher trainings.

System Testing

Additionally, the feasibility and use of proposed technology should be piloted on site prior to trial launch with study staff and potential participants. For example, technologies that are Internet-dependent will face issues when implemented in low-resource settings, particularly in rural areas. Whereas mobile Internet coverage is improving, pilot testing of all technologies will help to identify such implementation issues for troubleshooting.

Comparisons to In-Clinic Data

If data from more than one method of collection are going to be combined for analysis, then efforts should be made to harmonize across the data types. For instance, mobile phone versus in-clinic data variables should be comparable so that they can be compared at the stage of analyses, that is, they should have comparable questions, formats, and variables.

Participant Use

Iterative refinement of devices with user feedback on feasibility and acceptability is critical. Technologies will have variable participant acceptability depending on the setting and the type of technology. For example, use of an electronic fingerprinting technology to identify female sex workers in Zambia longitudinally within a mock HIV vaccine trial showed <50% uptake of the technology among women approached in the field (at their places of work) but >95% uptake within the clinic [11]. Pilot studies to assess technology acceptability by prospective participants before a trial are critical, as well as the understanding of what potentially modifiable barriers participants may face when taking up a technology. There may be particular concerns around confidentiality with the use of biometric devices.

Initial Successes May Not Be Sustained

Participation fatigue issues, described previously, can derail a study when initial success is not seen over the entire course of the study. Other issues that could result in the failure to maintain an early success include staff turnover, equipment failures (particularly when there is a lack of technical support), software upgrade issues that cause devices to become out of sync, or other changes to the overall system that affect the quality of the data to be collected.

Prepare for Some Percent of Failure

In designing a study, it is important to consider the effects of data that will be missed due to issues with the use of a chosen technology, especially when it is first implemented. Attempts to minimize the loss of data should be made throughout the study. Retraining during scheduled visits is very important. Identifying the challenges participants are experiencing in completing study procedures allows improvement of the user experience. Reminder strategies and plans to fit the mobile phone completion into the participant's daily routine can be selected in consultation with the participant. Study staff should expect participants' calls and provide support especially for those that default from study procedures. Regular check-ins (ie, telephonic contact and social networking applications) between study visits are important to keep the participants motivated for the daily survey submissions. It is also critical for a staff member to be trained to provide very technical information about mobile phone and Internet operation. For instance, users could unknowingly disable the Internet on their mobile phone and then not be able to enable it on their own.

Considerations for Study-Provided Devices

Devices May Be Manipulated by the Participants

In settings where mobile phone use may not be widespread, researchers may provide mobile phones as part of the participation in the study. Additionally, participants may be provided with the necessary airtime and data to perform study-related procedures. Providing a study phone can be advantageous. However, the disadvantage is that the user may misuse data and airtime provided for study purposes. To avoid participants using the study airtime for things unrelated to study, software can be installed to block data access to unrelated website that may affect the airtime for study purposes. Whereas safeguards can be put in place, technology-savvy people are often able to find a work-around.

For example, an app like "AppLock" can be used [52]. This App is password protected and Internet-enabled applications can be blocked by the data manager to ensure that uploaded data bundles are solely used for the project related application(s). Although participants may struggle to disable the blocking software, they would be able to reset the full phone, in which case the entire phone content would be erased. The phone would then have to be reset and the software reinstalled for study-related procedures to continue.

These problems can be addressed by providing sufficient data on a monthly basis for participants to meet both the research data collection and their personal needs. One concern for trials enrolling minors is that mobile data can be used by participants to access materials not desirable by their parents. Both the loss or damage concern and the data use issues can substantially impact budgets and need to be considered a priori.

Loss and Breakage Will Happen

Whereas researchers have found that provisioning mobile devices or data minutes is a successful recruitment strategy and method for incentivizing participants, it is important to remember that the devices will often be unintentionally lost or damaged by participants (5-10% replacement rate is common but may be as high as 30% depending on the study population; J Haberer, personal communication).

Better results can be achieved if participants take ownership in the research. One way to motivate safekeeping of the study phone is to let participants know upfront that they would keep the phone after study completion. This approach may not only increase the likelihood that the participants will give the study phone the extra care but may also increase their motivation to be adherent to all study procedures to the best of their abilities.

Data Integrity

As with any data-collection system, errors in the data will exist and need to be addressed by study staff. Technological solutions

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do offer some mechanisms to increase data quality such as automatic quality-control checks, which can be put in place to define the expected range for some data types. Additionally, participants may be shown a summary of their data before the data are officially submitted to the study, allowing them to catch obvious errors. However, technology can also introduce new data challenges. Duplicate data entries can be made in some systems, after which study staff need to establish which entry is valid for that particular day. Devices used to measure adherence, such as enhanced pill containers, could be opened by participants without medication consumption, leading to inaccurate data. Additionally, systems will respond differently to incomplete or partial data, such as when an Internet connection is lost mid-entry.

Conclusions

How to Move Forward in HIV Vaccine and Biomedical Prevention Trials

When considering how to move toward integration of digital technologies into HIV prevention clinical trials and observational studies, three guiding messages emerged at the meeting. Taken together, they can offer an informed and realistic approach to the challenges posed by new technologies: change is hard, things change rapidly, and support is critical. An approach that prepares for slower uptake and acceptance of new technology but includes flexibility to respond to rapid pace of change within technologies and addresses the support needed for both scenarios may be most successful.

Change is Hard

Regulatory authorities may be hesitant to accept new technology such as electronic source data due to concerns about security of source data, loss of data, and access by site. Change is also hard at the clinical research site level, which will carry much of the additional administrative burden of managing risks with new technology. For example, in the initial stages of introducing electronic case report forms, paper copies may need to be maintained as a backup to ensure regulatory compliance.

Technology Changes Rapidly

While dealing with potentially slow acceptance of change brought by new technologies, the HIV prevention field will at the same time need flexibility to respond to the rapid pace of change within technologies. Future-proofing is often impossible in this setting. Sponsors and research organizations should expect rapid obsolescence and continuing need for upgrading, refreshing, and tailoring as technology changes. For example, when using mobile data applications, offline solutions can quickly become obsolete because 4G cellular networks now have dense coverage in some countries [53].

New technologies do not obviate the need for responsible data processes, including continuing review of consent, privacy, security, ownership, and transparency. These practices are particularly important in changing legal environments. For example, if biometric information is collected in clinical trials, data security will need to be reassessed if the government develops national fingerprint or facial recognition databases, which would allow identification of participants.

Support is Critical

Infrastructure issues were noted as an expected key element for technology support. Despite the growth in reliable power and Internet systems globally, infrastructure weaknesses still complicate computer system use. Power outages, Internet connectivity, and local-area network (LAN) issues all require interventions to improve utilization and acceptance of digital technologies. In a study using cloud-based fingerprint biometric tracking, Internet connectivity frustrated site staff and led to a relatively high failure rate for fingerprint matching (N Kiwanuka, personal communication).

Technical support for staff can be challenging where staff are clinically trained but not fluent in technology. In one setting, the majority of clinically qualified staff trained to use a tablet technology had not worked with a touchscreen before [11]. Trial participants also require support for use of new technologies, particularly mobile health apps.

Whereas on-site support and partnering with local equipment vendors for on-site service can be useful, several investigators felt that specialized technologies were better suited to a central-help desk. As additional new technologies become available, often with different support requirements and a limited expertise-base, the ability to successfully provide technical support may be the limiting factor in expanded use of new clinical trial technologies, not regulatory authorities or user acceptance.

Summary

Digital technologies, especially if used in novel ways, provide a number of potential advantages to clinical research in trials related to HIV and AIDS and may greatly facilitate operations as well as data collection and analysis. These technologies may even allow answering questions that are not answerable with older technologies. However, they come with a variety of potential concerns for both the participants and the trial sponsors. The exact challenges and means for alleviation depend on the technology and on the population in which it is deployed. Nevertheless, in this guidance we aimed to summarize some common themes that are frequently encountered by researchers in this context and should be carefully considered before making a decision to include these technologies in their research. Finally, we encourage researchers to seek advice from organizations with past history and experience of applying digital technologies in HIV and AIDS clinical research.

Acknowledgments

The workshop and the follow-up discussions have been funded and organized by the Global HIV Vaccine Enterprise.

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The following people contributed to the development of these considerations at the workshop and via electronic communication: Iyore Ayanru, Andrew Beyer, Trevor Crowell, Alix Dunn, Esther Estes, Patricia Fast, Mathew Ferguson, Michele Fong Lim, Huub Gelderblom, David Glidden, Shannon Grant, Peter Guarino, Scott Hammer, Stacey Hannah, Christina Harris, David Hilmer, Matthew Johnston, Sarah Joseph, Julie Jouguelet, Anatoli Kamali, Dagna Laufer, Bhavna Maharaj, Megan McBride, Stan Mierzwa, Matthew Moyer, Harriet Park, Philip Renzullo, Gabriella Scarlatti, Peter Simpson, William Snow, Lisa Sunner, Thania Thorne, Bargavi Thayagarajan, Michael van der Ven, Carl Verlinde, Steven Wakefield, and Sabrina Welsh.

Dr Andriesen is supported by the HIV Vaccine Trials Network SDMC grant: NIAID UM1 AI068635. Dr Haberer receives grant funding from the National Institutes of Health, Bill and Melinda Gates Foundation, and USAID. Dr Dietrich received a Thuthuka post PhD funding award (2014-2016) from the South African National Research Foundation (NRF). Any opinion, finding, and conclusion or recommendation expressed in this material is solely the responsibility of the authors and does not necessarily represent the official views of the NIAID, National Institutes of Health (NIH), or SA NRF.

This work was funded in part by IAVI and made possible by the support of many donors, including the Bill & Melinda Gates Foundation, the Ministry of Foreign Affairs of Denmark, Irish Aid, the Ministry of Finance of Japan in partnership with The World Bank, the Ministry of Foreign Affairs of the Netherlands, the Norwegian Agency for Development Cooperation (NORAD), the United Kingdom Department for International Development (DFID), and the United States Agency for International Development (USAID). The full list of IAVI donors is available at the IAVI website. The contents of this manuscript are the responsibility of IAVI and do not necessarily reflect the views of USAID or the US Government.

We also thank Adam Winters and Iris Corbasson for excellent technical assistance in preparation of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AIDS: acquired immune deficiency syndrome
HIV: human immunodeficiency virus
JMIR: Journal of Medical Internet Research
LAN: local area network
PIN: personal identification number
RCT: randomized controlled trial
SMS: short message service
USSD: unstructured supplementary service data

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Edited by A Keepanasseril; submitted 15.02.17; peer-reviewed by I Montagni, J Zhang; comments to author 09.03.17; revised version received 26.04.17; accepted 29.04.17; published 31.07.17.

Please cite as:
Andriesen J, Bull S, Dietrich J, Haberer JE, Van Der Pol B, Voronin Y, Wall KM, Whalen C, Priddy F
Using Digital Technologies in Clinical HIV Research: Real-World Applications and Considerations for Future Work
J Med Internet Res 2017;19(7):e274
URL: http://www.jmir.org/2017/7/e274/
doi:10.2196/jmir.7513
PMID:28760729

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Corrigenda and Addenda

Correction: “You Sort of Go Down a Rabbit Hole...You’re Just Going to Keep on Searching”: A Qualitative Study of Searching Online for Pregnancy-Related Information During Pregnancy

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Related Article:

Correction of: http://www.jmir.org/2017/6/e194/

(J Med Internet Res 2017;19(7):e223) doi:10.2196/jmir.8227

The artice titled, “‘You Sort of Go Down a Rabbit Hole...You’re Just Going to Keep on Searching’: A Qualitative Study of Searching Online for Pregnancy-Related Information During Pregnancy” [J Med Internet Res 2017;19(6):e194], had several citation errors. These in-text citation errors have been corrected, as well as the resulting error in the numbering of the references, as follows:

“It would be beneficial for health professionals to provide pregnant women with information on reliable online sources and highlight them to the potential dangers of forums. HCP should suggest suitable sites to empower people [12], especially since previous research highlighted this as a concern for midwives that more and more pregnant women are searching information online [13].”

“This and prior research [5] note the dangers of seeking health information online due to the element of bias toward having access to “worst case scenarios.”

The old reference 13 (McManus) was deleted. The corrected and renumbered list of references appears below and in the corrected paper, re-published on the JMIR website on July 13, 2017, together with the publication of this correction notice. Because this was made after submission to PubMed, the correction notice has been submitted to PubMed. The corrected metadata have also been resubmitted to CrossRef.

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Edited by G Eysenbach; submitted 16.06.17; ###Reviewer names will be inserted here### published 13.07.17.

Please cite as:
Prescott J, Mackie L
Correction: "You Sort of Go Down a Rabbit Hole...You're Just Going to Keep on Searching": A Qualitative Study of Searching Online for Pregnancy-Related Information During Pregnancy
J Med Internet Res 2017;19(7):e223
URL: http://www.jmir.org/2017/7/e223/
doi:10.2196/jmir.8227
PMID:30578202

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