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Original Paper

Effects of a Web-Based Computer-Tailored Game to Reduce Binge Drinking Among Dutch Adolescents: A Cluster Randomized Controlled Trial

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Abstract

Background: Binge drinking among Dutch adolescents is among the highest in Europe. Few interventions so far have focused on adolescents aged 15 to 19 years. Because binge drinking increases significantly during those years, it is important to develop binge drinking prevention programs for this group. Web-based computer-tailored interventions can be an effective tool for reducing this behavior in adolescents. Embedding the computer-tailored intervention in a serious game may make it more attractive to adolescents.

Objective: The aim was to assess whether a Web-based computer-tailored intervention is effective in reducing binge drinking in Dutch adolescents aged 15 to 19 years. Secondary outcomes were reduction in excessive drinking and overall consumption during the previous week. Personal characteristics associated with program adherence were also investigated.

Methods: A cluster randomized controlled trial was conducted among 34 Dutch schools. Each school was randomized into either an experimental (n=1622) or a control (n=1027) condition. Baseline assessment took place in January and February 2014. At baseline, demographic variables and alcohol use were assessed. Follow-up assessment of alcohol use took place 4 months later (May and June 2014). After the baseline assessment, participants in the experimental condition started with the intervention consisting of a game about alcohol in which computer-tailored feedback regarding motivational characteristics was embedded. Participants in the control condition only received the baseline questionnaire. Both groups received the 4-month follow-up questionnaire. Effects of the intervention were assessed using logistic regression mixed models analyses for binge and excessive drinking and linear regression mixed models analyses for weekly consumption. Factors associated with intervention adherence in the experimental condition were explored by means of a linear regression model.

Results: In total, 2649 adolescents participated in the baseline assessment. At follow-up, 824 (31.11%) adolescents returned. The intervention was effective in reducing binge drinking among adolescents aged 15 years (P=.03) and those aged 16 years when they participated in at least 2 intervention sessions (P=.04). Interaction effects between excessive drinking and educational level (P=.08) and between weekly consumption and age (P=.09) were found; however, in-depth analyses revealed no significant subgroup effects for both interaction effects. Additional analyses revealed that prolonged use of the intervention was associated with stronger effects for binge drinking. Yet, overall adherence to the intervention was low. Analyses revealed that being Protestant, female, younger, a nonbinge drinker, and having a higher educational background were associated with adherence.

Conclusions: The intervention was effective for adolescents aged 15 and 16 years concerning binge drinking. Prevention messages may be more effective for those at the start of their drinking career, whereas other methods may be needed for those with a longer history of alcohol consumption. Despite using game elements, intervention completion was low.

Trial Registration: Dutch Trial Register: NTR4048; http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=4048 (Archived by WebCite® at http://www.webcitation.org/6eSJD3FiY)

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KEYWORDS

adolescents; alcohol drinking; binge drinking; cluster randomized controlled trial; serious games; computer tailoring

Introduction

Alcohol use in adolescents, especially dangerous drinking practices such as binge drinking (drinking ≥4/≥5 glasses of alcohol in one occasion for a girl/boy) and excessive drinking (drinking ≥10 glasses of alcohol on one occasion) [1], are associated with detrimental long- and short-term consequences. Alcohol use is the cause of 26% of all deaths in males and 10% of all deaths in females between the ages of 15 and 29 years in Europe [2]. Also, short-term consequences, such as physical fighting and injuries [3], dating violence, unintended pregnancies, and illicit drug use [4-6], are severe and influential experiences for adolescents. Particularly, the influence of alcohol on the developing brain can lead to serious brain damage, cognitive deficits, and learning disabilities [7-9].

In the Netherlands in 2011, 57.4% of adolescents aged 16 years and 61.9% aged 17 to 18 years reported that they had engaged in binge drinking at least once in the previous 30 days [10], with significantly more boys reporting binge drinking (70.5%) than girls (53.1%). Compared to other European countries, this is relatively high [11]. Moreover, a Dutch survey from 2013 shows that of the 16-year-old adolescents who reported drinking alcohol in the previous month, 79.9% also reported binge drinking [12]. However, these data were collected when adolescents were allowed to buy alcoholic beverages with an alcohol content of less than 15% when they turned 16 years of age (as of January 1, 2014, the legal age to buy any alcoholic beverages was increased to 18 years). Still, these adolescents grew up in an environment where drinking from the age of 16 was acceptable and relatively common [10], as the previously mentioned surveys show. Hence, targeting adolescents' motivation to decrease alcohol use and binge drinking is important.

Changing alcohol use in adolescents could be achieved with the help of Web-based computer-tailored interventions [13]. In the Netherlands, 97% of the population aged between 12 and 65 years has access to the Internet [14]. Differences in access between Dutch social classes range from 92% for lower-educated adolescents to 99% for higher-educated adolescents. Thus, Web-based computer-tailored health interventions have the potential to reach many people from various social classes and ages. These interventions provide the opportunity to tailor health messages to individual characteristics of the recipient (eg, demographics and motivational variables), which result in highly personalized and relevant messages that are more likely to attract attention [15]. Computer-tailored interventions have been shown repeatedly to effectively change various health behaviors and their determinants [16-18], although their effect sizes are generally small to medium. However, Web-based computer-tailored interventions suffer from high dropout rates (eg, one study reported a 37% dropout rate after 6 months [13] and another a 72% dropout rate after 12 months [19]; the mean adherence rate to Web-based health interventions is 50% [20]) with at least 2 negative consequences. First, high dropout rates during the intervention result in nonexposure to the intervention leading to reduced public health impact. Second, high dropout rates also result in less power to reveal intervention effects at follow-up because people who drop out during the intervention are also not likely to participate in a follow-up assessment [21].

This is related to a general difficulty engaging adolescents in health interventions [22,23]. Yet, using serious games (ie, games with the goal to educate people rather than merely entertain them) [24,25] to change health behaviors could lead to more attraction and participation [26,27], increased knowledge, and changed attitudes and behavior [24,25]. Consequently, our study employed a serious game as a method to provide computer-tailored feedback.

Furthermore, parents still play an important role in preventing adolescents from drinking too much alcohol. Studies have shown that setting clear rules [28,29] and good quality communication with the child about alcohol [30,31] has positive effects on the child in terms of less alcohol consumption. However, another study suggests that communication between parents and adolescents is virtually absent when Dutch adolescents turn age 16 [32]. Therefore, we also provided computer-tailored feedback to parents concerning how to set clear and consistent rules with regard to alcohol use and how to communicate clearly with their child about alcohol.

The aim of this study was to test the effectiveness of a Web-based computer-tailored intervention after 4 months to reduce binge drinking (ie, drinking ≥4/≥5 glasses of alcohol for a girl/boy on one occasion) in Dutch adolescents aged 15 to 19 years; as a secondary outcome, we also assessed the effects of the intervention on excessive alcohol use (ie, drinking ≥10 glasses of alcohol on one occasion) and alcohol consumption during the previous week (ie, the sum of glasses consumed during the previous week). Furthermore, we assessed differential intervention effects concerning age, gender, and educational level.

Methods

Study Design

As of January 1, 2014, the legal age to purchase alcohol in the Netherlands increased from 16 to 18 years [33], which had some implications for our study design. Originally, the baseline assessment was planned for October 2013 and the follow-up assessment for April 2014. However, to avoid the law change (and its potential impact on drinking behavior) taking place

between the baseline and follow-up assessments, we delayed the baseline assessment until after the law change was in effect in January 2014. Furthermore, we decided on a 4-month follow-up assessment instead of a 6-month follow-up because a 6-month follow-up assessment would have fallen in the summer vacation period.

We conducted a cluster randomized controlled trial (RCT) (trial registration number: NTR4048), randomizing Dutch schools of either lower secondary education and lower vocational training or higher secondary education into an experimental and a control condition. The experimental condition received the online intervention in the form of a game that contained computer-tailored feedback. The control condition only filled in the online baseline questionnaire. Both groups were given an online follow-up assessment after 4 months, responding to the same questionnaire as used in the baseline assessment. The study took place in the Netherlands between January and June 2014.

Participants and Procedure

Adolescents were recruited in schools. Information letters addressed to teachers and coordinators of the highest grades at secondary education schools (grades 4-6) and at vocational training schools were sent via postal mail. These information letters informed the teachers about the intervention and provided contact details and the address of the study website, so schools could obtain more information and subscribe to the study. All eligible schools in the Netherlands (approximately 600 schools) received an invitation. If schools did not respond, they were called 2 to 3 weeks later. Schools were randomly assigned to either the experimental or control condition after their consent to participate in the study. Schools were not blind to their condition because experimental schools had to plan 3 lessons for the intervention (one lesson for the baseline assessment and first game session, a second lesson for the second and third game session, and a third lesson for the 4-month follow-up assessment) and control schools had to plan 2 lessons (the baseline assessment and the 4-month follow-up).

Approximately 3 weeks before the intervention started, teachers were provided with a letter containing more information about the procedure, privacy, and confidentiality. All adolescents in the classes were provided with a letter on the day of the intervention to avoid them starting the intervention prematurely. The letter informed the adolescents that all their answers in this study would never be shared with teachers, parents, or any other third person; would be used for research purposes only; would be analyzed anonymously; and that they could end participation at any point in time. Adolescents were also made aware that, at the end of the study, they would participate in a lottery for 300 gift vouchers worth €25 each. Furthermore, adolescents were provided with a letter for their parents. In this letter, the parents were informed that their child participated in an online alcohol intervention at school and the parents were invited to visit a separate website specifically for parents, where they could take part in the parental component of the intervention. When starting with the intervention, teachers asked the adolescents to visit the study website and create an account. They were routed to the according condition (either control or experimental) based on the school they attended. Before starting with the baseline questionnaire, all adolescents had to check a box on the first page of the website that contained informed consent information confirming their informed consent. If they did not wish to participate or refused to provide informed consent, they could check an “I do not wish to participate in this study” box; they were thanked and could then close the intervention website (see Multimedia Appendix 1 for the CONSORT eHealth checklist filled out for this study).

Inclusion Criteria

Our main target group was adolescents aged 16 to 18 years. Because we were recruiting the adolescents in schools, we also included younger (15 years) and older (19 years) adolescents because they are often in the same class. Schools had to provide the adolescents with individual access to a computer with Internet connection.

Intervention

The idea of a game instead of a purely text-based computer-tailored intervention was first brought up by adolescents during focus group interviews [32]. During the development of the intervention, all materials and questions concerning the game (eg, its name, screenshots and characters of the game, realistic scenarios after drinking too much alcohol, realistic advice for adolescents who are trying to drink less in tempting situations, layout and design of the first version of the game) were presented to a Facebook panel. This panel consisted of a convenience sample of 24 adolescents aged 16 to 18 years, who provided us with feedback on those materials. The feedback was used to adapt the game to match the desires of the target group as closely as possible. After the development was completed, the game was pilot-tested at 5 schools to test the feasibility of the recruitment strategy, the design, and the content of the intervention. In total, 481 adolescents played the first game session and provided us with feedback about appreciation, comprehension, attractiveness, and level of personalization of the game. They were also asked about what they liked and disliked about the game. Based on this pilot, we shortened the game and the feedback messages were shortened and rewritten by a professional writer to make them more appealing to our target group. Originally, only the first game session was offered in the school and the adolescents were asked to continue with the game at home. After reviewing the feedback and the pilot data, we decided to make some changes to the design and to offer all 3 game sessions within the school setting.

The intervention, Alcohol Alert, consisted of an online baseline questionnaire, after which the adolescents played 3 sessions of the game “What happened?!”. In these game sessions, the adolescent wakes up after a night of partying and does not remember what happened the night before. The goal of this 2-dimensional game was to find out what happened. Each of the game sessions depicted one of the most common drinking situations for adolescents (ie, drinking at home, drinking in a bar, drinking at a party). The sequence of the 3 game sessions was tailored and dependent on how many glasses of alcohol the adolescent indicated to typically drink in each of these situations. The adolescent started with the drinking situation in which he or she indicated drinking the most alcohol. Thus, if the

adolescent indicated typically drinking 3 glasses at home, 5 glasses at a party, and 6 glasses in a bar, he or she would start with the bar scenario first, followed by the party scenario, and finally the home scenario. Each session started in the bedroom where the adolescent wakes up. The adolescent quickly discovers that something is wrong (eg, the wallet is missing in one session). The adolescent then navigates through different places in the game and talks to people he or she meets and gets clues about what happened the previous night (Figure 1).

During the game sessions, the adolescent received questions and feedback on an in-game cell phone (Figure 2). These questions and feedback were based on the I-Change Model [34], an integrated model based on theories such as the Attitude-Social Influence-Self-Efficacy Model [35], the Theory of Reasoned Action [36], the Theory of Planned Behavior [37], Social Cognitive Theory [38], the Health Believe Model [39], the Precaution Adoption Model [40], and the Transtheoretical Model [41]. The I-Change Model attempts to explain motivational and behavioral change and has been successfully used to design and evaluate health interventions previously [19,42,43]. The questions and computer-tailored feedback were based on the relevant concepts of the I-Change Model (ie, attitude, modeling, social norm, perceived pressure, and self-efficacy). Within the game, this was operationalized by presenting the in-game cell phone twice during every game session. During the first presentation of the first game session, the adolescents were asked questions about their attitude toward binge drinking and received immediate feedback to try to shift their attitude about binge drinking to be less positive. The first time the in-game cell phone was presented in the second scenario, questions about modeling of alcohol use and binge drinking were asked (ie, who in their family and friends engaged in binge drinking), and feedback was provided to help the adolescents to choose the right role models. The first time the cell phone was presented in the third scenario, questions concerning social norms (ie, if parents and friends approved of drinking) and perceived pressure (ie, whether the adolescents perceived pressure to binge drink from family or friends) were posed and the feedback messages tried to encourage adolescents to resist that pressure. The second time the cell phone was presented during each scenario, questions about situation-specific self-efficacy were posed (eg, in the bar scenario adolescents were asked how difficult it is for them not to binge drink in a bar). Feedback was provided to enhance self-efficacy and the adolescent was provided with action plans that he or she could use in that particular situation. We decided on this sequence based on the Ø pattern [44], which describes that people shift toward behavior change through first developing a favorable attitude, experiencing positive social influences, and finally developing high self-efficacy toward the behavior.

The content and methods used in the feedback messages varied depending on the message, but usually the answer of the respondent was repeated to enhance self-monitoring, correct assumptions were confirmed with positive feedback, and wrong assumptions were corrected with new information. All messages had a personal tone to show sympathy and to enhance commitment [45]. For example, the attitude questions assessed the pros (eg, “binge drinking helps me relax and connect easily with other people”) and cons (eg, “binge drinking makes me feel like I am losing control”) of binge drinking. The adolescent immediately received feedback on his or her overall attitude and for every pro and con specifically. In these feedback messages, the focus was on providing the participant with general (eg, “alcohol inhibits your brain’s natural inhibition system”) and personal (eg, “you might say or do things that you regret later”) consequences of alcohol to change attitude toward binge drinking to a more negative one. For more information about the content of the feedback messages, we refer to our study protocol [46]. Adolescents received 2 reminder emails to finish the game sessions if they did not do so at school; the first after 1 week and the second after 2 weeks. A week after the third game session, the adolescents were invited to revisit the intervention and received 2 reminder emails; the first after 1 week and the second after 2 weeks if they did not return. In this fourth session, which was not part of the game, alcohol use during the last week was assessed and the adolescents were provided with feedback about their use compared to Dutch drinking guidelines. Following this, the adolescents were asked if they had an event in the upcoming 30 days (eg, a party, wedding) where they usually drink 4 (for girls) / 5 (for boys) or more glasses of alcohol on such an occasion. If they responded positively, they were asked if they wanted to challenge themselves to drink less than they usually would. If they responded positively again, they were asked to indicate the date of the event and how many glasses they wanted to drink at most. They could then make their own action plans for how to achieve their goal or they could indicate from a list of action plans which one they would most likely follow to achieve their goal. If adolescents indicated that they had no event in the upcoming 30 days or that they did not wish to participate in the challenge, they only received advice on how action plans could help them to prevent binge drinking in the future. At the end of the fourth session, all adolescents were provided with the feedback they received during the game to boost their memory. One day before the drinking event, they were reminded by email that they accepted a challenge to drink less alcohol than they usually would for the event the next day. Two days after the event, they were invited to come back to the website to indicate if they met their goal. Reminder emails were sent after 1 and 2 weeks if they did not return. If they indicated they drank more than they had planned, they received feedback on how to do better next time and were given the opportunity to repeat the challenge. If they indicated that they had not exceeded their drinking maximum, they received congratulations and the intervention was over. For a detailed description of the development and the content of the intervention, we refer to the study protocol of this study [46].

After 4 months, the adolescents in both conditions responded to the online follow-up questionnaire in school. If they did not finish the follow-up assessment at school, they received 2 reminders to do so at 1 and 2 weeks after the official deadline for the schools.

Figure 1. Screenshot example from the game (In the bar: "No problem. I would suggest you keep it down a little next time...").

Figure 2. Screenshot example of the in-game cell phone (Question: "If I drink 4 glasses of alcohol or more I feel like I am losing control").

Parental Component

A separate component was added to the intervention to involve parents. During the development, a convenience sample of 14 parents provided us with feedback on the layout, usability, and content of the parental component. At baseline, adolescents in the experimental condition were asked to enter the email address of one of their parents. Parents then received an email inviting them to a separate website, where parents responded to a short questionnaire and could also receive computer-tailored feedback on how to set appropriate rules concerning alcohol use and how to communicate with their child about alcohol use. If the adolescent did not know the email address of the parent or did not wish to send an email to the parent, they could refuse to do so. They were informed that the letter they received for their parents contained all the information about the parental component and instructions on how parents could participate. A detailed description of the parental component can be found in the study protocol [46].

Measures

Demographics

At baseline, we assessed gender (0=female, 1=male), age (in years), educational level (1=higher secondary education, 0=lower secondary education and vocational training), religion

(Catholic, Protestant, Muslim, other religion, no religion), and ethnicity (Dutch, Antilles, Belgium, German, Suriname, Moroccan, Turkish, other; later dichotomized into 0=non-Dutch, 1=Dutch).

Binge Drinking, Excessive Drinking, and Weekly Consumption

We assessed different forms of alcohol use at baseline and at the 4-month follow-up. We assessed binge drinking, the primary outcome, with an open-ended question: "How often did you drink 4 (for girls) / 5 (for boys) or more glasses of alcohol on one occasion in the previous 30 days?" [47]. Binge drinking was later dichotomized (0=reported no binge drinking, 1=reported binge drinking). Furthermore, we assessed alcohol use in the previous week with 2 questions: "On which days during the past week did you drink alcohol?" (Monday to Sunday, I haven't drank in the past week, I never drink any alcohol) and how many glasses of alcohol they drank on each of the drinking days if they indicated that they drank at least one day during the past week. Weekly consumption was calculated by counting the total number of glasses they drank in the past week [48]. Finally, someone was characterized as an excessive drinker if they had at least one drinking occasion of 10 or more glasses of alcohol [1] during the previous week. Weekly consumption and excessive drinking were considered as secondary outcomes [46].

I-Change Concepts (Attitude, Modeling, Social Norm, Perceived Pressure, Self-Efficacy)

For a description on how these concepts were assessed, we refer to the study protocol [46]. Reliability and validity information about these concepts are presented in Table 1. The eigenvalue presents an estimate of the explained variance and should be at least 1 [49]. The McDonald hierarchical omega is an estimator for factor saturation regarding the general factor; the value is a less-biased alternative to Cronbach alpha [50]. Both indexes support comprehensive assessment of questionnaire quality [51].

Table 1. Eigenvalues and omega of the I-Change concepts.

Scale	Eigenvalue	Omega	Cronbach alpha
Pros	3.09	.87	.90
Cons	2.55	.78	.81
Modeling of alcohol use	2.75	.68	.74
Modeling of binge drinking	2.67	.46	.72
Social norm	4.37	.83	.92
Perceived pressure	4.69	.85	.94
Self-efficacy	6.41	.81	.94

Adherence

Adherence was assessed by counting the number of intervention sessions (not the baseline assessment or follow-up assessment) in which the adolescent participated ranging from zero (did not participate in a single intervention session) to 5 (participated in all 5 intervention sessions).

Power Analyses

The primary outcome was the difference in number of binge drinking occasions in the preceding 30 days for the experimental group compared to the control group. Based on prevalence data from the time the study was designed, we aimed at reducing reported binge drinking occasions from 70% to 60% in the previous 30 days. We used the Optimal Design Plus Empirical Evidence (version 3.0) program [52]. Because adolescents were nested in schools, a cluster RCT was needed. Using a conservative approach with an estimated intraclass correlation coefficient of .02, power of .80, significance level of .05, with approximately 100 students participating per school, and considering dropout of 50% of adolescents at primary follow-up, the program indicated that 30 schools should be included. To correct for unequal numbers of students per school, we added 14% more schools [53] and aimed to include 34 schools at baseline.

Statistical Analyses

This study constituted a design with 3 levels: repeated measurements, nested within adolescents, nested within schools. The data were analyzed using SPSS version 20. Descriptive statistics were used to describe the characteristics of the baseline sample. Differences between the conditions in the baseline sample were assessed using *t* tests for continuous variables and chi-square tests for discrete variables. Chi-square tests and *t* tests were further used to describe differences between completers and participants who did not return to the follow-up assessment after 4 months.

To determine the effectiveness of the program, we analyzed the data with a logistic regression mixed models analysis for the outcomes binge drinking and excessive drinking and a linear regression mixed models analysis for the outcome weekly consumption. These models allow for dependencies among observations obtained for students within a school. These analysis models also allow for data missing at random, which is less strict than the requirement of data missing completely at random [54]. The variables (ie, condition, gender, age, educational level, religion, ethnicity, parental participation) as well as the interaction effects between condition and gender, age, and educational level were entered as covariates into the analyses.

The associations between potential participant characteristics (gender, age, educational level, religion, ethnicity, and binge drinking at baseline) and adherence (ie, the number of intervention sessions the participant passed through) to the intervention were analyzed using a linear regression model.

Main effects were considered significant if $P \leq .05$. Interaction effects were considered significant if $P \leq .10$.

Ethics Committee Approval

This trial was reviewed by the Medical Ethics Committee of Atrium Orbis Zuyd and was classified as research that does not fall under the Medical Research Involving Human Subjects Act and needed no further approval (METC number: 12-N-104).

Results

Participation and Attrition

Figure 3 depicts a flowchart of the participating schools. In total, 44 schools were randomized into the experimental or control condition. Five schools in the control condition withdrew their participation before the baseline assessment started (2 schools of secondary higher education, 1 school of secondary lower education, 1 school of lower vocational training, and 1 school of secondary education mixed). Three schools in the control condition (all secondary higher education) and 2 schools in the experimental condition (1 lower vocational education, 1 higher secondary education) did not start with the baseline assessment and did not respond to our phone calls and emails. Most schools that dropped out before the intervention started indicated that they had logistical problems (eg, they had no computer room available to provide every adolescent with his or her own computer). Another school decided after randomization that the topic was too sensitive and they did not want to do that at school. In total, 2649 adolescents from 34 schools participated in the baseline questionnaire. The adolescents in the 2 conditions significantly differed from each other in various characteristics. Participants in the experimental condition were significantly younger, consisted of more females, had a higher educational level, more often indicated to be religious, and consisted of more participants who never drink, were less often binge and excessive drinkers, and had a lower weekly consumption than participants in the control condition (Table 2). Even though 27 schools participated in the 4-month follow-up questionnaire, only 824 of 2649 adolescents (response rate 31.11%) did so. Schools that withdrew participation at the follow-up assessment either reported trouble with finding a date due to the final exams of the classes or indicated that the adolescents were not keen to continue with the intervention and, therefore, the school decided to stop participation. Dropout analyses revealed that adolescents returning to the follow-up questionnaire were significantly younger, more often female, had a higher educational level, were more likely be religious, were more often Dutch, were less likely to be excessive drinkers, less likely to be binge drinkers, and had a lower weekly consumption (Table 3).

Figure 3. Flowchart of participation.

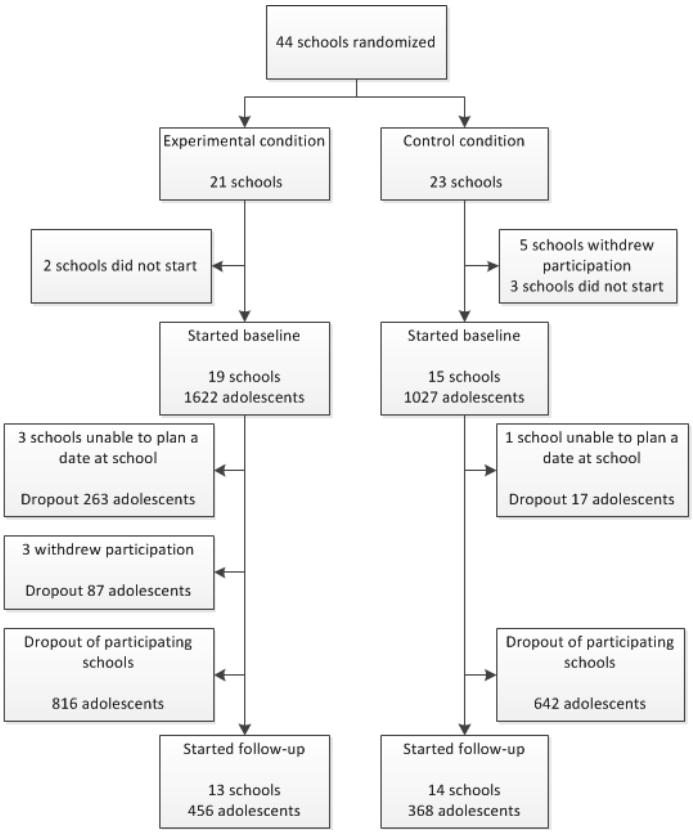

Table 2. Baseline characteristics of participants and differences between the experimental and control groups at baseline.

Variable[a]	Total N=2649	Experimental n=1622	Control n=1027	Baseline difference		*P*
				t (*df*)	χ^2 (*df*)	
Age (range 15-19 years), mean SD (missing=16)	16.3 (1.2)	16.0 (1.2)	16.7 (1.2)	15.01 (2633)		<.001
Gender, n (%) (missing=11)					38.6 (1)	<.001
Male	1395 (52.66)	766 (47.23)	629 (61.25)			
Female	1243 (46.92)	847 (52.22)	396 (38.56)			
Educational level, n (%) (missing=11)					92.6 (1)	<.001
High	1546 (58.36)	1056 (65.10)	490 (47.71)			
Low	1092 (41.22)	557 (34.34)	535 (52.09)			
Religion, n (%) (missing=17)					33.2 (4)	<.001
Catholic	610 (23.03)	407 (25.09)	203 (19.76)			
Protestant	180 (6.79)	133 (8.19)	47 (4.58)			
Muslim	165 (6.23)	82 (5.06)	83 (8.08)			
Other	131 (4.95)	81 (4.99)	50 (4.87)			
No religion	1546 (58.36)	907 (55.92)	639 (62.22)			
Ethnicity, n (%)					1.7 (1)	.19
Dutch	2326 (87.81)	1434 (88.41)	892 (86.85)			
Non-Dutch	323 (12.19)	188 (11.59)	135 (13.15)			
Alcohol use, n (%)						
Never	710 (26.80)	491 (30.27)	219 (21.32)		25.4 (1)	<.001
Binge drinking (missing=3)	1343 (50.70)	758 (46.73)	585 (56.96)		26.3 (1)	<.001
Excessive drinking (missing=18)	245 (9.25)	116 (7.15)	129 (12.56)		21.5 (1)	<.001
Weekly consumption, mean (SD) (missing=18)	4.0 (9.4)	3.4 (8.9)	5.1 (9.9)	4.57 (2631)		<.001
Parental participation						
Invited by adolescent, n		199	—			
Start, n (%)		91 (45.7)	—			
End, n (%)		76 (83.5)	—			

[a] Number of missing values per variable indicated as “missing.”

Table 3. Differences between adolescents that returned or dropped out at follow-up.

Variable[a]	Returned n=824	Dropped out n=1825	Dropout difference		*P*
			t (*df*)	χ^2 (*df*)	
Age (range 15-19 years), mean SD (missing=16)	16.2 (1.2)	16.4 (1.3)	–3.87 (2633)		<.001
Gender, n (%) (missing=11)				20.8 (1)	<.001
Male	381 (46.3)	1014 (55.56)			
Female	442 (53.7)	801 (43.89)			
Educational level, n (%) (missing=11)				68.0 (1)	<.001
High	579 (70.4)	967 (52.98)			
Low	244 (29.6)	848 (46.46)			
Religion, n (%) (missing=17)				9.5 (4)	.049
Catholic	208 (25.3)	402 (22.03)			
Protestant	46 (5.6)	134 (7.34)			
Muslim	46 (5.6)	119 (6.52)			
Other	31 (3.8)	100 (5.48)			
No religion	490 (59.7)	1056 (57.86)			
Ethnicity, n (%) (missing=0)				10.7 (1)	.001
Dutch	749 (90.9)	1577 (86.41)			
Non-Dutch	75 (9.1)	248 (13.58)			
Alcohol use, n (%)					
Never (missing=0)	229 (27.8)	481 (26.35)		0.5 (1)	.46
Binge drinking (missing=3)	370 (44.8)	973 (53.32)		16.7 (1)	<.001
Excessive drinking (missing=18)	50 (6.1)	195 (10.68)		14.6 (1)	<.001
Weekly consumption, mean (SD) (missing=18)	2.8 (6.5)	4.6 (10.4)	–5.51 (2631)		<.001

[a] Number of missing values per variable indicated as "missing."

Binge Drinking

At the baseline assessment, 758 of 1622 (46.73%) adolescents in the experimental and 585 of 1027 (56.96%) adolescents in the control condition reported binge drinking in the previous 30 days. At the follow-up assessment, 194 of 456 (42.6%) adolescents in the experimental condition and 184 of 368 (50.0%) adolescents in the control condition reported binge drinking in the previous 30 days. The returning sample did not differ on baseline drinking characteristics. They did not differ on being a drinker (control: 274/368, 74.4%; experimental: 322/456, 70.6%; χ^2_1=1.3, *P*=.25) on binge drinking (control: 167/368, 45.4%; experimental: 203/456, 44.5%; χ^2_1=0.4, *P*=.83), on excessive drinking (control: 28/368, 7.6%; experimental: 22/456, 4.8%; χ^2_1=2.7, *P*=.10), nor on weekly consumption (control: mean 3.2, SD 6.9; experimental: mean 2.4, SD 6.1; t_{819}=1.62, *P*=.11). There was a significant interaction effect between condition and age (*P*=.08) (Table 4). Age groups were analyzed separately using the pick-a-point approach [55] by centering the age variable for each year from ages 15 to 19. This way, the whole sample could be used to determine whether the intervention was effective for one or more of the age groups. Information about binge drinking prevalence at baseline and follow-up per age group are available in Table 4. Analyses revealed a significant effect of the intervention in 15-year-old adolescents (*P*=.03). Adolescents in the experimental group reported a significant decrease in binge drinking in the previous 30 days at 4 months after the intervention ended compared to adolescents in the control condition. Adolescents in the experimental group aged 16 years also engaged less in binge drinking after 4 months compared to the control group. This effect was not significant (OR 0.56, 95% CI 0.30-1.05, *P*=.07) (Table 5), but could be considered a small effect [56]. Furthermore, although participation of parents was very low (Table 2), when parents participated in the intervention, their participating child reported less binge drinking in the previous 30 days (*P*=.04). A higher educational level (*P*<.001), a lower age (*P*<.001), and being Protestant (*P*=.03), Muslim (*P*<.001), or a member of another religion (*P*=.03) (all analyzed in a model without interaction terms) were significant protective determinants of binge drinking (Table 5).

Table 4. Prevalence rates of binge drinking per age group.

Age (years)	Experimental condition, n/n (%)		Control condition, n/n (%)	
	Baseline n=1608	Follow-up n=453	Baseline n=1025	Follow-up n=368
15	222/688 (32.2)	51/180 (28.3)	54/173 (31.2)	35/105 (32.7)
16	255/479 (53.3)	71/155 (45.8)	153/303 (50.5)	57/128 (44.5)
17	146/246 (59.3)	40/64 (63.5)	200/288 (69.4)	52/76 (68.4)
18	81/112 (72.3)	11/22 (50)	111/144 (77.6)	20/26 (76.9)
19	53/83 (64.6)	19/32 (59.4)	67/117 (57.3)	20/30 (66.7)
Total	757/1608 (47.13)	192/453 (42.5)	585/1025 (57.1)	184/368 (50.1)

Table 5. Effects of the intervention on binge drinking, excessive drinking and weekly consumption in the complete model.

Variable[a]	Binge drinking		Excessive drinking		Weekly consumption	
	OR (95% CI)	*P*	OR (95% CI)	*P*	β (SE)	*P*
Condition (control)	0.40 (0.18-0.83)	.01	0.48 (0.18-1.25)	.13	1.82 (1.39)	.19
Gender (male)	1.11 (0.93-1.33)	.24	3.69 (2.74-4.97)	<.001	–2.64 (0.36)	<.001
Parental participation (yes)	0.60 (0.37-0.97)	.04	0.78 (0.30-2.04)	.61	0.83 (0.95)	.38
Educational level (high)	0.54 (0.38-0.76)	<.001	0.57 (0.37-0.89)	.01	2.14 (0.71)	.002
Age	0.74 (0.68-0.82)	<.001	0.70 (0.62-0.78)	<.001	1.30 (0.18)	<.001
Religion (no religion)						
Catholic	0.99 (0.80-1.23)	.91	0.92 (0.69-1.23)	.58	–0.03 (0.44)	.95
Protestant	1.56 (1.08-2.25)	.02	1.95 (1.05-3.64)	.04	–1.06 (0.73)	.15
Muslim	6.59 (4.00-10.88)	<.001	1.94 (0.93-4.05)	.08	–1.26 (0.86)	.14
Other	1.57 (1.05-2.36)	.03	1.82 (0.95-3.48)	.07	–0.88 (0.81)	.28
Ethnicity (Dutch)	1.22 (0.88-1.71)	.25	1.50 (0.90-2.50)	.10	–0.47 (0.65)	.47
Interaction effects						
Condition × gender	1.12 (0.77-1.62)	.55	0.60 (0.31-1.13)	.11	–1.00 (0.74)	.17
Condition × educational level	1.13 (0.54-2.34)	.75	2.15 (0.91-5.10)	.08	–1.96 (1.49)	.19
Condition × age	1.19 (0.98-1.43)	.08	1.17 (0.92-1.48)	.21	–0.32 (0.37)	.39
Age 15 (control)	0.47 (0.24-0.91)	.03				
Age 16 (control)	0.56 (0.30-1.05)	.07				
Age 17 (control)	0.66 (0.34-1.28)	.22				
Age 18 (control)	0.79 (0.38-1.63)	.52				
Age 19 (control)	0.93 (0.40-2.17)	.87				
High educational level			1.48 (0.38-5.74)	.57		
Low educational level			0.46 (0.14-1.49)	.19		

[a] Reference category of categorical variables is indicated within parentheses.

Excessive Drinking

At the baseline assessment, 116 of 1622 (7.15%) adolescents in the experimental condition and 129 of 1027 (12.56%) adolescents in the control condition engaged in excessive drinking. At the follow-up assessment, 28 of 456 (6.1%) adolescents in the experimental and 37 of 368 (10.2%) adolescents in the control condition reported excessive drinking.

There was a significant interaction effect between condition and educational level (*P*=.08). However, further analyses revealed no significant subgroup effects for either higher- or lower-educated adolescents (Table 5). Protective determinants of excessive drinking were being female (*P*<.001), a higher educational level (*P*=.01), and being younger (*P*<.001).

Weekly Consumption

At baseline, adolescents in the experimental condition drank a mean of 3.4 (SD 8.9) standard glasses of alcohol in the previous week. Adolescents in the control condition drank a mean of 5.1 (SD 9.9) standard glasses of alcohol in the previous week. At the follow-up assessment, adolescents in the experimental condition reported a mean consumption of 3.3 (SD 7.7) and adolescents in the control condition reported a mean consumption of 4.6 (SD 8.9) standard glasses of alcohol during the previous week. Although the effects were in the expected direction, no significant effects of the intervention were found for weekly consumption. The analysis only revealed that being female (P<.001), having a higher educational level (P=.002), and being younger (P<.001) (all analyzed in a model without interaction terms) were significant determinants with a protective effect on weekly consumption (Table 5).

Adherence

After the baseline assessment, adolescents in the intervention condition were supposed to start with the first game session. Of 1622 adolescents who were randomized into the experimental condition, only 1097 (67.63%) started with the first game session. Only 467 adolescents (28.79%) returned to the second and only 347 (21.39%) adolescents to the third game session. Just 27 (1.66%) adolescents returned to the fourth session at home, and zero participated in the fifth home session.

Subsequently, to investigate the effects of adherence, we decided to rerun the analyses with the subsample of the group that completed the different game sessions. We made 3 groups: the first group consisted of all adolescents who participated in the first game session, the second group consisted of adolescents who also participated in the second game session, and the third group did all 3 game sessions. Descriptive analyses of prevalence of binge drinking per age group and per adherence group can be found in the Multimedia Appendix 2. The effects for binge drinking are summarized in Table 6.

Table 6. Results for binge drinking for adolescents who participated in 1 or more, 2 or more, and all 3 game sessions.

Age (years)[a]	≥1 session n=1097		≥2 sessions n=467		All 3 sessions n=347	
	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
Condition (control)	0.31 (0.14-0.66)	.003	0.14 (0.05-0.37)	<.001	0.13 (0.04-0.37)	<.001
Condition × age	1.34 (1.09-1.65)	.007	1.77 (1.31-2.40)	<.001	1.72 (1.23-2.40)	.002
15	0.41 (0.21-0.81)	.01	0.24 (0.11-0.57)	.001	0.22 (0.09-0.54)	.001
16	0.55 (0.29-1.04)	.07	0.43 (0.20-0.95)	.04	0.37 (0.16-0.87)	.02
17	0.74 (0.38-1.45)	.38	0.77 (0.33-1.78)	.54	0.64 (0.26-1.60)	.34
18	0.99 (0.46-2.12)	.98	1.36 (0.50-3.67)	.54	1.10 (0.37-3.27)	.86
19	1.33 (0.54-3.25)	.53	2.41 (0.73-8.02)	.15	1.89 (0.50-7.10)	.35

[a] Reference category of categorical variables is indicated within parentheses.

Again, we found a significant interaction effect with age for all 3 groups (P=.007 for adolescents that participated in at least 1 session; P<.001 for adolescents that participated in at least 2 sessions; P=.002 for adolescents that engaged in all 3 game sessions). When engaging in at least 1 session, only 15-year-old adolescents reported less binge drinking (P=.01). The effect sizes increased when 15-year-olds adhered longer to the intervention (after 1 session: OR 0.41, 95% CI 0.21-0.81; after 2 sessions: OR 0.24, 95% CI 0.11-0.57); after 3 sessions: OR 0.22, 95% CI 0.09-0.54). A similar pattern was found for 16-year-old adolescents. There was a significant effect of the intervention after 2 sessions (OR 0.43, 95% CI 0.20-0.95, P=.04) which became stronger after 3 sessions (OR 0.37, 95% CI 0.16-0.87, P=.02). There was no significant effect for older adolescents. The analyses for excessive drinking revealed a significant interaction effect between condition and educational level (OR 2.37, 95% CI 0.98-5.73, P=.05) for adolescents that adhered to at least 1 session. However, the subgroup effects for higher (OR 0.87, 95% CI 0.22-3.52, P=.85) and lower (OR 0.46, 95% CI 0.12-1.83, P=.27) educated adolescents were both not significant. Weekly consumption revealed a similar result with a significant interaction effect with educational level (β=–0.22, SE 1.27, P=.09) for adolescents that completed at least one session, but only small and nonsignificant subgroup effects for higher- (β=–0.19, SE 0.94, P=.84) and lower- (β=0.17, SE 2.68, P=.95) educated adolescents. Furthermore, there was a significant interaction effect between condition and age on weekly consumption for adolescents that completed at least 2 sessions (β=–0.99, SE 0.52, P=.05) and for those who completed at least 3 sessions (β=–1.03, SE 0.59, P=.08); however, although the effects were more positive for the younger age groups, no effect reached a significant level. Finally, significant predictors of adherence were being Protestant, being female, being younger, having a higher educational background, and being a nonbinge drinker (Table 7).

Table 7. Predictors of adherence (number of sessions completed by the adolescents).

Variable[a]	β (SE)	*P*
Catholic (no religion)	0.039 (0.049)	.05
Protestant (no religion)	0.097 (0.080)	<.001
Muslim (no religion)	–0.049 (0.100)	.03
Other religion (no religion)	–0.010 (0.095)	.62
Gender (female)	–0.046 (0.040)	.02
Age	–0.138 (0.018)	<.001
Nationality (not Dutch)	0.023 (0.075)	.33
Educational level (lower)	0.088 (0.044)	<.001
Binge drinking (not binge drinking)	–0.066 (0.042)	.001

[a] Religion was entered as a dummy variable (Catholic, Protestant, Muslim, other religion). Reference category of categorical variables is indicated within parentheses.

Discussion

In this study, a Web-based computer-tailored intervention to reduce binge drinking in adolescents aged 15 to 19 years was tested using a cluster RCT. An overall effect of the intervention on binge drinking behavior was not found, but the intervention was effective in reducing binge drinking in adolescents aged 15 and 16 years. No additional effects were found for the secondary outcomes, excessive drinking, and weekly consumption.

That interventions to reduce alcohol use in adolescents are more effective in younger adolescents is in line with previous work [57]. Our effect sizes suggest that the intervention effect increased when adolescents adhered more to the intervention. This effect was only visible in the adolescents aged 15 and 16 years. A reason why the intervention was more successful in younger adolescents could be that younger adolescents tend to be more susceptible to peer influences than older adolescents [58]. Particularly in the second and third game sessions, we focused on social influences, such as modeling, social norms, and perceived pressure to drink from family and friends. Younger adolescents may have benefited more from this than older adolescents. Furthermore, analysis of the determinants of adherence did indicate that adolescents who adhered to the intervention were significantly younger in comparison with those who stopped prematurely. If an intervention is not used the way it is supposed to be used, its impact on health and behavior will be very limited and the public health impact probably weakened [21]. The high dropout rate of the older adolescents could explain why no effect was detected in their age group. Most adolescents initiate alcohol use between the ages of 11 to 15 years. The mean age for Dutch adolescents to first try alcohol is 13 years; the mean age for starting to drink alcohol on a weekly basis is 15 years [10]. Consequently, a possibility is that older adolescents may already have developed a kind of habit of engaging in binge drinking and other change methods more focused on changing habits, such as counterconditioning or stimulus control, are needed [59]. This might also mean that the real effect of the intervention might be stronger after a longer time period because the younger adolescents might not develop such strong habits in the next 2 years. Another possibility why older adolescents tended to drop out more could be that the game was not as appealing to those adolescents as it was to younger adolescents. Qualitative process evaluations could give more insights into what adolescents liked and what they did not like, and thereby provide future interventions with valuable input.

Adherence rates generally were low. There was a clear drop in participation between the baseline assessment and the first game session and another significant drop between the first and second game sessions. The analyses of adherence indicated that females, Protestants, younger adolescents, and nonbinge drinkers adhered better to the intervention. Particularly the last finding is not atypical in health promotion. In an intervention targeting multiple lifestyle behaviors (including alcohol use), people who adhered more to the program were also adhering more to the national health guidelines [60]. In other words, people who behaved in a more unhealthy way dropped out earlier in the program. Another study found that people with an unhealthy lifestyle were more likely to visit a health intervention website, but that people with a healthier lifestyle were more likely to complete the health intervention [61]. Yet, as health promotion programs are particularly important for groups that do not already have a healthy lifestyle, further research is definitely needed to identify how to better involve binge-drinking adolescents. Perhaps more attention needs to be directed toward premotivational determinants, such as knowledge, cues to action, and risk perception [34,62]. Starting an intervention with the focus on these factors and raising awareness that there is a problem with binge drinking might increase adolescents' willingness to reconsider and change their behavior [63].

In our intervention, we tried to motivate adolescents to adhere to the intervention by designing a serious game that carried computer-tailored advice. Although we did not test the specific effect of the game on motivation (eg, by comparing it to a nongame intervention), adherence rates were far from optimal. A possible explanation might be that alcohol use is very common among Dutch adolescents [10,12,32] and adolescents probably do not feel the disturbing negative consequences of alcohol yet. Rather, they experience the positive aspects that

come with alcohol use, such as facilitating social interaction, and they might not want to change their alcohol use [64]. Furthermore, because participation was voluntary, adolescents were aware that they could stop participation at any point without having to indicate the reasons why. This could have caused adolescents to drop out of the intervention prematurely and is a consequence of the low threshold to participate in Web-based interventions (ie, it is easy to start participating but also as easy to stop participating).

Another point was that whole schools dropped out before and during the intervention. The differences in characteristics of adolescents who did not return to the follow-up assessment compared to those who did return (adolescents who dropped out were older, male, had a lower educational background, were less likely to be religious, were more often non-Dutch, were more likely to be binge drinkers, excessive drinkers, and had a higher weekly consumption) can partly be explained by the dropout of the whole school. Furthermore, comparable characteristics of people who dropped out of the follow-up assessment have been reported in other studies as well [13,19,42].

High dropout rates in Web-based interventions are not uncommon [16,65]; therefore, a 50% dropout rate was taken into account in the power calculation. However, dropout rates at follow-up were higher than the expected 50%, which could also result in too little power of the analyses to detect possible effects of this intervention [21]. Although we sent emails to remind adolescents to return to the intervention website, there might be other possibilities to increase revisiting numbers. Newer research is focusing on the content and timing [66] of those reminders and how other prompts, such as a text message to a mobile phone, can remind participants to revisit the intervention website [67].

Also important is our finding that parental participation in the parental component was associated with significantly lower rates of binge drinking among adolescents, which might be an indication that the parental component was an important addition to the intervention. However, due to methodological choices in parent recruitment (ie, adolescents invited their parents to participate), those data are observational rather than experimental and strong claims about the effect cannot be made. It is possible that other factors, such as family attachment, influenced the positive results. However, the low participation of parents is notable. On the one hand, just a small proportion of adolescents actually invited their parents to take part in the intervention. That could be an indication that adolescents do not feel the need or do not want to talk about the subject with their parents. On the other hand, of the 199 adolescents who invited their parents, which is likely a very selective group of adolescents already, only 91 parents actually visited the website. Other studies that focused on parent-child communication about risky sexual behavior also reported low attendance rates of parents [68,69]. Generally, interest in Internet-delivered interventions has been shown to be quite low [16,70]. It could also indicate that parents may not feel involved in the alcohol use of their child. This has also come to surface in focus group interviews held with adolescents and parents [32], where parents indicated that they stopped talking with their child about alcohol and stopped setting rules when they turned age 16. Even after the change in law, there seems to be no immediate change in this parental behavior.

A strength of this study is that it is theory-based and was preceded by extensive qualitative and quantitative research. Furthermore, the target group was included and consulted during the whole development process [32]. However, despite all these efforts to make the intervention as interesting and appealing to the target group as possible, the dropout rates were very high, which made it very difficult to reveal effects of the intervention. Further, although some significant effects on behavior were found, these effects have to be interpreted with caution because of the high dropout rate.

In this study, only relatively short-term outcomes of the intervention were assessed. It is advisable to add more long-term assessments to evaluate what the true effects are after 12 or 24 months, or even after a longer time period.

Another limitation is that all outcome measures were based on self-reports, which is more likely to result in greater underestimation of alcohol use compared to daily diaries [71]. This underestimation is probably mostly caused by forgetting [48]. However, we tried to keep self-reports as accurate as possible (eg, by asking for alcohol use in the previous week and not in a typical week). Furthermore, because the groups were randomized, this underestimation is probably equally distributed among the intervention and control groups and, therefore, does not influence the overall results of the study.

Finally, adolescents from the experimental and control conditions differed on alcohol use (ie, binge drinking, excessive drinking, and weekly consumption) as well as on several baseline characteristics (ie, gender, age, educational background, religion) which was probably caused by the relatively high dropout of schools in the control condition after randomization (5 schools withdrew participation before the baseline assessment). There were no differences on baseline drinking measures for the returning sample, but they were added in the analyses as covariates to control for the baseline differences of the whole sample.

Computer-tailored feedback can be an effective way to reduce binge drinking in adolescents aged 15 and 16 years. Also, participation of parents in those interventions may be beneficial and more research is needed to increase parental involvement. Further research is needed to increase adherence to eHealth interventions and to implement these interventions in practice; thereby, increasing their effectiveness and public health impact.

Conflicts of Interest

Hein de Vries is scientific director of Vision2Health, a company that licenses evidence-based innovative computer-tailored health communication tools. No other authors reported any conflicts of interest.

Multimedia Appendix 1

CONSORT-eHealth Checklist.

[PDF File (Adobe PDF File), 931KB - jmir_v18i2e29_app1.pdf]

Multimedia Appendix 2

Prevalence rates of binge drinking per age and adherence group.

[PDF File (Adobe PDF File), 16KB - jmir_v18i2e29_app2.pdf]

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Abbreviations

RCT: randomized controlled trial

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Original Paper

Changes in Physical Activity Following a Genetic-Based Internet-Delivered Personalized Intervention: Randomized Controlled Trial (Food4Me)

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Abstract

Background: There is evidence that physical activity (PA) can attenuate the influence of the fat mass- and obesity-associated (*FTO*) genotype on the risk to develop obesity. However, whether providing personalized information on *FTO* genotype leads to changes in PA is unknown.

Objective: The purpose of this study was to determine if disclosing *FTO* risk had an impact on change in PA following a 6-month intervention.

Methods: The single nucleotide polymorphism (SNP) *rs9939609* in the FTO gene was genotyped in 1279 participants of the Food4Me study, a four-arm, Web-based randomized controlled trial (RCT) in 7 European countries on the effects of personalized advice on nutrition and PA. PA was measured objectively using a TracmorD accelerometer and was self-reported using the Baecke questionnaire at baseline and 6 months. Differences in baseline PA variables between risk (AA and AT genotypes) and nonrisk (TT genotype) carriers were tested using multiple linear regression. Impact of *FTO* risk disclosure on PA change at 6 months was assessed among participants with inadequate PA, by including an interaction term in the model: disclosure (yes/no) × *FTO* risk (yes/no).

Results: At baseline, data on PA were available for 874 and 405 participants with the risk and nonrisk *FTO* genotypes, respectively. There were no significant differences in objectively measured or self-reported baseline PA between risk and nonrisk carriers. A total of 807 (72.05%) of the participants out of 1120 in the personalized groups were encouraged to increase PA at baseline. Knowledge of *FTO* risk had no impact on PA in either risk or nonrisk carriers after the 6-month intervention. Attrition was higher in nonrisk participants for whom genotype was disclosed (P=.01) compared with their at-risk counterparts.

Conclusions: No association between baseline PA and *FTO* risk genotype was observed. There was no added benefit of disclosing *FTO* risk on changes in PA in this personalized intervention. Further RCT studies are warranted to confirm whether disclosure of nonrisk genetic test results has adverse effects on engagement in behavior change.

Trial Registration: ClinicalTrials.gov NCT01530139; http://clinicaltrials.gov/show/NCT01530139 (Archived by WebCite at: http://www.webcitation.org/6XII1QwHz)

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KEYWORDS

FTO; physical activity; personalized intervention; randomized controlled trial; genetic testing; disclosure; behavior change; Web based

Introduction

The prevalence of physical inactivity in Europe and worldwide is high [1]. Given that physical inactivity is among the top risk factors for noncommunicable diseases [2], finding effective ways to achieve long-lasting improvements in physical activity (PA) remains a major challenge [3]. While previous intervention strategies have mainly focused on a "one-size-fits-all" approach to change behavior, recent studies have used personalized approaches, such as tailored Web-based interventions [4,5]. There is inconsistent evidence on whether these personalized approaches are more effective at increasing PA than standard guidelines, and effects, when present, are often small and with short-term efficacy [6]. Concurrently, there has been a growing interest in using genetic information to personalize lifestyle interventions [7]. Although disclosure of such information does not appear to have unintended adverse effects, more randomized controlled trials (RCTs) are needed to establish whether gene-based personalized interventions promote greater behavior change than conventional "one-size-fits-all" interventions [8]. In particular, data on whether providing genetic information leads to an increase in PA are lacking.

The fat mass- and obesity-associated (*FTO*) gene has provided strong evidence of the genetic susceptibility to obesity. Polymorphisms in this gene located in intron 1 and exon 2 have been shown to be consistently and strongly associated with obesity-related markers [9,10]. For instance, individuals homozygous for the higher-risk allele, AA, of single nucleotide polymorphism (SNP) rs9939609 in the FTO gene *FTO* weighed, on average, 3 kg more and had 1.7-fold increased odds of having obesity compared with those homozygous for the lower-risk allele, TT [11]. Moreover, there is increasing evidence that the *FTO* genetic susceptibility to obesity can be modulated by lifestyle factors, and that PA, for example, may attenuate the effects of the *FTO* genotype on obesity-related traits [12-17]. However, to our knowledge there is no data on whether disclosing information on *FTO* genotype can motivate individuals to increase their PA. Elucidating whether genetic-based advice can promote improvements in PA behaviors may help in the design of more effective interventions, especially when tailored to individuals who would benefit most from increasing their PA.

As part of the Food4Me study (ClinicalTrials.gov number: NCT01530139)—a Web-based RCT in 7 European countries—we investigated the effects of 3 levels of personalized advice on changes in PA, including a level with genetic information on *FTO* [18,19]. See Multimedia Appendix 1 for the CONSORT-EHEALTH checklist [20]. We found that personalized feedback in general led to greater improvements in self-reported PA, but not in objectively measured PA, compared with standard guidelines [19]. However, we did not investigate the effect of disclosing genetic-based information on PA change, and whether the response differs between carriers of a genetic risk and nonrisk carriers. Thus, the aim of these analyses was to assess the impact of knowledge of *FTO* risk status on change in self-reported and objectively measured PA in Food4Me participants.

Methods

Subjects

Subjects were participants of the Food4Me study, a 6-month, Web-based RCT on personalized nutrition and lifestyle conducted in 7 European countries—Germany, Greece, Ireland, the Netherlands, Poland, Spain, and the United Kingdom. As outlined elsewhere [18], 1607 adults aged ≥18 years were randomized to the study. Exclusion criteria included no or limited access to the Internet, following a prescribed diet, or

having altered nutritional requirements because of a medical condition. The local ethics committee of each recruiting center approved the study protocol and all subjects provided informed consent digitally before participating.

Study Design

Participants were randomly allocated to one of the 4 groups—Level 0: standard, nonpersonalized, dietary and PA guidelines; Level 1: dietary and PA advice based on current diet and PA; Level 2: dietary and PA advice based on current diet, PA, and phenotype (eg, waist circumference and blood cholesterol); and Level 3: dietary and PA advice based on current diet, PA, phenotype, and genotype (eg, *FTO*). The randomization scheme has been described previously [18]. All data were collected remotely following standardized operating procedures. At baseline, participants received study kits by post containing all necessary materials, such as an accelerometer and DNA collection kit (see the Physical Activity Assessment and Genotyping sections below), to perform measurements at home, but used their own scales to measure body weight. Printed instructions were included and demonstration videos were available on the Food4Me website [18,21].

On the allocated study day and following an 8-hour overnight fast, participants collected a buccal cell sample for DNA; measured their height, weight, and waist circumference; and started wearing an accelerometer. The buccal cell sample was returned to the research center in a prepaid stamped addressed envelope and anthropometric measurement values were self-reported online. Questionnaires to be completed online the same day included the Baecke PA questionnaire (see the Physical Activity Assessment section below). Participants repeated the measurements, except DNA collection, at 3 and 6 months [18].

Following measurements at baseline and 3 months, participants received, at both time points, a personalized (Levels 1-3) or nonpersonalized (Level 0) report, including feedback on PA according to their group. The personalized feedback provided was based on a predefined set of algorithms, including anthropometric, PA (Levels 1-3), phenotypic (Levels 2 and 3), and genotypic (Level 3 only) data. Results in the personalized report were compared with recommendations for each anthropometric, PA (Levels 1-3), and phenotypic (Levels 2 and 3) item, using 3-color graded lines—green: good; amber: improvement recommended; and red: improvement strongly recommended. In addition, Level 3 participants received information in their report about 5 diet- and lifestyle-related genes [18]. For *FTO*, the message was "A specific variation of this gene is associated with a greater need to maintain a healthy body weight and engage in physical activity. A healthy weight combined with exercise may provide added health benefits for these individuals." Participants were informed whether they were carriers of the *risk* variant for the *FTO* SNP rs9939609 (*yes* or *no*, if they were genotyped AA or AT, or TT, respectively). Each personalized report (Levels 1-3) also contained a specific message related to body weight and PA. Additionally, for Level 3 participants this specific message referred to *FTO*. For example, for an AA/AT participant with increased body mass index (BMI), increased waist circumference, and low PA, the message was "We recommend reducing your body weight and waist circumference to a healthy normal range because you have a genetic variation that can benefit by reducing these 2 obesity markers. Also, your physical activity level is too low." Full details of the study design have been published elsewhere [18].

Physical Activity Assessment

Objective Physical Activity

PA was assessed objectively using the TracmorD triaxial accelerometer (Philips Consumer Lifestyle, the Netherlands) [22,23]. Participants were instructed to wear the accelerometer every day while awake, except when taking a shower, for the entire duration of the 6-month study. Participants uploaded data every 2 weeks onto the study server via the Internet. Data were recorded with a time-sampling interval of 1 min. A day was considered valid if the participant had worn the TracmorD accelerometer between 10 and 18 h. Wear time was defined as 24 h minus nonwear time. To define nonwear time, we adapted the recommendations of Choi et al [24] to the TracmorD accelerometer. R software version 3.1.2 (The R Foundation) [25] was used for PA data processing.

Daily PA level (PAL)—the ratio of total energy expenditure to basal metabolic rate—was derived from activity counts [22]. Time spent in sedentary behavior—corresponding to <1.5 metabolic equivalents (METs)—and moderate- and vigorous-intensity PA—3 to <6 METs and ≥6 METs, respectively—were calculated based on the application of thresholds for activity energy expenditure (AEE) equivalent to the METs thresholds. Daily AEE was calculated as follows:

Daily AEE = (0.9 × daily PAL - 1) × BMR (1)

where the daily basal metabolic rate (BMR) is estimated using the Oxford equations developed by Henry, based on sex, age, and weight [26].

PA estimates were calculated over a 2-week period at baseline and 6 months. This 2-week assessment period occurred before any feedback was given for the corresponding time point. Sufficient PA data at each time point was defined as having at least 3 valid weekdays and 2 valid weekend days of accelerometer wear during the 2-week period. For individuals with sufficient PA data, mean data per day were calculated based on all valid week and weekend days of the assessment period as follows:

Mean = (mean for weekdays × 5 + mean for weekend days × 2) / 7 (2).

For sedentary time and time spent in moderate PA and vigorous PA, weekly estimates were calculated as follows:

Mean = (mean for weekdays × 5 + mean for weekend days × 2) (3).

Self-Reported Physical Activity

At each time point, participants completed the Baecke questionnaire online [27] based on their PA during the last month. This short, extensively validated questionnaire [28-30] is composed of 3 sections—work, sport, and nonsport

leisure—with indices ranging from 1 to 5 and a sum total (ie, total activity index) ranging from 3 to 15. Scores were calculated at baseline and month 6, according to the questionnaire protocol [27].

Genotyping

Participants collected a buccal cell sample at baseline, using Isohelix SK-1 DNA buccal swabs and Isohelix Dri-capsules (LGC Genomics, Hertfordshire, UK). Samples were returned to the recruiting centers and shipped to LGC Genomics, who extracted the DNA and used competitive allele-specific polymerase chain reaction (KASP) genotyping assays to provide biallelic scoring of SNP rs9939609 in the *FTO* gene.

Statistical Analyses

Data are presented as means (SD) for continuous variables and as percentages for categorical variables, unless otherwise stated. A chi-square test was used to test if the observed *FTO* genotype counts were in Hardy-Weinberg equilibrium [31]. To examine if there was an association between PA and *FTO* genotype, we used baseline data and robust multiple linear regression models, based on computation of SMDM estimates [32] to account for violation of the normality assumption. *FTO* genotype was operationalized as *risk* (AA and AT) and *nonrisk* (TT).

To study the impact of knowledge of *FTO* risk status on changes in PA, we used two approaches. In the first approach or primary analysis, we investigated whether personalized advice based on genetic information (ie, *FTO* risk) was more effective at increasing PA than personalized advice without genetic-based information in *FTO* risk and nonrisk carriers. In this analysis, we compared Level 3 participants who received personalized advice to increase PA, including disclosure of *FTO* risk, with participants who received personalized advice to increase PA without any genetic-based information (pooled Levels 1 and 2). As a secondary analysis, we assessed whether personalized advice based on genetic information (ie, *FTO* risk) was more effective at increasing PA than standard guidelines (ie, nonpersonalized advice) in *FTO* risk and nonrisk carriers. This analysis compared Level 3 participants with the control group—Level 0, nonpersonalized guidelines. In order to match the characteristics of both groups, participants in the control group were included only if they had insufficient baseline PA (ie, they would have been advised to increase their PA if they had not been in the control group). For both primary and secondary analyses, we used robust multiple regression models, including an interaction term between *FTO* risk (*yes* or *no*) and disclosure of genetic information (*yes* or *no*). If there was no significant interaction, we looked at the main effects after removing the interaction term from the model. Models were adjusted for age, sex, country, BMI, season, accelerometer wear time, and baseline PA variable as appropriate. Additional sensitivity analyses were run, stratifying by sex and by tertile of baseline PA variables. Attrition rates between groups were compared using Pearson's chi-square tests. R software version 3.1.2 (The R Foundation) [25] was used to perform all analyses and the significance level was set at $P<.05$.

Results

Attrition Rate and Compliance

A total of 1607 individuals were randomized into the study (see Figure 1) and 127 (7.90%) of them dropped out before starting the trial; their characteristics will be reported elsewhere. Genotype and PA data were available for 1279 of the 1480 (86.42%) starters, which were therefore included in the baseline analysis (see Figure 1). Although sufficient accelerometer data were defined as having a minimum of 3 valid weekdays and 2 valid weekend days of accelerometer wear, 77.56% (992/1279) of subjects had 10 or more valid days of accelerometer wear at baseline—mean 11.3 days (SD 2.4): 8.2 weekdays (SD 1.9) and 3.2 weekend days (SD 0.8).

Among the 1120 participants who received personalized advice (Levels 1-3), 807 (72.05%) were advised to increase their PA following assessment of baseline PA. Similarly, in the control group (Level 0), 276 of 360 (76.7%) participants would have been advised to increase their PA if the algorithms applied to Levels 1-3 had been applied to the control group (see Figure 1). For these participants with inadequate PA, attrition rate was similar between groups (14-15%, $P=.45$) at month 6 (see Figure 1). In the group where *FTO* risk was disclosed (Level 3), participants with the nonrisk (TT) genotype were more likely to drop out of the intervention than the at-risk (AA/AT) participants—attrition rate 22% (TT) versus 12% (AA/AT); odds ratio (OR) 2.04, 95% CI 0.96-4.29, $P=.04$. This was also the case when considering all participants in Level 3 (ie, not only those advised to increase their PA)—attrition rate 20% (TT) versus 11% (AA/AT); OR 2.17, 95% CI 1.13-4.17, $P=.01$ (see Table 1). There were no significant differences in attrition rates after 6 months between risk and nonrisk carriers in any other groups.

Although only 157 out of 1083 (14.50%) participants with inadequate PA had dropped out by month 6, compliance with wearing the accelerometer decreased during the study. Thus, 46.45% (503/1083) of subjects had data on *FTO* genotype, objective PA, and self-reported PA for both baseline and month 6, and were included in the analyses on change in PA (see Figure 1). Of these, 85.5% (430/503) and 68.0% (342/503) had 10 days of valid accelerometer wear at baseline and month 6, respectively. Mean number of valid days of accelerometer wear for these participants was 11.9 days (SD 2.1) at baseline—8.6 weekdays (SD 1.7) and 3.3 weekend days (SD 0.7)—and 10.4 days (SD 3.0) at month 6—7.7 weekdays (SD 2.3) and 2.7 weekend days (SD 1.1). This was similar for all intervention groups (data not shown for Levels 0-3).

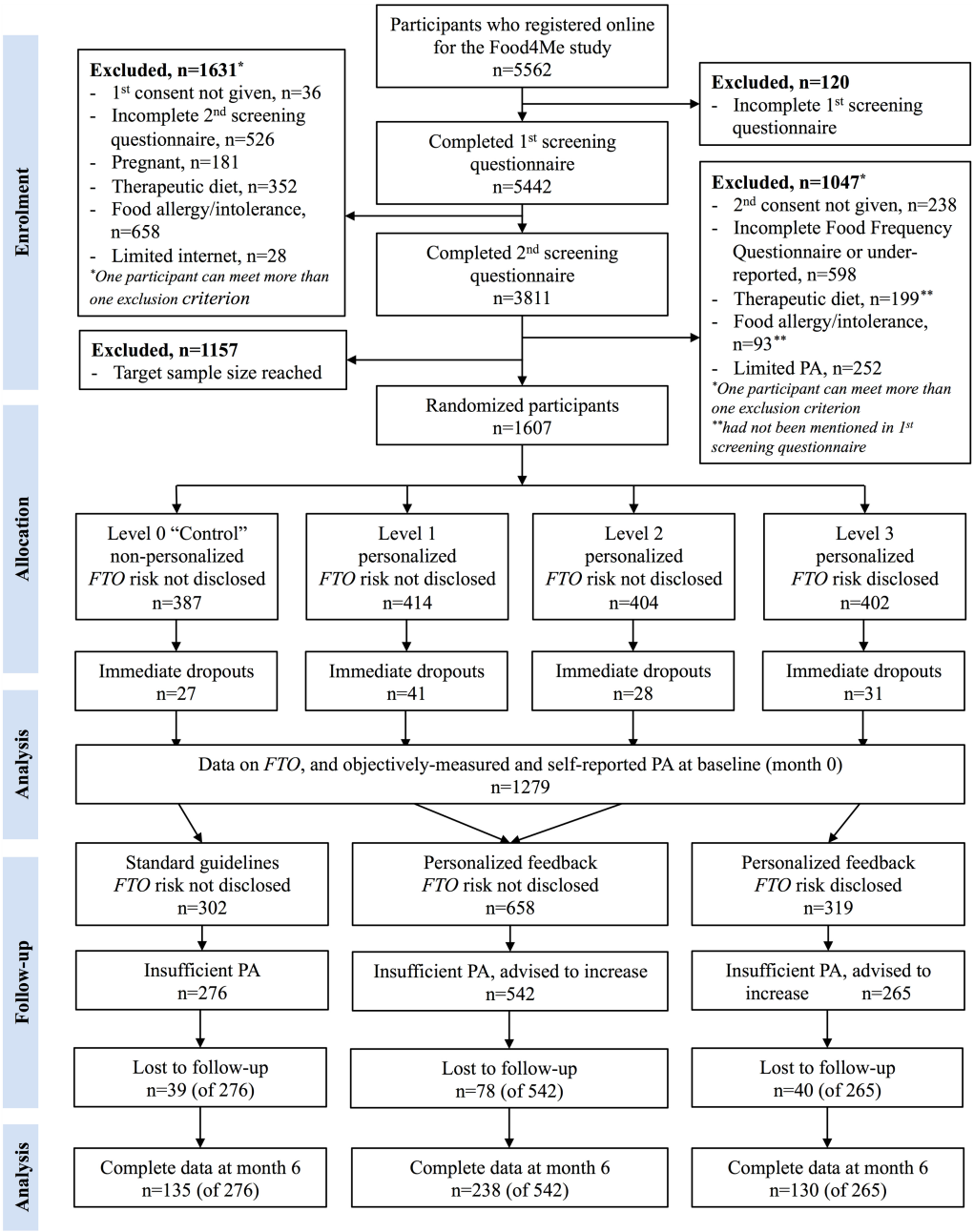
Table 1. Attrition rates after 6 months by intervention level.

Group characteristics	Standard guidelines		Personalized, nongene-based advice				Personalized and gene-based advice	
	Level 0		Level 1		Level 2		Level 3	
	TT[a]	AA/AT[a]	TT	AA/AT	TT	AA/AT	TT	AA/AT
Participants, n	112	247	127	244	117	255	113	257
Dropouts, n (%)	13 (11.6)	34 (13.8)	19 (15.0)	40 (16.4)	11 (9.4)	38 (14.9)	23 (20.4)[b]	27 (10.5)[b]

[a]TT and AA/AT are the nonrisk and risk genotypes, respectively, for the fat mass- and obesity-associated (*FTO*) rs9939609.

[b]Significant difference in attrition rate between *FTO* TT and AA/AT genotypes for Level 3 participants (P=.01).

Figure 1. Flowchart of study procedures. Participants in Level 0 (controls) received standard, nonpersonalized guidelines during the intervention, whereas participants in Levels 1-3 received personalized advice. PA: physical activity; FTO: fat mass- and obesity-associated gene.



Physical Activity and *FTO* Genotype

The characteristics of the 1279 participants with baseline PA data both from accelerometers and self-reports, as well as data on *FTO* genotype, are presented in Table 2. Most participants were white, 743 (58.09%) were women, and 588 (45.97%) were overweight or obese. Genotype frequency for *FTO* rs9939609

did not deviate from Hardy-Weinberg equilibrium (TT=405, TA=641, and AA=233; *P*=.48).

Table 2. Characteristics of the participants included in baseline analysis.

Variables		Overall (n=1279)	*FTO*[a] risk status	
			Risk (AA/AT) (n=874)	Nonrisk (TT) (n=405)
Ethnicity (white), n (%)		1239 (96.87)	848 (97.0)	391 (96.5)
Sex (women), n (%)		743 (58.09)	520 (59.5)	223 (55.1)
Age in years, mean (SD)		40 (13)	40 (13)	40 (13)
Height (m), mean (SD)		1.71 (0.09)	1.71 (0.09)	1.72 (0.09)
Weight (kg), mean (SD)		74.8 (15.8)	75.2 (16.1)	73.9 (15.2)
BMI[b] (kg/m^2), mean (SD)		25.5 (4.8)	25.7 (4.9)	25.0 (4.5)
Overweight (BMI 25.0-29.9 kg/m^2), n (%)		379 (29.63)	270 (30.9)	109 (26.9)
Obese (BMI ≥30.0 kg/m^2), n (%)		209 (16.34)	156 (17.8)	53 (13.1)
Accelerometer wear time (hours), mean (SD)		14.4 (1.1)	14.4 (1.1)	14.4 (1.0)
Number of valid days, mean (SD)		11.3 (2.4)	11.3 (2.4)	11.3 (2.4)
Participants per season, n (%)				
	Winter	377 (29.48)	266 (30.4)	111 (27.4)
	Spring	720 (56.29)	480 (54.9)	240 (59.3)
	Summer	99 (7.74)	73 (8.4)	26 (6.4)
	Autumn	83 (6.49)	55 (6.3)	28 (6.9)
Participants per country, n (%)				
	Germany	174 (13.60)	116 (13.3)	58 (14.3)
	Greece	174 (13.60)	124 (14.2)	50 (12.3)
	Ireland	178 (13.92)	123 (14.1)	55 (13.6)
	The Netherlands	214 (16.73)	148 (16.9)	66 (16.3)
	Poland	177 (13.84)	130 (14.9)	47 (11.6)
	Spain	181 (14.15)	121 (13.8)	60 (14.8)
	United Kingdom	181 (14.15)	112 (12.8)	69 (17.0)
FTO genotype: AA/AT/TT, n (%)		233/641/405 (18.22/50.12/31.67)	N/A[c]	N/A

[a]*FTO*: fat mass- and obesity-associated gene.

[b]BMI: body mass index.

[c]N/A: not applicable.

We found no association between objectively measured PAL (*P*=.35), moderate PA (*P*=.28), vigorous PA (*P*=.24), or sedentary time (*P*=.71) at baseline and *FTO* risk status (see Figure 2, section a). Similarly, there was no significant difference in baseline self-reported PA between risk and nonrisk carriers (*P*=.76) (see Figure 2, section b).

Primary Analysis: Effect of Disclosing *FTO* Genotype Status on Change in Physical Activity

Table 3 displays the PA characteristics of genotyped participants advised to increase their PA at baseline, with objective PA and self-reported PA data at baseline and month 6.

Figure 2. Physical activity in *FTO* rs9939609 risk (AA/AT, n=874) and nonrisk (TT, n=405) carriers. *FTO*: fat mass- and obesity-associated gene.

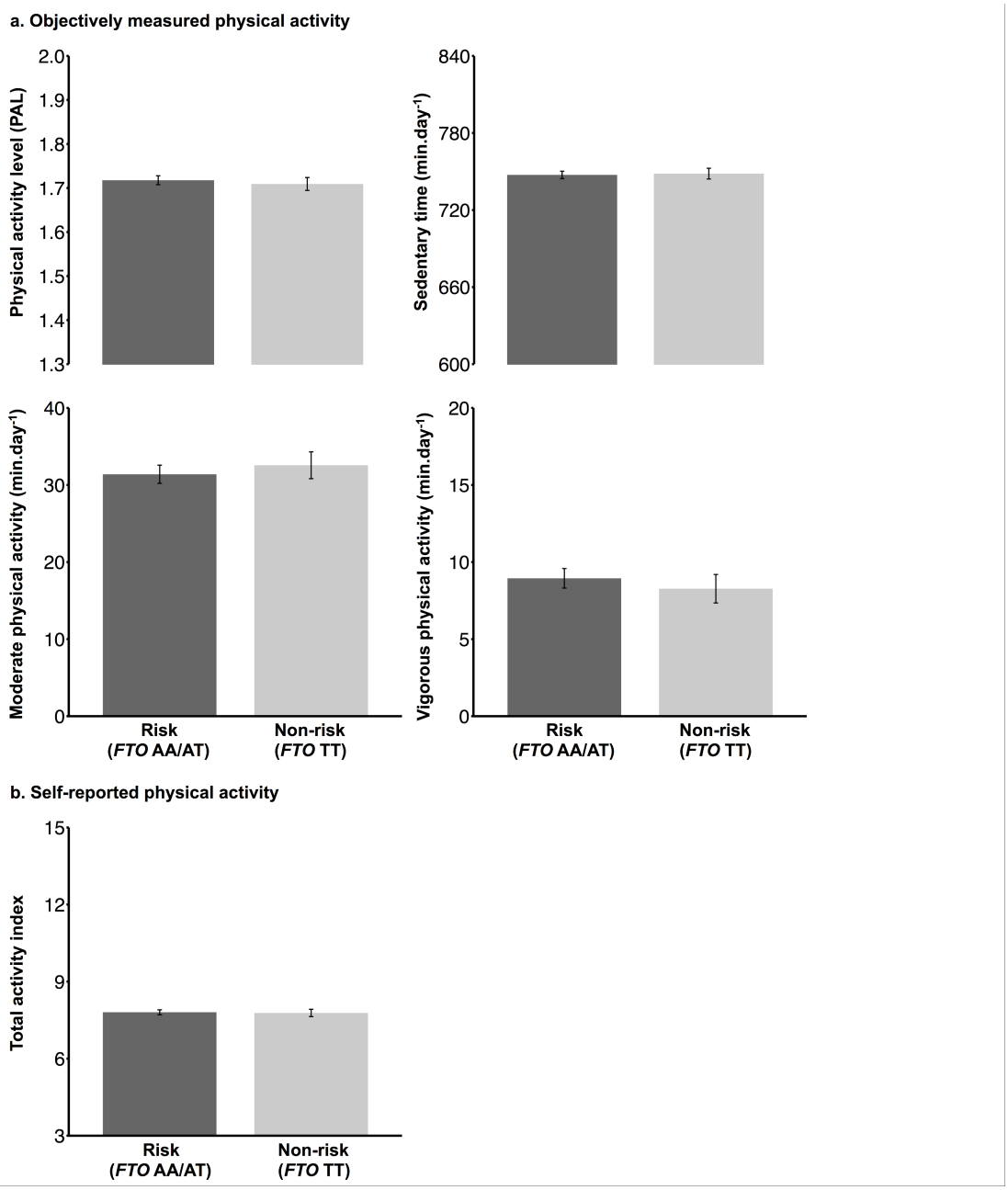


Table 3. Changes in physical activity (PA) from baseline to month 6 for participants receiving personalized advice to increase their PA.

Variables	Disclosure (Level 3)		Nondisclosure (Levels 1 and 2)	
	FTO[a] risk AA/AT (n=91), mean (SD)	*FTO* nonrisk TT (n=39), mean (SD)	*FTO* risk AA/AT (n=160), mean (SD)	*FTO* nonrisk TT (n=78), mean (SD)
Objective PA [b]				
Daily PAL [c]				
Month 0	1.64 (0.10)	1.67 (0.08)	1.68 (0.10)	1.67 (0.10)
Month 6	1.66 (0.14)	1.70 (0.13)	1.70 (0.14)	1.70 (0.17)
Moderate PA (min/week)				
Month 0	174 (124)	209 (98)	199 (111)	189 (112)
Month 6	206 (146)	249 (120)	218 (145)	221 (130)
Vigorous PA (min/week)				
Month 0	37 (54)	48 (67)	54 (73)	49 (64)
Month 6	49 (76)	57 (89)	64 (93)	61 (91)
Sedentary time (min/week)				
Month 0	5449 (483)	5391 (479)	5327 (505)	5433 (485)
Month 6	5271 (606)	5153 (449)	5172 (541)	5139 (579)
Self-reported PA: total activity index				
Month 0	7.46 (1.49)	7.51 (1.31)	7.49 (1.37)	7.69 (1.30)
Month 6	8.00 (1.37)	7.89 (0.99)	7.84 (1.29)	7.99 (1.44)

[a]*FTO*: fat mass- and obesity-associated gene.

[b]PA: physical activity.

[c]PAL: physical activity level.

There was no significant interaction between disclosure of genetic information and *FTO* risk status on change in objectively measured or self-reported PA (all $P>.25$); this is illustrated in Figure 3. There was also no effect of knowledge of *FTO* genotype on objectively measured or self-reported PA (all $P>.10$) (see Table 3 and Figure 3).

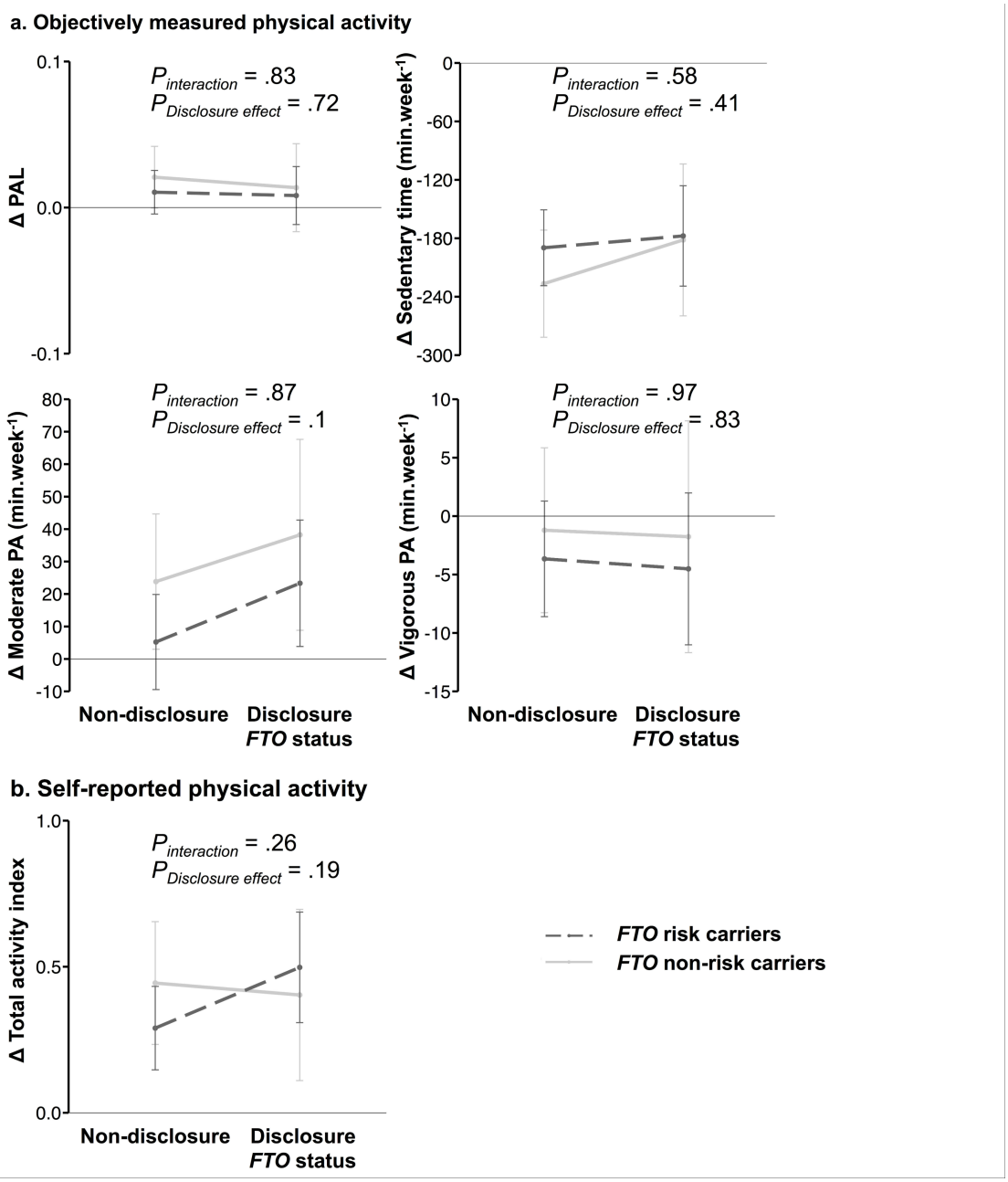
Secondary Analysis: Personalized Feedback Including Disclosure of Genetic Information Compared With Standard Guidelines

Comparisons between participants in the highest level of personalization (Level 3) who were advised to increase their PA, and control participants (Level 0) who would have been advised to increase PA if they had been in a personalized group, are given in Multimedia Appendix 2. There were no significant interactions between intervention levels and *FTO* risk status on change in PA. Change in objectively measured PA did not differ significantly between Level 3 and Level 0 participants for both risk and nonrisk carriers. However, Level 3 participants, irrespective of *FTO* risk status, had greater changes in self-reported PA than Level 0 participants (see Multimedia Appendix 2).

Sensitivity Analyses

Results and conclusions were similar when carrying out the analyses in men and women separately or after stratifying analyses by tertile of baseline PA variables (data not shown).

Figure 3. Effect of knowledge of FTO risk status on change in physical activity (PA) in risk (AA/AT) and nonrisk (TT) carriers. Nondisclosure FTO risk carriers, n=160; nondisclosure FTO nonrisk carriers, n=78; disclosure FTO risk carriers, n=91; disclosure FTO nonrisk carriers, n=39. FTO: fat mass- and obesity-associated gene.



Discussion

Principal Findings

Our main findings identified that there was no association between objectively measured or self-reported PA and *FTO* risk status. To our knowledge, our study is the first to investigate the impact of *FTO* genotype-based feedback on measured change in PA in the context of a personalized lifestyle intervention. We hypothesized that knowledge of carriage of *FTO* risk would lead to an increase in PA. However, we found no evidence that disclosing such information had any positive or negative effects on PA after a 6-month intervention.

Comparison With Previous Work

In the last decade, there has been a growing interest in personalizing lifestyle interventions using genetic tests. This has been done using DNA-based disease risk estimates, primarily in smokers or individuals at risk of certain conditions, such as Alzheimer's disease [8]. The hope was that providing such genetic information would motivate recipients to make beneficial behavioral changes beyond what could be achieved without such information. It is unclear whether knowledge of being predisposed to a greater genetic risk of disease would promote positive behavioral change and whether knowledge of only a small genetic risk (ie, a "lower" genetic risk) predisposition would lead to counterproductive behaviors under false reassurances [33]. In their 2010 review, Marteau et al reported no effect of adding DNA-based disease risk estimates

compared with a non-DNA-based approach, in terms of smoking cessation, PA, or use of medication/vitamins. A beneficial effect of DNA-based risk estimates on dietary behavior was reported, although no benefit on intention to change dietary behavior was observed [8]. Since then, Hollands et al also observed no effect of communicating DNA-based risk assessments for Crohn's disease on smoking cessation, compared with standard risk assessment [34]. Grant et al reported that diabetes genetic risk counseling did not alter self-reported motivation or adherence to a prevention program in overweight individuals at risk for diabetes [35]. Although the design of our study was different because we did not aim to recruit individuals specifically at risk of a certain disease, our results are in line with the results of most studies performed so far. Recently, Meisel et al showed that young healthy individuals receiving *FTO* feedback in their weight control advice felt more prepared to control their weight than subjects receiving weight control advice only. However, this did not translate into behavioral change [36].

Evidence in favor of disclosing genetic information is thus limited. Even the favorable findings for dietary behavior change mentioned above in the review by Marteau et al are weak [8]. They are based on only 2 studies [37,38], which did not find significant effects when each study was evaluated individually. More recently, Nielsen et al concluded that disclosing genetic information for personalized nutrition resulted in greater improvements in intake of some dietary components compared with general population-based dietary advice. In reality, this was true only for sodium intake, but not for caffeine, vitamin C, or added sugars, which were also studied. In addition, only individuals with the high-risk genotype status for the *ACE* gene reduced their sodium intake more than controls based on self-reported food intake, not on objective biomarkers of intake [39]. Similarly, Hietaranta-Luoma et al reported that personal genetic information based on *ApoE* might have positive effects on triglyceride values and waist circumference, but this was observed only in the high-risk ε4+ individuals [40].

Data suggest that providing genetic test results indicating a higher genetic risk does not lead to fatalism [8]. Furthermore, there is no indication that disclosing only a small genetic risk or a lower-risk test result promotes counterproductive behaviors. Similarly, in our study we found no differences in change in PA between individuals aware of their nonrisk *FTO* status and individuals aware of a risk, or not aware of their genotype. However, we did observe that the attrition rate was significantly greater among individuals informed of their nonrisk *FTO* status as compared to the other groups. Given the amount and variety of information provided to participants during the Food4Me study, it seems unlikely that this genetic information would be responsible for the higher number of dropouts. Nonetheless, this should be studied further, as it may indicate that such individuals felt the intervention was less relevant for them. Grant et al also reported that subjects receiving lower-risk genetic results showed lower intent to do exercise compared with controls, although there were no differences in terms of attendance to the diabetes prevention program [35].

Personalized feedback led to greater improvements in self-reported PA, but not objectively measured PA, compared with standard guidelines, as reported previously [19]. Discrepancies between self-reported and objectively measured PA have been noted by others. For instance, Wanner et al, in a Web-based tailored PA intervention, reported some improvements in self-reported PA after 6 weeks and 13 months of follow-up, but no differences between individuals in tailored and control groups, and no improvement in objectively measured PA for any group [41]. However, in our study we did find greater improvements in self-reported PA in tailored groups as compared with the controls. It could be that participants desired to comply with recommendations and that receiving more personalized feedback (Levels 2 and 3) increased this desire further. Furthermore, here we show that the bigger improvements in self-reported PA reported earlier are irrespective of *FTO* genotype, and are not related to knowing one's risk status for *FTO*. Thus, it is unlikely that subjects with the high-risk variant would feel more pressured to report that they did better, compared with those with the low-risk variant. Finally, we did not observe an association between *FTO* risk and PA measured objectively or self-reported. This supports studies published thus far that have used mainly self-reported data [15,42,43].

Strengths and Limitations

This study is the first to report the impact of disclosing information on *FTO* risk status on measured changes in PA. Our PA questionnaire has been validated against doubly labeled water and accelerometry [27,30,44], and has been used in large European cohorts before [45,46]. However, self-reports introduce large measurement error [47] and the Baecke questionnaire is no exception [48]. Thus, a strength of this study was the objective assessment of PA using triaxial accelerometers. Although accelerometers underestimate certain activities, such as cycling, swimming, or resistance training, the TracmorD model used in this study has been validated against doubly labeled water [22] and it has been shown to be reliable and accurate [49-51].

By design, we recruited individuals interested in taking part in a personalized intervention on nutrition and lifestyle, which is less representative than a European-wide survey. Nonetheless, our participants were broadly representative of the European adult population, most of whom had adequate nutrient intakes but could benefit from improved dietary choices and greater PA [52]. Given that Food4Me was an intervention that targeted multiple dietary and lifestyle behaviors, the genetic results might have also been diluted by the amount of information provided. Moreover, the genetic feedback was a positive reinforcement. Participants with the higher-risk genotype would *only* benefit more by reducing their weight or increasing their PA. It is possible that the impact would have been greater if participants had been made more aware of the links between obesity and lifelong ill health. Furthermore, genetic feedback provided by health professionals skilled in genetic counseling might have been more effective that written feedback. However, this would have been more expensive and outside the scope of this study, which was designed to test the effects of an Internet-delivered intervention. Such interventions are thought to offer considerable advantages in terms of reach, scalability, and sustainability [53]. Attrition rates (~15%) were as expected and compliance with the measurements was good, except for wearing the monitor.

Only half of the participants had accelerometer data for both baseline and month 6—whereas >75% had self-reported PA data at both time points—which limited the size of the sample analyzed in the PA analyses. It is possible that wearing the monitor for 6 months was too demanding for the amount of feedback given. It may be important for future studies that participants be able to visualize their activity levels, in real time, whenever desired (eg, on an accompanying website). Improvements in activity measurement may reduce participants' confusion and/or frustration. Having personalized coaches available, who can also operate online, may have motivated participants to wear their accelerometer and to improve their PA, although this also means extra costs. For the sole purpose of assessment, better compliance may be obtained by sending out monitors and collecting them back directly after assessment [54]. In spite of this, our sample size was acceptable, and the results did not change when looking at all self-reported PA data available.

Conclusions

There was no added benefit of knowledge of *FTO* risk on change in PA in this intervention study. Although there were no differences in outcome measures between participants informed of a nonrisk and those informed of a risk, or those not informed of their *FTO* risk status, the nonrisk subjects were more likely to drop out of the study by 6 months. More studies are needed to confirm whether disclosure of lower-risk genetic test results has adverse effects on engagement in behavioral changes. Before that, more effort should be devoted to identify the features necessary to engage individuals, how to frame the feedback, and how to coach effectively, especially those at risk, to reduce health inequalities.

Acknowledgments

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Authors' Contributions

JCM was the Food4Me intervention study coordinator. CFMM performed the statistical analysis for the manuscript. ERG, LB, YM, IT, CAD, JAL, JAM, WHMS, HD, MG, and JCM contributed to the research design. CFMM, CCM, RSC, SNC, COD, CW, HF, RF, ALM, SK, JHa, CPL, GM, AS, MG, MCW, and JCM conducted the intervention. CFMM, WHMS, CCM, AG, and JHo contributed to physical activity measurements. CFMM, CCM, KML, and WHMS drafted the paper. All authors contributed to a critical review of the manuscript during the writing process. All authors approved the final version to be published.

Conflicts of Interest

JH and AG are employed by Philips. The other authors have no competing interests.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1 [20].

[PDF File (Adobe PDF File), 677KB - jmir_v18i2e30_app1.pdf]

Multimedia Appendix 2

Changes from baseline in physical activity (PA) for participants who received the highest level of personalized advice (including genetic information, Level 3) and told to increase their PA, and for the controls who received standard guidelines (Level 0), but would have been advised to increase their PA if they had not been controls. Data are presented as mean (SD). *FTO*: fat mass- and obesity-associated gene.

[PDF File (Adobe PDF File), 26KB - jmir_v18i2e30_app2.pdf]

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Abbreviations

AEE: activity energy expenditure
BMI: body mass index
BMR: basal metabolic rate
CIBERobn: Centro de Investigación Biomédica en Red-Fisiopatología de la Obesidad y Nutrición
FTO: fat mass- and obesity-associated gene
IZZ: National Food & Nutrition Institute
KASP: competitive allele-specific polymerase chain reaction
MET: metabolic equivalent
MUMC+: Maastricht University Medical Centre +
N/A: not applicable
NUTRIM: Nutrition and Translational Research in Metabolism
OR: odds ratio
PA: physical activity
PAL: physical activity level
RCT: randomized controlled trial
SNP: single nucleotide polymorphism
UCD: University College Dublin
ZIEL: Zentralinstitut für Ernährungs- und Lebensmittelforschung

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Original Paper

Effectiveness of an Activity Tracker- and Internet-Based Adaptive Walking Program for Adults: A Randomized Controlled Trial

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Abstract

Background: The benefits of physical activity are well documented, but scalable programs to promote activity are needed. Interventions that assign tailored and dynamically adjusting goals could effect significant increases in physical activity but have not yet been implemented at scale.

Objective: Our aim was to examine the effectiveness of an open access, Internet-based walking program that assigns daily step goals tailored to each participant.

Methods: A two-arm, pragmatic randomized controlled trial compared the intervention to no treatment. Participants were recruited from a workplace setting and randomized to a no-treatment control (n=133) or to treatment (n=132). Treatment participants received a free wireless activity tracker and enrolled in the walking program, Walkadoo. Assessments were fully automated: activity tracker recorded primary outcomes (steps) without intervention by the participant or investigators. The two arms were compared on change in steps per day from baseline to follow-up (after 6 weeks of treatment) using a two-tailed independent samples *t* test.

Results: Participants (N=265) were 66.0% (175/265) female with an average age of 39.9 years. Over half of the participants (142/265, 53.6%) were sedentary (<5000 steps/day) and 44.9% (119/265) were low to somewhat active (5000-9999 steps/day). The intervention group significantly increased their steps by 970 steps/day over control (P<.001), with treatment effects observed in sedentary (P=.04) and low-to-somewhat active (P=.004) participants alike.

Conclusions: The program is effective in increasing daily steps. Participants benefited from the program regardless of their initial activity level. A tailored, adaptive approach using wireless activity trackers is realistically implementable and scalable.

Trial Registration: Clinicaltrials.gov NCT02229409, https://clinicaltrials.gov/ct2/show/NCT02229409 (Archived by WebCite at http://www.webcitation.org/6eiWCvBYe)

(J Med Internet Res 2016;18(2):e34) doi:10.2196/jmir.5295

KEYWORDS

physical activity; walking; intervention; adaptive; effectiveness; RCT

Introduction

Over a third of US adults are considered sedentary (taking on average fewer than 5000 steps/day) [1], and the average adult takes only 6540 steps/day [2], well short of the 10,000 steps per day target commonly used in public health campaigns. Behavior change interventions using pedometers have been shown to result in moderate increases in physical activity [3,4]. Steps goals are a key predictor of change, with high goals (eg, 10,000 steps/day) associated with the largest increases in physical activity and intervention effect sizes [3,4]. However, even modest increases in activity can yield clinically significant health benefits: an additional 1000 steps/day has been linked to lower body mass index, lower waist-to-hip ratio, and greater insulin sensitivity [5]. Moreover, such goals may require an increase in activity that is hard to reach for certain individuals (eg, those who are sedentary) or difficult to achieve on a daily basis, raising concerns of poor program adherence and high attrition [6]. Smaller, gradual goals may offer a good alternative to high goals for physical activity interventions.

Previous interventions have explored this approach by tailoring goals to a participant's physical activity level and increasing them by fixed increments (eg, 10% over baseline every 2 weeks or 400 steps/day every week) [3,7,8]. But fixed increments assume a constant, linear trajectory that is seldom observed in health behavior change. For instance, life events (such as sickness or a change in work schedules) and weather may prevent linear progress typically assumed in structured progressive physical activity programs. Fixed goals fail to take into account natural fluctuations in behavior or adjust accordingly. By contrast, goals that dynamically adapt to an individual's current activity level promptly respond to changes (in either direction) to remain adequately attainable and potentially keep individuals adherent longer while gradually moving them toward higher levels of activity. The effectiveness of adaptive goals was examined in a study that contrasted them to fixed, high goals. In the intervention for overweight adults, system-generated goals were tailored to the participant's baseline activity level and adjusted over time to reflect changes in activity. Control group participants received a fixed goal of 10,000 steps/day regardless of physical activity level. Adams et al observed that over 6 months incremental, adaptive goals led to larger increases in physical activity than a fixed daily steps goal of 10,000 steps/day [9].

Adaptive interventions can be effective but have not yet been scaled nor tested in a varied population. A large-scale implementation requires the automation of data collection, goal setting, goal messaging, and feedback. The increasingly sophisticated and popular "activity trackers" from manufacturers such as Fitbit, Jawbone, or Fitlinxx enable the implementation of an adaptive goal-setting mechanic. These activity trackers use multi-axial accelerometers to detect walking or running behavior, including tracking steps similarly to mechanical pedometers. Current activity trackers can wirelessly stream data either to a mobile phone or to a local computer, and from there, send the data to other services or programs. Feedback is provided on the activity tracker itself and/or via other programs with which it is paired. Since the activity data is digital, all goal-setting operations (data download, steps goal calculation, and goal messaging) can be automated in real time using a centralized data store and software. A digital, automated implementation could have a wide reach at low cost and potentially, considerable public health impact.

We developed an adaptive walking intervention (Walkadoo) designed to leverage wireless activity trackers and be highly scalable. The intervention is automated, stand-alone, and does not require in-person meetings or staff time to be delivered (apart from the distribution of activity trackers.) The current study examines the effectiveness of an automated adaptive intervention in increasing steps.

Methods

Intervention

Walkadoo [10] is a freely available, open access, Internet-based program that pairs with a range of activity trackers to increase walking behavior. Activity trackers wirelessly and automatically send data to the program throughout the day via sync points, or a Bluetooth connection and the Internet. Participants receive daily steps goals in the morning via email (unless the participant opts out), an optional text message (SMS), on the website, or directly on the activity tracker for those with the option. Participants can opt to receive up to 4 pre-scheduled text messages per day: previous day's step count, today's goal, mid-day step count, and/or goal completion notification (see Figure 1). At any time and as often as they like, participants can text the word "steps" to the program to learn the step count after their last data sync and be reminded of their goal for the day, or they can follow their progress through their activity tracker or on the website. Participants receive virtual rewards (points, levels, and badges) for performing certain actions and reaching milestones such as completing a steps goal, achieving a personal best, and engaging socially with the community (eg, by encouraging other participants via "smiles" and comments, or by participating in group competitions) (see Figure 1).

The adaptive daily steps goals are the central feature of the program. The system generates goals that are tailored to the participant based on their most recent activity level. The goal-setting algorithm is modeled on a rank-order percentile approach developed following principles of behavioral economics and operant shaping [9]. The approach requires continuous measurements of daily activity to rank, from lowest to highest, the measurements in a 9-day moving window and compute a goal based on a percentile criterion (eg, 60th). The program's algorithm uses a range percentile criterion slightly above the user's 50thpercentile, with added algorithmic compensations for insufficient data in the early periods of program use. An additional algorithm randomly selects the exact value of the goal within the range, creating day-to-day variations in difficulty levels that introduce a game-like element of surprise. Figure 2 presents an example of the approach with data from a sample participant during the intervention phase (additional examples can be found in Multimedia Appendix 1.) No major alterations were made to the intervention design over the course of the trial.

Figure 1. Examples of text messages participants can opt to receive (left) and reward notifications on the main website (right).

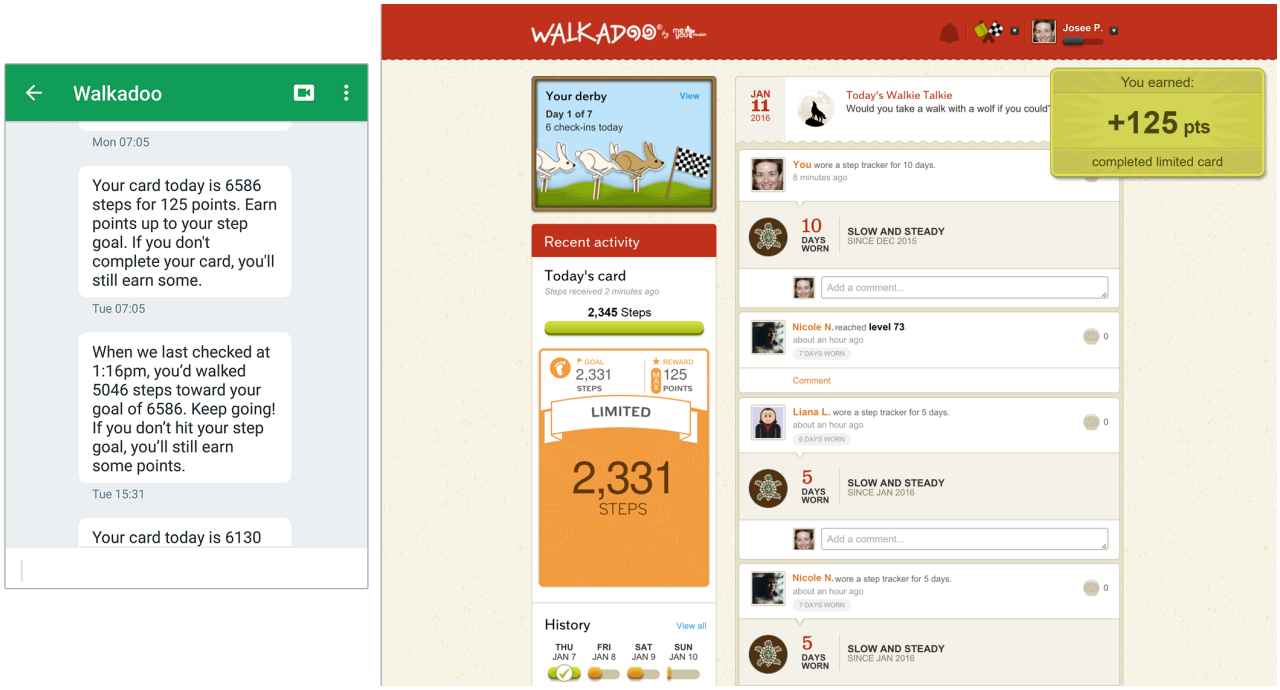
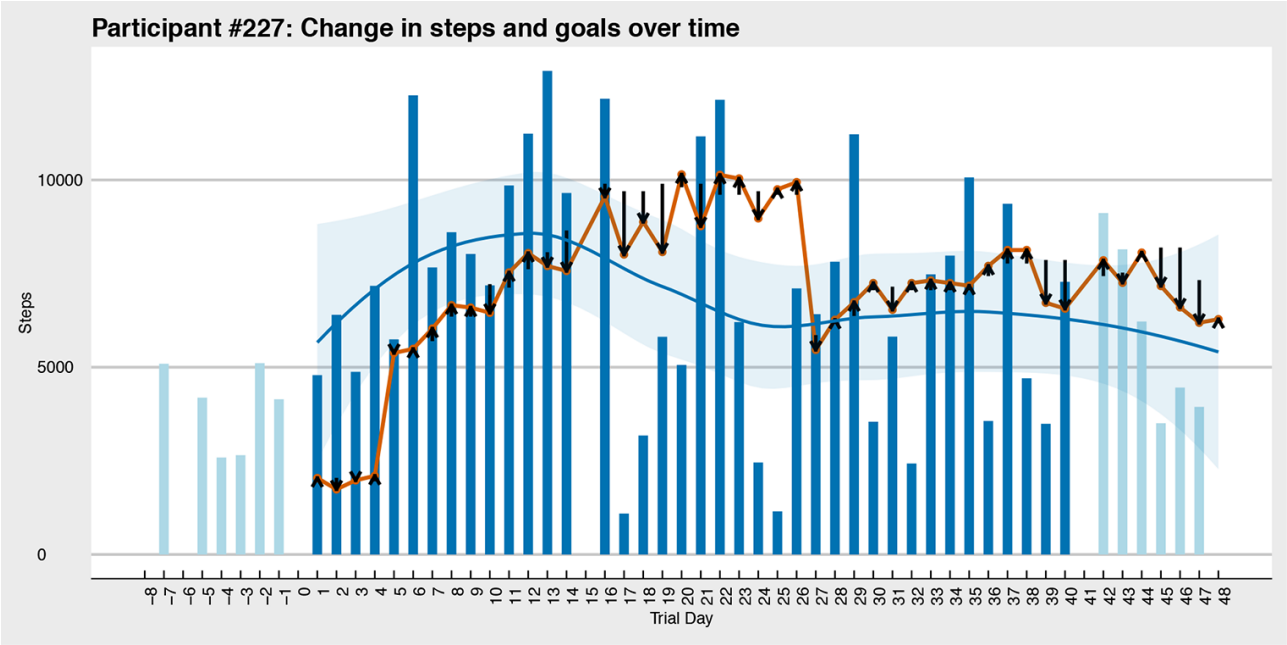


Figure 2. Sample participant steps and goals (actual steps taken are represented by blue bars with an associated trend line and surrounding confidence band; light blue bars indicate run-in data collection and follow-up periods; goals provided to users are represented in red; black arrow markers indicate the direction and magnitude of the random adjustment applied). These random adjustments averaged 2945 steps in either direction. Run-in data are presented here but are not used by the algorithm to preserve generalizability.



Study Design

The study was a single-site, two-arm randomized controlled trial examining changes in daily steps between a control group asked to continue with their normal routine and an intervention group enrolled in the Walkadoo program. The single-site pragmatic trial was conducted in a real-world workplace setting between early September 2014 and mid-November 2014. It included a 1-week run-in period during which baseline measurements were taken and a 6-week follow-up. The relatively short follow-up aimed to shorten the lag before the learnings from the trial could be fed back into the intervention design cycle in an iterative development model [11]. Schulman Associates Institutional Review Board (IRB) approved the full study protocol and the Johns Hopkins University School of Medicine IRB deemed the subsequent analysis protocol non-human subjects research.

Recruitment

Participants were employees of Healthways Inc, a multinational company that delivers disease management and well-being improvement solutions. Study recruitment was coupled with

standard enrollment in a workplace health program for 599 headquarter-based employees, which included a 3-day program launch onsite event and promotional efforts (such as email announcements and display of posters) that were led by the company's human resources department. The onsite event marked the start of program availability and the period during which employees could pick up a free activity tracker.

Study recruitment took place during the onsite event. Study staff distributed activity trackers and answered questions that individuals had regarding study participation. Employees interested in participating in the study were instructed to go online to provide informed consent and complete the eligibility check. The study-specific instructions were provided verbally, in a handout, and by email. The beginning and end of study phases were staggered with recruitment over 3 days. Participants incurred no cost to use the activity tracker and/or program.

Eligibility

A total of 64.8% of employees (388/599) expressed interest and were assessed for eligibility. Individuals logged on to a password-protected website to provide informed consent (participants indicated consent by checking a box and clicking an "I agree to participate" button) and answer a screening questionnaire. Exclusion criteria were failure to complete registration, prior use of Walkadoo, self-reported limited physical mobility, projected lack of Internet access for 4 or more days during the study period, and insufficient activity tracker wear during the run-in period (see below).

Run-In Period

The run-in period began the day after individuals picked up their activity tracker and lasted 7 days to establish a baseline. Individuals were instructed to wear their activity tracker for at least 12 hours each day. At the end of the 7-day period, participants who met the minimal activity tracker wear criterion (at least 10 hours a day on a minimum of 4 days including 1 weekend day) were randomized.

Randomization

We generated randomization assignment sequences that were stratified by baseline physical activity levels. The physical activity strata were sedentary (<5000 steps/day on average), low to somewhat active (5000-9999 steps/day on average), and active to highly active (≥10,000 steps/day on average) [12]. The enrollment system randomly allocated participants to either arm in a 1:1 ratio. Participants were notified of their randomization assignment via email and received instructions based on their trial arm and were therefore not blinded.

Control Group

After the run-in period, participants in the control group were instructed not to wear their activity tracker and to maintain their daily activity routine for 6 weeks (until follow-up.)

Intervention Group

Intervention participants were provided user accounts and prompted to complete formal registration into Walkadoo. Participants were instructed to install the provided universal serial bus (USB) dongle and synchronization software on their home computer, allowing the activity tracker to sync data with the program whether the participant was at work or at home. The visual feedback on the activity tracker (see Measurements for detail) was activated for intervention participants for the remainder of the study.

Follow-Up

After 6 weeks, all participants received an email asking them to wear their activity tracker for at least 10 hours a day for the next 7 days. Participants without sufficient data (who did not provide data for at least 10 hours a day on a minimum of 4 days including 1 weekend day, the same wear time criterion as for baseline measurements) were granted another 7-day window for a second attempt. All study participants were allowed to keep the activity tracker at the end of the study, while only participants who completed follow-up received a US $25 Amazon gift card as compensation for their time.

Measurements

Primary outcome measures were steps recorded by the activity tracker. Steps were estimated using the Pebble+ (Fitlinxx Inc), a commercially available wireless accelerometer designed to be worn on the hip or shoe. An earlier version of this activity tracker had been shown to have similar accuracy to research-grade accelerometers (YAMAX and Actigraph) during treadmill and over ground walking (from 2-8 mph) [13]. Step data automatically offloaded throughout the day via wireless sync points that were positioned on each floor so as to cover the whole office area. Visual feedback on the activity tracker (a circle that gradually lit up to indicate relative progress toward the day's steps goal, without a step count) was disabled at baseline for both study arms and was enabled for the rest of the study in the intervention arm only. The activity tracker reports data in 20-minute increments. Wear time was estimated from the earliest and latest moments of activity during the day. Process data including site visits and email opens were collected for the intervention arm.

Analysis

The primary outcome was the difference between arms in the change in steps per day from baseline to follow-up. Mean steps per day were calculated as the total number of steps taken on valid days (ie, with at least 10 hours of wear time) divided by the number of valid days (range 4-7 days). A subgroup analysis was planned to examine change in steps per baseline activity level as stratified. The secondary outcome was the difference between arms in the proportion of study participants who increased their steps per day by 1000 steps, which is the smallest change in activity that has been linked to health outcomes [5].

Statistical significance for the between-group difference in change in steps per day from baseline to follow-up (primary outcome) was assessed using a two-tailed independent-samples *t* test. A priori we decided to report the *t* test as the main analysis to estimate the mean differences in change in steps per day by study arm. To evaluate the robustness of the unadjusted analysis, we used a repeated-measures mixed-effect model with all available baseline and follow-up data that met the activity tracker wear time requirement. We estimated the mean difference from baseline to follow-up as a function of group

assignment and adjusted for age, race, and gender and baseline physical activity stratum. The proportional difference for increases of 1000 steps/day between study arms (secondary outcome) was assessed using a chi-square test. We conducted a sensitivity analysis to evaluate for significant selection bias by participants lost to follow-up. We re-calculated the main analysis using all available follow-up data over the 2 assessment weeks, eliminating the minimum follow-up data requirement. Analyses were performed using SAS, version 9.4. Significance level was set at $P<.05$ for all analyses.

Results

Participant Characteristics

A total of 388 employees were assessed for eligibility with 30 excluded due to no informed consent, incomplete registration, or not meeting inclusion criteria. Among the 358 candidates who completed the run-in period, 93 were excluded because they failed to meet the minimum activity tracker wear criterion. There were 265 participants randomized to the Walkadoo intervention (n=133) and the control arm (n=132) (see Figure 3).

The baseline characteristics of the study population overall and by arm are shown in Table 1.

Overall, two-thirds (175/265, 66.0%) were women and one-third (90/265, 31.3%) had an annual household income of less than US $60,000. Physical activity level was classified as sedentary for over half (142/265, 53.6%) of participants and low to somewhat active for (119/265, 44.9%). During baseline data collection, participants wore their activity tracker for at least 10 hours on an average of 6.4 days, with an overall average of 14.4 hours/day (see Table 1). The two arms did not differ in their wear time at baseline (control: mean 14.6, SD 1.3; intervention: mean 14.4, SD 1.1, $P=.23$) or at follow-up (control: mean 14.4, SD 1.3; intervention: mean 14.7, SD 1.6, $P=.21$).

We collected complete follow-up data for 217 (81.9%, 217/265) participants. The 48 participants without complete data were similar to those with complete data in terms of baseline physical activity level, race/ethnicity, income, and education (see Multimedia Appendix 2).

Indicators of program participation in the treatment group are presented in Table 2. Participants wore their activity tracker on 78.6% of days (33.0/42 days) on average. Participants opened 21.9% of their daily emails (9.2/42 days) and visited the website every 3.6 days on average (11.8/42 days). The opening of text messages cannot be tracked and is not reported. Participants completed their steps goals on average on 18.3 days (SD 6.6, IQR=7) out of 42. In the sixth and last week of treatment, 97.7% (130/133) of intervention participants still wore their activity tracker, opened emails, and/or visited the website.

Effect of the Intervention

From baseline to follow-up, participants in the intervention arm increased their activity by a mean of 309 steps/day (SD 1874). Activity in the control arm decreased by a mean of -661 steps/day (SD 1824). Change over baseline statistically differed between the intervention and control arms (difference=970 steps/day; $P<.001$; see Table 3). The repeated-measures model confirmed a statistically significant difference in change from baseline between the two arms, with the intervention group showing an increase of 845 steps/day over control (arm x time point interaction, $P<.001$, 95% CI 463-1228).

Table 1. Baseline characteristics of randomized participants.

	Total (N=265)	Control (n=132)	Intervention (n=133)	*P* value[a]
Age in years, mean (SD)	39.9 (11.7)	39.6 (12.0)	40.3 (11.4)	.65
Women, n (%)	175 (66.0)	92 (69.7)	83 (62.4)	.21
Race/ethnicity, n (%)				.99
White	205 (77.4)	101 (76.5)	104 (78.2)	
Black	30 (11.3)	15 (11.4)	15 (11.3)	
Hispanic	4 (1.5)	2 (1.5)	2 (1.5)	
Asian	11 (4.2)	5 (3.8)	6 (4.5)	
Other	7 (2.6)	4 (3.0)	3 (2.3)	
Don’t know	8 (3.0)	5 (3.8)	3 (2.3)	
Education, n (%)				.81
High school or vocational school	11 (4.1)	7 (5.3)	4 (3.0)	
Some college	30 (11.3)	14 (10.6)	16 (12.0)	
College graduate	124 (46.8)	61 (46.2)	63 (47.4)	
Post-graduate	98 (37.0)	49 (37.1)	49 (36.8)	
Don’t know/Prefer not to answer	2 (0.8)	1 (0.8)	1 (0.8)	
Annual income, $US				.61
<$60,000	83 (31.3)	45 (34.1)	38 (28.6)	
$60,000-$120,000	73 (27.6)	34 (25.8)	39 (29.3)	
> $120,000	56 (21.1)	27 (20.4)	29 (21.8)	
Don’t know/Prefer not to answer	53 (20.0)	26 (19.7)	27 (20.3)	
Baseline physical activity level, n (%)				.99
Sedentary (<5000 steps/day)	142 (53.6)	71 (53.8)	71 (53.4)	
Low to somewhat active (5000-9999 steps/day)	119 (44.9)	59 (44.7)	60 (45.1)	
Active to highly active (≥10,000 steps/day)	4 (1.5)	2 (1.5)	2 (1.5)	
Number of valid[b] days, mean (SD)	6.4 (0.8)	6.3 (0.8)	6.4 (0.8)	.51
Hours of wear per day, mean (SD)	14.4 (1.2)	14.4 (1.3)	14.4 (1.1)	.68
Has 2 (vs 1) valid[b] weekend days, n (%)	172 (64.9)	88 (66.7)	84 (63.2)	.55

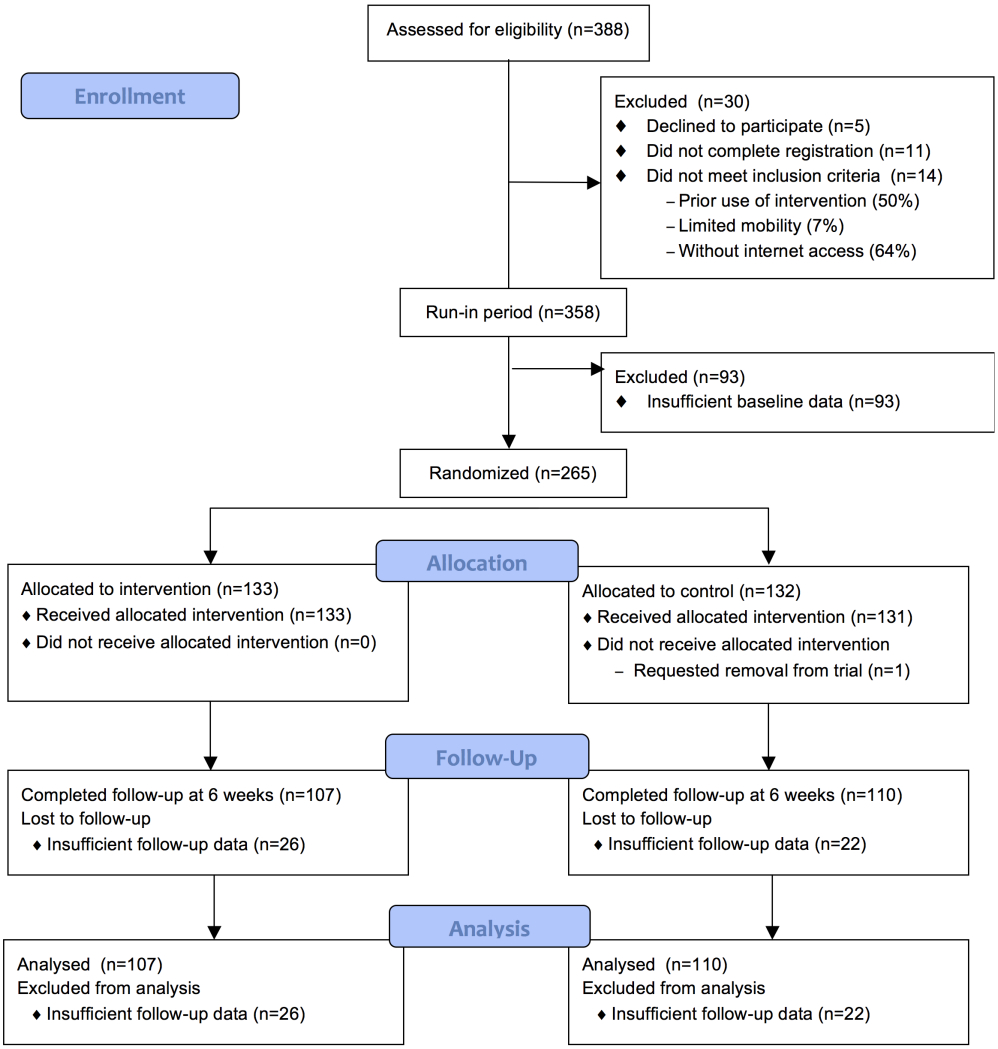
[a]Comparisons were performed by chi-square tests for categorical variables and independent samples two-tailed *t* tests (means) and Wilcoxon rank sum tests (medians) for continuous variables.

[b]A valid day is defined as having at least 10 hours of activity tracker wear time.

Table 2. Indicators of program use for participants in the intervention arm (n=133): number of days (of 42) that participants wore their activity tracker (as shown by >100 steps recorded), opened their daily email at least once, and visited the website at least once.

	Activity tracker worn	Email opened	Website visited
Mean (SD)	33.0 (11.6)	9.2 (10.4)	11.8 (11.2)
Range	0-42	0-42	0-39
IQR	12	14	19

Figure 3. CONSORT diagram.



We conducted the pre-specified stratified analyses by baseline activity level stratum (see Table 3). Among the sedentary group, the intervention arm had a mean increase of 595 steps/day (SD 1558), which was statistically significantly higher than the control arm (47 steps/day, SD 1299, P=.04). The low to somewhat active group decreased regardless of treatment but significantly more so in the control arm (intervention: -110 steps/day; control: -1286 steps/day, P<.001).

In a sensitivity analysis, we evaluated primary outcome on a sample including an additional 35 participants who had some available follow-up data but had failed to meet the minimal activity tracker wear criterion. In this sample of participants (252/265, 95.1%), the 130 participants in the control arm reduced their mean steps per day by -753 (SD 1836) while the 122 participants in the intervention arm increased their mean steps per day by 80 (SD 1999). The statistically significant between-group difference (P<.001) was consistent with the primary findings.

Finally, participants in the intervention arm were more likely to achieve an increase of 1000 steps/day as compared with the control arm (n=32 or 29.9% vs n=18 or 16.4%, respectively, P=.018).

Table 3. Steps/day at baseline and follow-up, and change from baseline to follow-up among participants who met the minimum activity tracker wear criterion[a] for follow-up data collection (n=217).

Physical activity at baseline[b]	Control, mean (SD)	Intervention, mean (SD)	*P* value[c]
All (control n=110; intervention n=107)			
Baseline	5412 (2251)	5102 (1901)	.27
Follow-up	4751 (1834)	5411 (2277)	.02
Change from baseline to follow-up	-661 (1824)	309 (1874)	<.001
Sedentary (<5000 steps/day) (control n=59; intervention n=58)			
Baseline	3820 (1061)	3769 (970)	.79
Follow-up	3867 (1654)	4363 (1517)	.09
Change from baseline to follow-up	47 (1299)	594 (1558)	.04
Low to somewhat active (≥5000-9999 steps/day) (control n=49; intervention n=48)			
Baseline	6992 (1275)	6580 (1310)	.12
Follow-up	5706 (1466)	6470 (2075)	.04
Change from baseline to follow-up	-1286 (1783)	-110 (2106)	.004

[a]Minimum activity tracker wear criterion for follow-up data collection required 4 days with at least 10 hours of activity tracker wear time including 1 weekend day.

[b]Per-stratum comparisons excluded the 3 participants who had 10,000+ steps/day at baseline.

[c]Comparisons performed with independent samples two-tailed *t* tests.

Discussion

Principal Findings

We evaluated an intervention designed to increase steps using daily adaptive goals tailored to an individual's current activity level. In a worksite environment, the walking program increased steps by a mean difference of 970 steps/day over control. This magnitude, while modest, has been previously correlated with improvements in body mass index and insulin sensitivity over time [5].

The findings were observed in both sedentary (<5000 steps/day) and non-sedentary (5000-9999 steps/day) individuals. Sedentary individuals represent 36.1% of the US population and are more likely to have multiple risk factors such as smoking or obesity [1], making them a critical population for public health programs. Of note, only 4 participants (1.5% total; two in each arm) were classified as active to highly active at baseline (taking at least 10,000 steps/day), as compared to 16.3% of Americans in the 2005-2006 NHANES cohort [1]. Active to highly active individuals may not have been interested in a walking program or may have been discouraged from participating in the trial if they had another activity tracker, since participants were asked to refrain from using activity trackers other than the one provided for the trial. Our results suggest that an adaptive walking program has the potential to benefit broad segments of the population as 83.7% of US adults take <10,000 steps/day [1].

The between-group difference at follow-up was partially driven by a decrease in steps in the control group. Baseline activity might have been higher due to reactivity (an immediate and temporary increase in physical activity due to wearing an activity tracker.) A reactivity effect has been previously reported, although it is unusual with "sealed" activity trackers with inactive or hidden visual feedback [14]. The decline in steps from baseline to follow-up we observed may represent a regression to a true baseline behavior as reactivity wore off. Alternatively, the intervention may have attenuated the known seasonal decline in light physical activity between summer and fall [15], when the trial was conducted. Like previous investigators, we have no way to verify either hypothesis conclusively, although the findings reinforce the importance of randomized controlled designs for testing the effectiveness of behavior change interventions.

The program showed convincing engagement levels. Participants wore their activity tracker on most (78.6%) days and remained active into their sixth week of treatment (77.7% interacted with the program at least once). Email open rates were tracked by the use of an embedded image that may be suppressed by certain email clients and underestimate actual rates. It is worth noting that participants could receive their daily steps goals in several ways other than opening the email: the steps goal could be read in the email subject line itself, received and requested by text message, found on the website, or tracked on the activity tracker. However, there are no standard metrics available for direct comparison. We encourage researchers to report intervention usage data so reference points can be found in the literature.

A strength of this trial was its pragmatic approach in a real-world workplace setting. We recruited trial participants from an employee population who received Walkadoo as part of their workplace wellness program offering. Our findings add to the evidence that physical activity interventions can be effective in the workplace [16-18] where employees tend to sit at their desks for long periods. This program was effective despite not being

designed specifically or exclusively for workplace implementations. We demonstrated that an adaptive program can be automated and made scalable using a simple wireless activity tracker.

Despite the pragmatic approach, several limitations to this trial should be noted. The chosen study population was one of convenience and the generalization of our findings will require extension and replication in future work. With respect to measurements, the manufacturer's directions for wearing the activity tracker indicated it could be worn on the hip or on the shoe. Although placement may limit the comparison of steps with more standardized methods and devices, our analyses appropriately focused on individual change scores. As part of the pragmatic approach we used a relatively short follow-up period to ensure prompt availability of the results to program development teams, evaluators, and purchasers [11]. Still, sustainability of the effect remains to be demonstrated.

Conclusions

The evolution of mechanical pedometers to digital activity trackers has opened the doors for interventions, such as Walkadoo, that leverage real-time access to data, predictive analytics, and algorithmic detection of activity patterns. While widely available activity trackers promote exercise monitoring, their largest public health impact could be on simple walking activity.

The results of this pragmatic trial confirm that dynamic programs tailored to the individual are a realistic and scalable alternative to fixed goals and that they can be effective in shifting health behavior in a real-world population. Future interventions will also be able to draw from the rich dataset provided by modern activity trackers to set goals that are not just tailored to the individual, but also adapt in real time to behavior or the environment, such as weather or physical geo-location. Perhaps more importantly, newer activity trackers, including the most recent generation of mobile phones, can detect more complex activities, such as stair climbing, while also providing the resolution to detect periods of sedentary behaviors (sitting or inactivity). Programs that can effect change across such an array of active and inactive behaviors could directly impact public health for adults who move too little or sit too much. Such an elusive but promising potential merits additional research and attention.

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Authors' Contributions

JP and NC conceived and supervised the study. GJ, WB, ML, H-CY, and JC contributed to study design and assisted with the write-up. NS, WB, ML, H-CY, GJ, and JC had full access to all of the data, performed the analyses, and can act as guarantors for the analyses. JP, GJ, and NC led the writing. All participants in this process are represented as authors on the manuscript.

Conflicts of Interest

JP and NC are full-time employees of MeYou Health and own stock in Healthways Inc, the parent company of MeYou Health. WB, ML, GJ, H-CY, JC, and NS are faculty or employees of the Johns Hopkins University and were paid through an institutional consulting agreement with Healthways for work in designing the study and analyzing the data.

Multimedia Appendix 1

Examples from participants.

[PDF File (Adobe PDF File), 1MB - jmir_v18i2e34_app1.pdf]

Multimedia Appendix 2

Supplemental table.

[PDF File (Adobe PDF File), 224KB - jmir_v18i2e34_app2.pdf]

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Original Paper

Effects of a Web-Based Intervention for Stress Reduction in Primary Care: A Cluster Randomized Controlled Trial

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Abstract

Background: Preliminary findings suggest that Web-based interventions may be effective in achieving significant stress reduction. To date, there are no findings available for primary care patients. This is the first study that investigates a Web-based intervention for stress reduction in primary care.

Objective: The aim was to examine the short-term effectiveness of a fully automated Web-based coaching program regarding stress reduction in a primary care setting.

Methods: The study was an unblinded cluster randomized trial with an observation period of 12 weeks. Individuals recruited by general practitioners randomized to the intervention group participated in a Web-based coaching program based on education, motivation, exercise guidance, daily text message reminders, and weekly feedback through the Internet. All components of the program were fully automated. Participants in the control group received usual care and advice from their practitioner without the Web-based coaching program. The main outcome was change in the Perceived Stress Questionnaire (PSQ) over 12 weeks.

Results: A total of 93 participants (40 in intervention group, 53 in control group) were recruited into the study. For 25 participants from the intervention group and 49 participants from the control group, PSQ scores at baseline and 12 weeks were available. In the intention-to-treat analysis, the PSQ score decreased by mean 8.2 (SD 12.7) in the intervention group and by mean 12.6 (SD 14.7) in the control group. There was no significant difference identified between the groups (mean difference –4.5, 95% CI –10.2 to 1.3, *P*=.13).

Conclusions: This trial could not show that the tested Web-based intervention was effective for reducing stress compared to usual care. The limited statistical power and the high dropout rate may have reduced the study's ability to detect significant differences between the groups. Further randomized controlled trials are needed with larger populations to investigate the long-term outcome as well as the contents of usual primary care.

Trial Registration: German Clinical Trials Register DRKS00003067; http://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?=DRKS00003067 (Archived by WebCite at http://www.webcitation.org/6eXk0PXmO)

(J Med Internet Res 2016;18(2):e27) doi:10.2196/jmir.4246

KEYWORDS

Web-based; randomized controlled trial; life stress; stress reduction

Introduction

Nowadays, almost all people worldwide experience increased stress. In the last few years, many studies have found an enormous increase of stress in adults, teenagers, and children [1]. Especially in Western countries, the rise in workload has resulted in a rapid growth of the number of employees experiencing psychological problems related to occupational stress [2]. In 2006, an international survey revealed that approximately 75% of the general population in developed countries reported stress on a daily basis. In addition, 44% of Americans surveyed in 2010 specified that they had experienced a growth in stress over the past 5 years [3].

There are few findings known for a Web-based intervention in primary care because most eHealth interventions for stress have been evaluated in workplace settings. Stress could be perceived as such a minor problem that it does not require any treatment or professional assistance [4]. However, there is no doubt that chronic stress clearly is a risk factor for a wide range of mental and physical health problems, such as metabolic syndrome [5], diabetes [6], cardiovascular disease [7,8], ischemic stroke [9], and depression [10-12]. Internet-based interventions have shown to be effective in community and clinical settings, including the treatment of depression [13-16], sleep disorders [17], weight reduction [18], smoking cessation [19], and stress reduction [20-27]. Some studies have also failed to find any effects on stress [28-30]. A meta-analysis showed that cognitive behavioral interventions are more effective in stress reduction than other techniques, such as relaxation techniques, multimodal programs, and organization-focused interventions [31]. Additionally, it has been noted on the basis of several trials that the effect sizes from Internet-based stress management programs were close to estimations of face-to-face cognitive behavioral interventions [31,32]. To use health care resources at an optimal level, graded treatment systems represent attempts to improve the efficiency and access to mental health. In a first attempt, low-cost interventions are offered. For those who are not sufficiently helped by the initial low-cost intervention, more intensive and costly interventions are then used in a second step [33]. In addition to the well-established intensive and costly interventions [34], the need to implement and to verify interventions with low financial and accessibility thresholds is still demanded [35,36]. Therefore, a Web-based program was developed that combines an individually tailored strategy for stress reduction with automated advice and feedback elements based on cognitive behavioral therapy (see Multimedia Appendices 1 and 2). In the cluster randomized trial reported subsequently, we investigated whether adult primary care patients who wanted stress reduction and used a fully automated 12-week Web-based coaching program did reduce their stress more effectively than with usual care by general practitioners (GPs).

Methods

Design

The study was designed as a 2-arm, unblinded, cluster randomized controlled trial. At the beginning of the study, approximately 2000 Bavarian GPs received a fax by the Bavarian Association of General Practitioners with information about the research project. The only inclusion criteria for GPs were interest in participating in the study and Internet access within their practice. All interested GPs were sequentially registered for randomization. After giving written consent, the participating GPs were randomized to either the interventional or the control arm. The sequence of randomization used (cluster allocation ratio 1:1) was provided by a methodologist, who did not participate in the execution of the study, via the program Research Randomizer [37]. Randomization was concealed by using sequentially numbered, opaque, sealed envelopes held by the study coordinator. Randomization was performed on the cluster level for logistical reasons (less complicated informed consent, only one intervention per doctor's practice, limited resources requiring less training visits). Before starting the recruitment of patients, physicians received detailed instructions from the research team on the study process (both intervention and control group) and on the coaching program (only intervention group). Physicians in both groups received a detailed introduction with all study documents by post. A separate visit of all participating physicians in the intervention group took place afterwards to instruct them about the Web-based intervention with the help of case studies and to eliminate ambiguities on site with all involved GPs and the participating medical staff. Physicians assigned to the control arm were asked to change nothing in their usual way of counseling and to treat participants in the same manner as if they would have been nonparticipants. There was no structured documentation of the care provided. The patients recruited by physicians for the intervention received free access to the Web-based coaching program. The patients in the control arm were advised by the GPs in their individual way of usual measures to reduce stress. The study was approved by the Medical Ethics Committee of the Technische Universität München (April 19, 2011) and was in accordance with ethical standards for human experimentation established by the Declaration of Helsinki. All participants gave written informed consent. A data and safety monitoring board was established before the beginning of the study. The study was registered on the German Clinical Trials Register (registration number: DRKS00003067). The CONSORT eHealth checklist is shown in Multimedia Appendix 3.

Participants and Procedures

Participating physicians were GPs in Bavaria, Germany. The GPs were requested to recruit individuals with a desire for stress reduction. Individuals who were at least 18 years of age and had Internet access were potentially eligible. GPs were asked to exclude individuals younger than 18 years, with insufficient German language skills, who did not have Internet access, suffered from a psychiatric disorder, or had a psychiatric disorder documented in the past.

After the GP decided that the patient was recommendable to participate, an information form was given and discussed with the patients and a participation form had to be signed. At the same time, baseline data acquisition took place. All participants were asked to fill in a standardized questionnaire with the GP. The standardized questionnaire consisted of the following

information: age, sex, height, weight, family status, physical activity level, and the Perceived Stress Questionnaire (PSQ). The PSQ assesses subjectively experienced stress independent of a specific and objective occasion; therefore, it can be widely used without the restrictions based on age, gender, or profession. This instrument is particularly of interest if perceived stress has to be asked directly without inferring it from control or coping appraisals. In addition to providing an overall score, it also provides scores on different facets of perceived stress, such as worry, tension, joy, and demands. Participants of the intervention group received a password to the webpage, which allowed free access to the program. Participants in both groups were requested to document the follow-up evaluation together with their physician after 12 weeks. The follow-up was comprised of a repeated PSQ and information about possible adverse events. Physicians in the intervention and control group received €25 per participant for time and effort. Participants in the intervention group received free access to the stress-reduction program, which would usually cost €49. Participants in the control group received €10 as an incentive to come to their doctor's practice for the follow-up investigation after 12 weeks. All physicians could contact the study coordinator by phone or email at any time. During the trial, a status survey was carried out on a regular basis every 6 to 8 weeks to check the number of enrolled patients and to remind about pending follow-ups. These calls were also used to solve any problems that had occurred. In addition, every 6 to 8 weeks written feedback about the number and status of participants was sent to the GPs to ensure a smooth process of the trial. No methodological changes were made during the entire study period.

Intervention

A specific website was developed for the participants to allow log-ins without charge [38]. After completion of a preassessment, the program generated a personalized coaching program based on the participants' physical characteristics and their everyday behavior. The coaching program was based on the generally accepted principles of cognitive behavioral therapy and combined psychoeducation and motivational techniques with behavioral therapeutic elements [39]. The content of the coaching program aimed at achieving a lasting change of behavioral patterns with the help of individualized education, motivation, exercise guidance, daily text message reminders, and self-monitoring via the Internet. The framework of the program was based on the idea by Oetting [40]. The intervention was exclusively Web-based and was not integrated into the practice system. The development and operation of the Web-based stress-reduction program was carried out by WeCARE GmbH, Göttingen, Germany. The coaching program was subdivided into 12 different constitutive modules. The module learning objectives were:

1. Being strong against stress
2. Your personal stress profile
3. Your personal stress patterns
4. Your path to more calmness
5. Release tension and recharge
6. Stress caused by grief
7. Be strong—even without others
8. Components of balance
9. Stress—the knight in shining armor
10. Stress-free—even in the workplace
11. Active against the pressure
12. Find peace and relaxation
13. On the way to relief
14. Now you are your own coach

Each module was carried out for 1 week and contained particular tasks, which were supported by corresponding daily text message reminders. The participant had to perform a specific task each day and received a corresponding daily text message in accordance to the specific task. The reminder contained adapted information to maintain motivation, to impart daily tips, and to encourage daily performance of the respective task. The specific daily tasks were offered on the first day of each module. The coaching program also offered a variety of printed material (eg, relaxation exercises, questionnaires, information, instructions, self-assessments, agreements) which were connected to the respective task and included interactive buttons, video clips, and learning progress quizzes to examine learning success (Figure 1). All components of the program were fully automated without the involvement of the GPs.

At the end of each week, participants were asked to give feedback via the Internet concerning their condition, level of motivation, and whether or not they did their weekly tasks (Figure 2).

Participants could also communicate with one another through a forum or ask a HausMed team member in case they had any questions. There was no limitation to the frequency of website use, but participants were given a goal of using the website at least once a week. Due to data privacy, the ethics review board did not allow the use of automatically documented access and adherence data. No changes were made to the coaching program within the study period.

Figure 1. Screenshot of the stress-reduction Web-based program showing specific daily tasks, including interactive buttons, video clips, and learning progress quizzes.

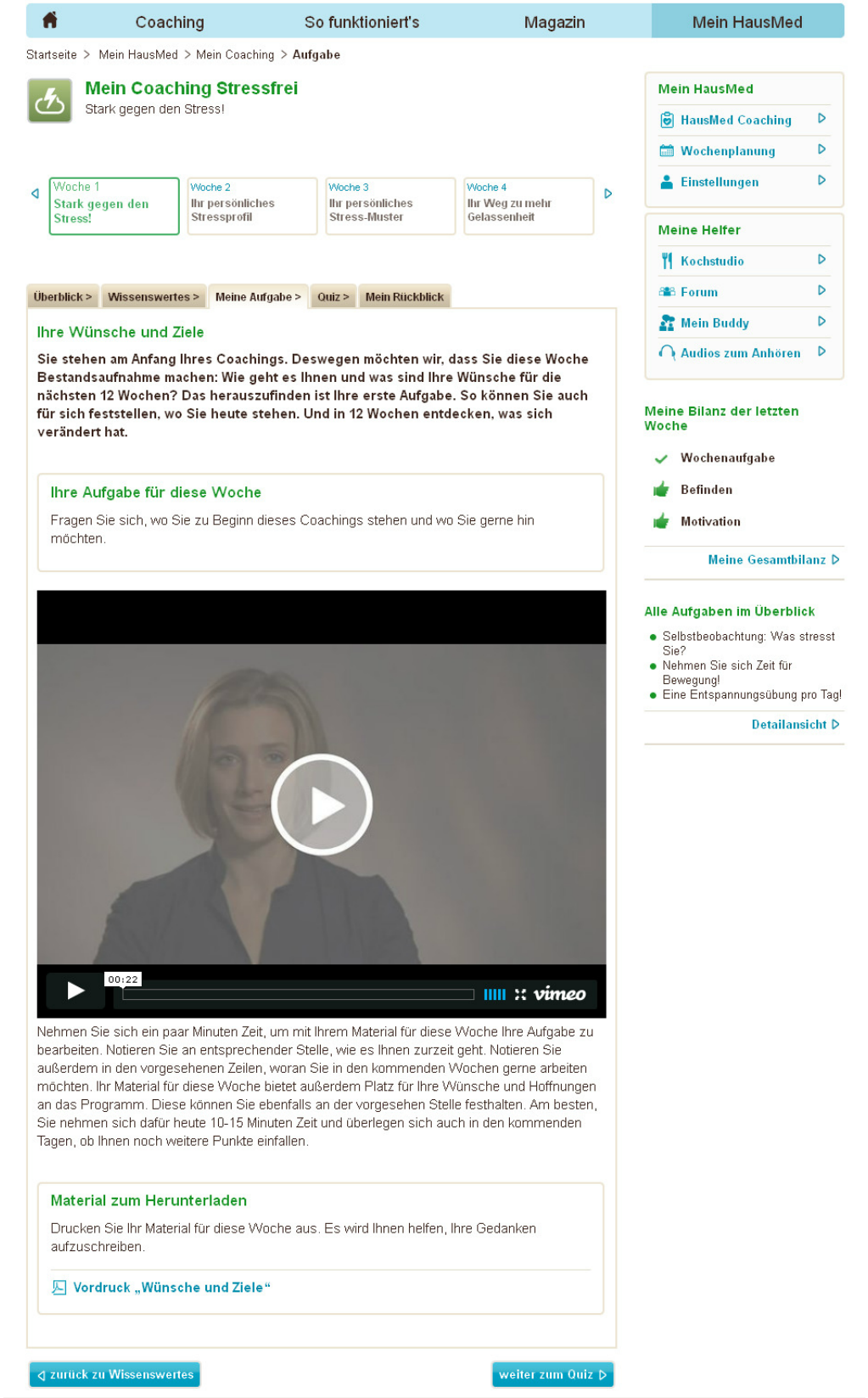
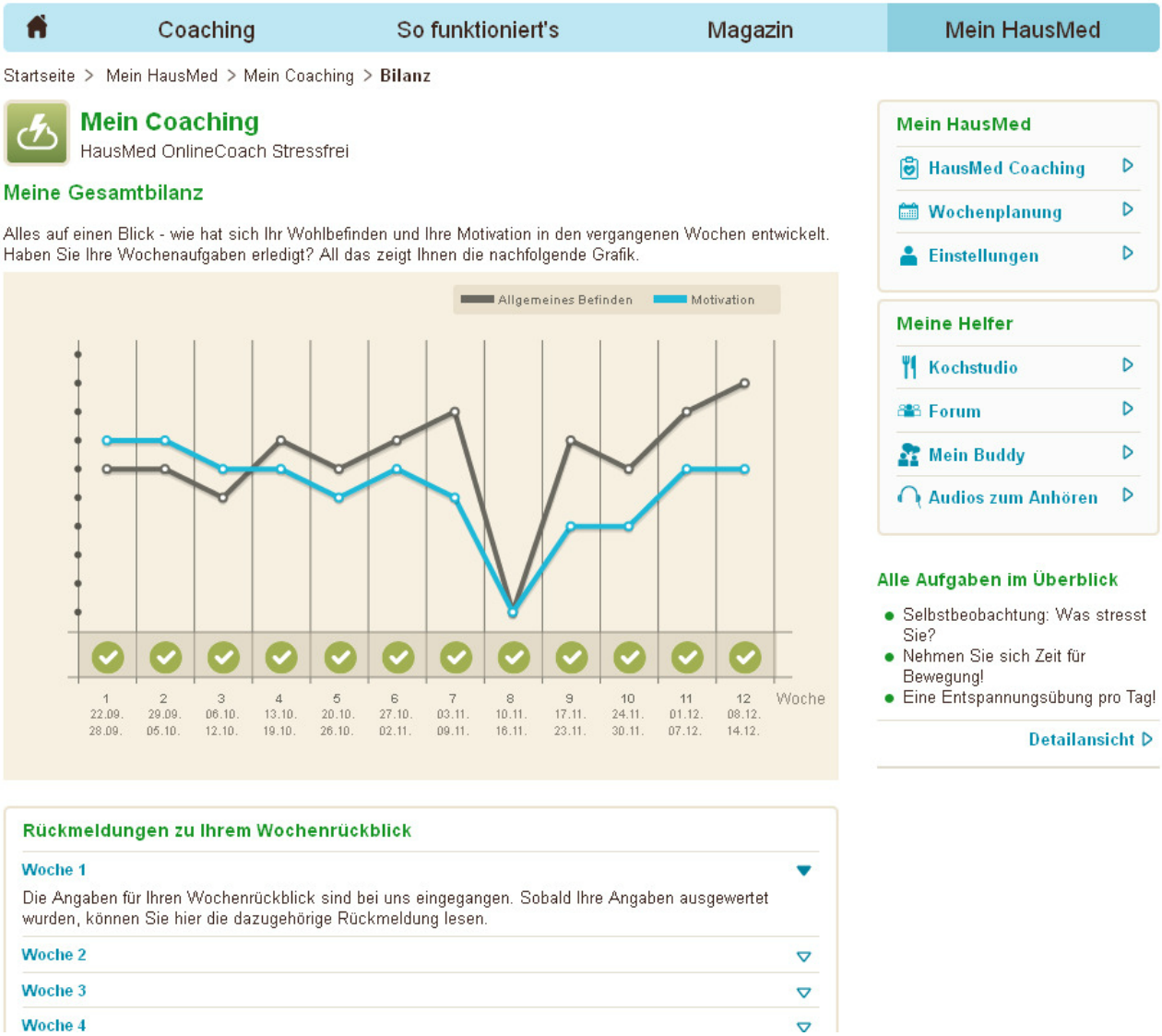


Figure 2. Screenshot of graph of condition (black curve), motivation (blue curve), and information about whether the weekly tasks were done or not (green check mark).



Outcome Measures

The primary outcome measure was the difference of the overall PSQ score between baseline and follow-up. Secondary outcome measures were the subscale differences between baseline and follow-up (ie, worries, tension, joy, and demands with a range from 0-100).

Statistics

Sample size calculation was performed with G*Power 3 correcting for the cluster design (estimated intracluster correlation coefficient=.05, expected average cluster size=3); correction of the sample size calculated by G*Power using the formula described in Campbell et al [41] for 2-sided testing (alpha of 5% and power of 80%, standardized mean difference=0.5). Using these assumptions, the calculated total sample size for primary outcome was 142 participants. Taking expected attrition into account, we aimed at recruiting a total of 180 participants and 80 GPs.

Originally, we had planned to use linear mixed models for investigating treatment effects, with multiple imputations based on propensity score methods to replace missing values. Our study substantially failed the recruitment target (leading to very low power), cluster size was highly variable, and many practitioners only recruited a single patient (13 or 35 GPs) or 2 patients (9 GPs). This made it impossible to reliably calculate an intracluster correlation coefficient. Therefore, we decided to perform the main analysis using the Student *t* test without accounting for the clusters for complete cases (CC; cases with PSQ values available at baseline and follow-up). Given the relevant and unequally distributed amount of missing data, we performed additional intention-to-treat analyses (ITT) replacing missing values by baseline values. For the main outcome (overall PSQ score) we performed secondary CC and ITT analyses of covariance adjusting for baseline score. It should be noted that ignoring the cluster structure leads to smaller *P* values and more narrow confidence intervals [42]. Therefore, we further conducted generalized estimating equations as a sensitivity analysis to take account of practices as patient clusters. The intracluster coefficient in the 13 practices recruiting 3 or more participants was .06 (95% CI -0.2 to 0.5). The findings of this analysis must be interpreted with great caution due to

the problems described previously. All analyses were performed using SPSS version 19.0. The presented *P* values are 2-sided and subject to a significance level of 5%.

Results

Originally, 92 GPs were interested in participating and were randomized, but 16 GPs withdrew early after randomization (7 GPs from the intervention and 9 GPs from the control group) and 41 GPs (25 GPs from the intervention and 16 GPs from the control group) did not recruit any participants for the study (Figure 3). Altogether, 93 patients were recruited by 35 GPs (40 patients by 14 GPs in the intervention group; 53 patients by 21 GPs in the control group) between April 18, 2011 and July 1, 2013. In all, 45 of 93 (60%) participants were female and the mean age was 42.2 years (SD 11.5). Overall, 15 participants had incomplete data in the intervention group, 11 did not show up for the measurement at 12 weeks, 3 participants had incomplete follow-up data, and 1 participant had incomplete baseline data. In the control group, 4 participants had missing values at 12 weeks. For 74 participants (25 from the intervention and 49 from the control group), information on PSQ was available both at baseline and after 12 weeks. The proportion of noncompleters (intervention: 15/40; control: 4/53) was significantly higher in the intervention group than in the control group (χ^2_1=12.6, *P*<.001). The intervention and control groups were similar at enrollment regarding gender, age, employment status, family status, and physical activity (Table 1).

Table 1. Baseline characteristics of participants at enrollment (N=93).

Characteristic	Intervention n=40	Control n=53	Mean difference	*P*
Age (years), mean (SD)	40.6 (11.0)	42.7 (11.8)	2.2	.37[a]
Gender, n (%)				>.99[b]
Females	24 (60.0)	31 (49.4)		
Males	16 (40.0)	22 (50.6)		
Employment, mean (SD)	2.5 (0.9)	2.4 (1.0)	0.1	.31[c]
Employment status, n (%)				
In training	2 (5.0)	3 (5.7)		
Full time	23 (57.5)	38 (71.7)		
Part time	13 (32.5)	7 (13.2)		
Seeking work	0 (0)	1 (1.9)		
Retired	1 (2.5)	3 (5.7)		
Other	1 (2.5)	1 (1.9)		
Family status, mean (SD)	2.6 (0.9)	2.2 (0.9)	0.4	.12[c]
Family status, n (%)				
Living alone	7 (17.5)	15 (28.3)		
Living in partnership	8 (20)	18 (34)		
Living in partnership with a child or children	20 (50)	17 (32.1)		
Living alone with a child or children	5 (12.5)	3 (5.7)		
Physical activity, mean (SD)	1.7 (1.2)	1.5 (1.3)	0.2	.43[d]
Physical activity, n (%)				
Daily	8 (20)	15 (28.3)		
Several times per week	12 (30)	16 (30.2)		
Once a week	6 (15)	7 (13.2)		
Irregular	13 (32.5)	11 (20.8)		
Almost never	1 (2.5)	4 (7.5)		

[a] Student *t* test.

[b] Fisher exact test.

[c] Chi-square test.

[d] Mann-Whitney *U* test.

Stress levels decreased in both groups from baseline to follow-up (Table 2). In the CC analysis, overall PSQ scores were reduced by mean 13.1 (SD 13.9, *P*=.02) points in the intervention group and mean 13.7 (SD 14.8, *P*<.001) in the control group. In the ITT analysis, reductions were by mean 8.2 (SD 12.7, *P*=.07) and mean 12.6 (SD 14.7, *P*<.001), respectively. Group differences within both analyses were nonsignificant. After adjustment for baseline differences between the groups, overall PSQ scores remained nonsignificant for the CC population (mean difference –0.3, 95% CI –7.1 to 6.5, *P*=.93) and for the ITT population (mean difference –4.2, 95% CI –10.2 to 1.3, *P*=.13). The secondary analysis using a generalized estimating equation also showed a nonsignificant result (*P*=.45).

Table 2. Results of the primary outcome measure (overall PSQ score) from baseline to 3-month follow-up for complete-case and intention-to-treat analyses.

Outcome	Intervention, mean (SD)	Control, mean (SD)	Cronbach alpha	Difference	
				Mean (95% CI)	*P* [a]
Complete case	n=25	n=49			
Baseline	55.5 (18.8)	56.8 (18.0)	.86	–1.3 (–10.2, –7.7)	.78
Follow-up	42.5 (19.7)	43.1 (19.4)	.91	–0.7 (–10.2, 8.9)	.89
Difference	–13.1 (13.9)	–13.7 (14.8)		–0.6 (–7.7, 6.5)	.34
Intention-to-treat	n=40	n=53			
Baseline	55.0 (19.2)	56.2 (17.4)	.86	–1.2 (–8.8, 6.4)	.76
Follow-up	46.9 (20.5)	43.6 (18.7)	.90	3.3 (–4.8, 11.4)	.42
Difference	–8.2 (12.7)	–12.6 (14.7)		–4.5 (–10.2, 1.3)	.13

[a]*P* values are from Student *t* test.

The results from the secondary subscales (worries, tension, joy, and demands) also revealed no significant group differences for either the CC or ITT analyses (Table 3). The ITT analysis revealed no significant differences for worries (mean difference –4.6, 95% CI –10.6 to 1.4, *P*=.13), tension (mean difference 1.0, 95% CI –8.4 to 6.3, *P*=.78), joy (mean difference 3.6, 95% CI –3.0 to 10.2, *P*=.28), and demands (mean difference –2.8, 95% CI –9.7 to 4.2, *P*=.44).

Figure 3. Participant flow of the study.

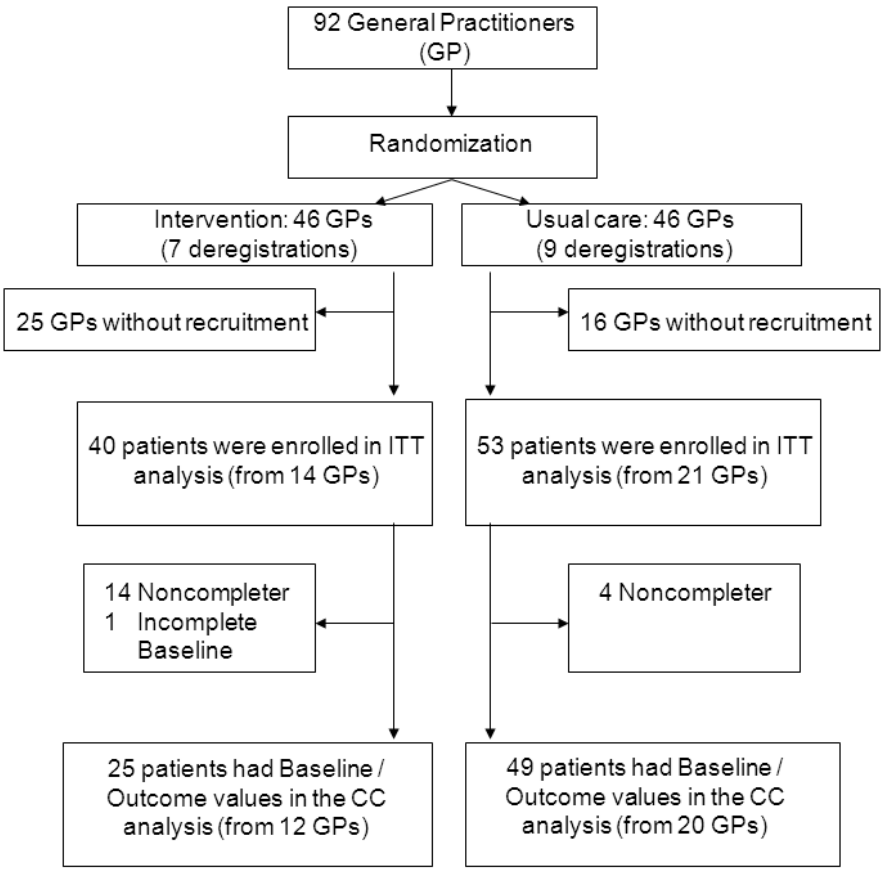


Table 3. Results of the secondary outcome measures (worries, tension, joy, and demands) at baseline and at 3-month follow-up for intention-to-treat and complete-case analyses.

Outcome	Intervention, mean (SD)	Control, mean (SD)	Cronbach alpha	Difference	
				Mean (95% CI)	*P* [a]
Intention-to-treat	n=40	n=53			
Worries					
Baseline	41.2 (22.0)	40.4 (22.6)	.90	0.8 (–8.0, 9.6)	.86
Follow-up	36 (22.7)	30.8 (20.5)	.93	5.2 (–3.8, 14.1)	.25
Difference	–5.2 (13.6)	–9.6 (16.3)		4.4 (–10.7, 1.9)	.17
Tension					
Baseline	64.5 (22.4)	64.3 (18.6)	.89	0.2 (–8.2, 8.7)	.96
Follow-up	49 (25.7)	47.8 (21.2)	.92	1.2 (–8.5,10.9)	.81
Difference	–15.5 (18.9)	–16.5 (17.7)		1.0 (–8.6, 6.6)	.80
Joy					
Baseline	46 (24.2)	39.7 (24.7)	.91	6.3 (–3.9, 16.4)	.23
Follow-up	51.5 (23.8)	50.7 (22.9)	.94	0.8 (–8.9, 10.5)	.87
Difference	5.5 (13.7)	10.9 (19.5)		5.4 (–1.8, 12.6)	.14
Demands					
Baseline	61.5 (22.5)	60.0 (18.4)	.92	1.5 (–6.9, 9.9)	.72
Follow-up	50.2 (23.3)	46.4 (20.0)	.94	3.8 (–5.2, 12.7)	.41
Difference	–11.3 (17.4)	–13.6 (18.3)		2.3 (–9.7, 5.2)	.55
Complete case	n=25	n=49			
Worries					
Baseline	38.9 (20.6)	41.2 (21.1)	.90	–2.3 (–12.6, 8.0)	.66
Follow-up	32.0 (20.2)	30.9 (21.3)	.94	1.1 (–9.1, 11.4)	.83
Difference	–6.9 (16.5)	–10.3 (16.7)		3.4 (–11.5, 4.7)	.41
Tension					
Baseline	64.5 (22.2)	64.1 (19.0)	.89	0.5 (–9.4, 10.3)	.93
Follow-up	43.7 (23.9)	46.3 (21.1)	.93	–2.5 (–13.3, 8.3)	.64
Difference	–20.8 (18.9)	–17.8 (17.7)		3.0 (–5.9, 11.9)	.51
Joy					
Baseline	44.5 (26.2)	38.6 (24.6)	.92	5.9 (–6.4, 18.2)	0.34
Follow-up	53.3 (25.7)	50.5 (23.0)	.94	2.9 (–8.8, 14.6)	0.63
Difference	8.8 (16.5)	11.8 (20.1)		3.0 (–6.3, 12.3)	0.52
Demands					
Baseline	63.2 (22.0)	60.5 (18.9)	.92	2.7 (–7.1, 12.5)	.59
Follow-up	47.5 (21.5)	45.9 (20.6)	.95	1.6 (–8.6, 11.9)	.75
Difference	–15.7 (19.6)	–14.7 (18.6)		1.0 (–8.2, 10.3)	.82

[a]*P* values are from Student *t* test.

Adverse events from 2 participants were documented. In the intervention group, one participant reported family and workplace problems, whereas in the control group one participant specified an adverse event without further details. The authors did not consider that these adverse events were directly related to the intervention.

Discussion

To the best of our knowledge, this study is the first study to investigate a Web-based stress-reduction intervention in primary care. We found that the fully automated Web-based coaching program was not effective for achieving stress reduction compared to usual care. The mean PSQ score decreased in both groups without a significant group difference. Thus, this trial could not show any advantages compared to usual care. Nevertheless, previous findings revealed that stress reduction can be delivered effectively via the Internet [20-27]. Most computer-based interventions for stress have been evaluated in workplace settings [21,22,27,29,43]. For example, Ruwaard and colleagues [43] demonstrated that an Internet-based cognitive behavioral treatment of work-related stress was more effective in reducing stress than a waiting control group. Few studies have evaluated the impact of a Web-based intervention in the general population [26,44]. However, the content of the evaluated interventions and the methodological approaches offered great variability. Zetterqvist and colleagues [26] found that an Internet self-help intervention for relaxation training, exercises (cognitive and behavioral restructuring), and information could be effective in reducing symptoms of stress. Drozd et al [44] demonstrated from a RCT that a Web-based intervention based on mindfulness and metacognitive exercises lead to a reduction of stress. Both studies recruited their participants through webpages or newspaper articles. This might be due to the involvement of a different study population compared to this study sample for which recruitment was carried out by GPs. In addition, the condition and contents of usual care in general practice are not equivalent to a waiting list or a simple online information offer. Therefore, the results from the 2 studies mentioned previously are not directly comparable with this study; furthermore, it is unlikely that this study could discover greater group differences than these previous ones. This is due, firstly, to the comparison of usual care instead of a waiting list or simple online information. Secondly, it might be possible that the mere participation in the control group with the advice from the GP to reduce stress started an autonomous process that led to a reduced level of stress even without exact knowledge about usual care. Another reason why the findings from this study are inconsistent with previous findings is because they were collected in different settings and there might be a “black box” phenomenon or a lack of understanding about how and why some interventions work and others do not. The particular setting and the realization of the intervention may be crucial for their effectiveness. To date, there is insufficient knowledge about the impact of different implementations of Web-based interventions. Due to limited funds, the implementation of this study was designed quite basically. The shortcomings caused by this may have had an influence on the findings from this study. Therefore, the diversity of different kinds of implementation of Web-based interventions should be addressed more in further studies.

One meta-analysis showed that mindfulness can have a broad range of health benefits [45]. Chiesa and colleagues [46] stated that mindfulness-based stress-reduction interventions are generally effective. Another meta-analysis found that cognitive behavioral interventions are more effective than other interventions [31]. Wilhelmsen et al [47] illustrated within a qualitative study that Internet-based cognitive behavioral interventions may add a structured agenda to consultations and simultaneously empower patients. Otherwise, they have shown how challenging and complex it is to conduct an Internet-based cognitive behavioral intervention deployed from GPs in primary care. In summary, current evidence for stress reduction shows that cognitive behavioral interventions seem to be the most effective treatment for a Web-based approach. To this end, further studies are necessary to investigate different modalities of Web-based interventions to learn more about the black box phenomenon. In addition, this trial confirmed the well-known problem that Web-based interventions are often accompanied by a high attrition rate [48]; the significantly higher proportion of noncompleters in the intervention group underlines this fact.

One strength of this study was the embedding of the study in a realistic primary care setting. However, some important methodological aspects for the interpretation of the study results need to be considered. First of all, the randomization of this study was conducted at the GP level before individual participants were included. Thus, physicians knew whether they recruited patients for the intervention or the control group, which could lead to bias. Secondly, due to the highly variable cluster sizes the statistical analysis of our data was not straightforward. Classical linear mixed models taking the cluster design into account could not be used because of numerical problems. Therefore, we used a simple Student *t* test (which ignores intracluster correlation) and an additional multilevel analysis (which performs inadequately when cluster sizes differ) as the sensitivity analysis. Third, according to our power calculations, the target number of participants was not reached due to slow recruitment of participants; the study had to be stopped at a certain point, which may have reduced the study’s ability to detect significant differences between the groups. Fourth, participating GPs were self-selected, training and supervision were very basic, and other implementation components, such as administrative support, were not available due to limited funding. Fifth, due to strict data privacy requirements we could not access the automatically documented data about the extent participants accessed and used the program. Sixth, the proportion of participants without follow-up values was definitely higher in the intervention than in the control group. This could be because participants in the control group received a small financial incentive, whereas those in the intervention group did not. Therefore, participants in the intervention group might have been less willing to make an additional practice visit after completing the program than those in the control group. Finally, the content of usual care was not further evaluated. The practitioners for the control group were asked to change nothing in their usual way of counseling and to treat their participants in the same manner as usual. There was no additional documentation of the counseling provided.

Our findings suggest that this tested Web-based coaching program was not effective for achieving stress reduction compared to usual care. The change from baseline was similar to usual primary care. The limited statistical power and the high dropout rate may have reduced the study’s ability to detect

significant differences between the groups. Further randomized controlled trials are needed to investigate larger populations, the long-term outcomes, and the content of usual primary care.

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Authors' Contributions

AS, KL, and MM designed the study. MM wrote the initial protocol with supervision from AS and KL. MM coordinated the study with MH. MM, KL, AS, MH, and SW did the analysis. MM drafted the manuscript with contributions from AS, KL, SW, and MH. All authors read and approved the final manuscript. MM is the guarantor.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Video Presentation.

[MP4 File (MP4 Video), 20MB - jmir_v18i2e27_app1.mp4]

Multimedia Appendix 2

Waiting room adverstisement.

[PPT File (Microsoft PowerPoint Presentation), 1MB - jmir_v18i2e27_app2.ppt]

Multimedia Appendix 3

CONSORT-eHealth (V 1.6.1) checklist [49].

[PDF File (Adobe PDF File), 17MB - jmir_v18i2e27_app3.pdf]

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Abbreviations

CC: complete case
GP: general practitioner
ITT: intention-to-treat
PSQ: Perceived Stress Questionnaire

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Original Paper

An eHealth Diary and Symptom-Tracking Tool Combined With Person-Centered Care for Improving Self-Efficacy After a Diagnosis of Acute Coronary Syndrome: A Substudy of a Randomized Controlled Trial

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Abstract

Background: Patients with cardiovascular diseases managed by a person-centered care (PCC) approach have been observed to have better treatment outcomes and satisfaction than with traditional care. eHealth may facilitate the often slow transition to more person-centered health care by increasing patients' beliefs in their own capacities (self-efficacy) to manage their care trajectory. eHealth is being increasingly used, but most studies continue to focus on health care professionals' logic of care. Knowledge is lacking regarding the effects of an eHealth tool on self-efficacy when combined with PCC for patients with chronic heart diseases.

Objective: The objective of our study was to investigate the effect of an eHealth diary and symptom-tracking tool in combination with PCC for patients with acute coronary syndrome (ACS).

Methods: This was a substudy of a randomized controlled trial investigating the effects of PCC in patients hospitalized with ACS. In total, 199 patients with ACS aged <75 years were randomly assigned to a PCC intervention (n=94) or standard treatment (control group, n=105) and were followed up for 6 months. Patients in the intervention arm could choose to use a Web-based or mobile-based eHealth tool, or both, for at least 2 months after hospital discharge. The primary end point was a composite score of changes in general self-efficacy, return to work or prior activity level, and rehospitalization or death 6 months after discharge.

Results: Of the 94 patients in the intervention arm, 37 (39%) used the eHealth tool at least once after the index hospitalization. Most of these (24/37, 65%) used the mobile app and not the Web-based app as the primary source of daily self-rating input. Patients used the eHealth tool a mean of 38 times during the first 8 weeks (range 1–118, SD 33) and 64 times over a 6-month period (range 1–597, SD 104). Patients who used the eHealth tool in combination with the PCC intervention had a 4-fold improvement in the primary end point compared with the control group (odds ratio 4.0, 95% CI 1.5–10.5; *P*=.005). This improvement was driven by a significant increase in general self-efficacy compared with the control group (*P*=.011). Patients in

the PCC group who did not use the eHealth tool (n=57) showed a nonsignificant composite score improvement compared with those in the control group (n=105) (odds ratio 2.0, 95% CI 0.8–5.2; *P*=.14).

Conclusions: We found a significant effect on improved general self-efficacy and the composite score for patients using an eHealth diary and symptom-tracking tool in combination with PCC compared with traditional care.

Trial Registration: Swedish registry, Researchweb.org, ID NR 65 791.

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KEYWORDS

person-centred care: telemedicine; mobile health; eHealth; patient-centered care; self-efficacy; acute coronary syndrome

Introduction

Acute coronary syndrome (ACS) is an acute manifestation of coronary heart disease that includes myocardial infarction and unstable angina pectoris. In patients with ACS, eHealth studies have shown positive health-related outcomes [1-4]. “eHealth” is a relatively recent term for health care practice, which encompasses a variety of actions referring to health services and information delivered or enhanced through the Internet and related technologies [5,6]. As such, eHealth is an umbrella concept comprising all sorts of communication and information technology aimed at supporting and facilitating patients’ perception of well-being [7].

In contrast to eHealth, remote monitoring considers monitoring a disease from an objective perspective and implies 1-way communication between health care professionals and patients [8]. Such objective systems may limit the patient’s ability to participate in treatment decisions and to take full responsibility for their illness, which are essential elements in person-centered care (PCC). A PCC approach focuses on the patient as a person rather than on the disease alone, and implies that the patient has self-capacities that are valuable resources in an active partnership between the patient and health care professionals [9]. Increasing evidence suggests that patients with a diagnosis of cardiovascular disease who receive PCC, including active involvement in their care, shared decision making, and a structured follow-up, have better outcomes. Such improved outcomes include reduced uncertainty in illness, improved activity in daily living, a shorter hospital stay, and reduced costs of health care when compared with conventional care [10-12]. A central concept in PCC is self-efficacy [13], which is based on a person’s belief and confidence in achieving a certain task, rather than the actual execution and outcome of the task [14]. Higher levels of self-efficacy are associated with improved concordance between health care professionals and patients regarding prescribed treatment and increased physical activity for patients with congestive heart failure [15]. Findings of a recent review, focusing on chronic care management and eHealth, implied that most eHealth interventions are designed for 1-way communication and are driven by the logic of the health care professional rather than the patient’s [16]. Another review, analyzing over 350 studies within the area of eHealth and chronic disease management [17], showed that the majority of eHealth interventions studied were monitoring signs, and very few of those studies (n=4), in fact none within the cardiovascular field, had self-rated symptom reporting, hence sidestepping the patients’ experience of their illness and symptoms.

Consequently, there is a lack of knowledge about whether such solutions can be used in a PCC approach to strengthen a patient’s self-efficacy. Therefore, this study aimed to investigate the effect of a Web- and mobile-based eHealth diary and symptom-tracking tool (henceforth eHealth tool) combined with a PCC intervention in patients hospitalized for an ACS event.

Methods

Study Design and Setting

This study was part of a randomized intervention study: Person-centered Care after Acute Coronary Syndrome (PACS study, Swedish registry, Researchweb.org, ID NR 65 791) [18]. The PACS study evaluated the effects of a PCC intervention in patients with ACS throughout 3 health care levels (hospital, outpatient clinics, and primary care) compared with usual care alone. A detailed description of the study methods and findings has been reported previously [18]. In summary, patients were eligible for study inclusion if they were younger than 75 years, admitted for suspected ACS, and subsequently diagnosed with either myocardial infarction or unstable angina pectoris. Patients were included at 2 hospital sites within a university hospital setting in the western part of Sweden. Patients were excluded at admission if they met at least one of the following exclusion criteria: aged ≥75 years; not willing to participate; currently listed at a private primary care center or at a primary care center in another region; having no permanent address; being planned for heart surgery, such as coronary artery bypass grafting; having cognitive impairment; having known alcohol or drug abuse; having a survival expectancy of <1 year; or participating in a conflicting study. A total of 199 patients were randomly assigned in the main PACS study, with 105 patients in the control group and 94 patients in the intervention group.

For this substudy, all of the patients in the control group of the original PACS study were included and compared with those in the intervention group of PACS who chose an eHealth tool (eHealth group). The patients who were included in the eHealth group received the same structured PCC approach as described in the main PACS study [18] and were also given the choice to use the optional eHealth tool as a complement. Based on a structured PCC approach, every patient received the PCC intervention regardless of whether they chose the eHealth tool. Briefly, this approach builds upon the patients’ narrative used to identify their personal opportunities and barriers during cardiac rehabilitation after ACS. The condensed narrative,

agreed on by the patient, physician, and registered nurse (PCC team), is documented in a PCC health plan. The PCC health plan includes the patient's goals, expectations, and follow-up actions (date, time, and place). The focus is on each person's resources and is the joint responsibility of both the health care professionals and the patients [9]. The PCC teams at each health care level (hospital, outpatient, and primary care) had access to the PCC health plan throughout this continuum of care, and discussed and revaluated or altered the PCC health plan with the patient if necessary [18].

The eHealth tool consisted of a mobile app and access to a webpage, and the patient had the option to use the webpage or the mobile app, or both. Patients who were enrolled in the control group were managed according to standard rehabilitation, which followed guideline-directed care that was compliant with Swedish standards. Patients in the control group answered questionnaires and instruments, similar to the eHealth group, at baseline, 4 weeks, 8 weeks, and 6 months.

The eHealth Intervention

Mobile App

The mobile app consisted of 3 modules: (1) a self-rated fatigue scale, (2) a symptom trend graph, and (3) a built-in accelerometer within the phone to provide a daily average of the patient's physical activity level (Table 1). Because fatigue is a common symptom after ACS [19], the self-rating scale was inspired by the Multidimensional Fatigue Inventory questionnaire by Smets et al [20]. The original Multidimensional Fatigue Inventory questionnaire is a validated, 20-item multidimensional fatigue questionnaire consisting of 5 dimensions: general fatigue, physical fatigue, activity, motivation, and mental fatigue. To minimize the number of items and still cover these dimensions, we enabled patients to self-rate their symptoms of physical and mental fatigue, as well as their motivation and activity levels (Table 2). The activity measurement within the mobile app automatically collected data throughout the entire day from the built-in accelerometer. The app calculated a mean daily level of energy expenditure, which was visualized for the patient on a symptom trend graph to be followed up and evaluated with registered nurses in the project if necessary. Patients also had the opportunity to show their trend graph to health care professionals during the follow-up period.

Table 1. Functional similarities and differences between the webpage and the mobile app eHealth interventions.

Webpage	Mobile app
Rating of fatigue	Rating of fatigue
Visual symptom trend graph over time	Visual symptom trend graph over time
Free-text diary function	Daily activity measurement using a built-in accelerometer
Chat function	
Personal links to relevant webpages	

Table 2. Patient self-rating of fatigue used in the webpage and mobile app eHealth interventions.

Dimension	Rating
Physical fatigue	I feel that I am in great condition
	I feel that I am in good condition
	I feel that I am in fair condition
	I feel that I am in poor condition
Mental fatigue	I have no problem concentrating
	I have to make an effort to concentrate
	I have to make a huge effort to keep concentrating
	I cannot concentrate at all
Motivation	I want to do a lot of things
	I only do the most necessary things
	I have no motivation to do anything
	I dread doing anything at all
Activity level	I feel very active
	I manage what needs to be done
	I get very little done
	I do nothing

Webpage

The webpage consisted of 5 modules: (1) self-rated symptoms of fatigue (same as on the mobile app described above), (2) a symptom trend graph, (3) a diary function for free-text entries to capture the everyday experience using the patient's own words, (4) a chat function with other patients and registered nurses within the study, and (5) personal links to relevant webpages and the ability to upload documents (Table 1). The text diary was open for text input until midnight the same day. After this time, the patient could not revise the written text regarding that day. The webpage and the mobile app synchronized the data.

A registered nurse at the hospital asked all of the patients in the eHealth group if they were interested in using the eHealth tool. Patients had the opportunity to borrow a mobile phone with the eHealth app preinstalled or to download it for use on their own mobile phone. Users were registered with a username and password on the webpage, and the online webpage was connected to the mobile app. An introductory demonstration, which required the patient to test the eHealth tools, was provided by a registered nurse who was familiar with the study so that patients could start using the tools freely during their hospital stay. Additional training could be requested if needed. Patients also had access to a video demonstration online for further information. The patients themselves decided on the frequency and patterns of use of the eHealth tools. After 8 weeks, the registered nurse and physician at the primary care center asked patients whether they wanted to return (if borrowed) or continue to use the mobile phone. Access to the webpage had no time restriction.

Instruments

We evaluated patient-reported scores on the General Self-Efficacy Scale (GSES) using the Swedish version [21] of the original GSES [22]. The GSES, a unidimensional scale and universal construct, is validated in several countries [23]. The Swedish validated version of the GSES has high internal consistency (alpha = .90) [21]. The GSES is a 10-item instrument that measures patients' beliefs and confidence in accomplishing certain tasks, rather than the actual execution and outcome of these tasks. Each item is rated by the patient on a 4-point Likert scale, in which 1 = not at all true, 2 = hardly true, 3 = moderately true, and 4 = exactly true. Total scores ranging from 10 to 40 are calculated, with higher totals indicating higher levels of general self-efficacy.

Patients in the control and eHealth groups filled out the GSES instrument at baseline at the hospital, and at 4 weeks, 8 weeks, and 6 months.

Primary End Point

The primary end point was a composite of changes in general self-efficacy, return to work or prior activity level, and rehospitalization or death. Each patient was classified as improved, deteriorated, or unchanged. An increase of 4.6 units in the GSES has been suggested to show the minimal clinical important difference for patients [24]. A patient was classified at 6 months as improved in the composite score as follows: self-efficacy had increased by ≥5 units and the patient was not readmitted for unscheduled cardiovascular reasons or death; and the patient had returned to work or previous physical activity level (improved from sedentary to moderate activities or better, or maintained or improved from moderate to demanding or strenuous activities) [25].

Those patients who had neither deteriorated nor improved were considered unchanged. Patients were dichotomized into improved versus deteriorated or unchanged status.

Statistical Analyses

Patients in the PCC intervention group who had used the eHealth tool at least once after discharge were included into this substudy and compared with the control group. We used descriptive statistics, such as frequency, mean, median, range, and SD, to describe user patterns. Between-group differences were tested using Fisher exact test for dichotomous variables and the Mann-Whitney *U* test was used for continuous variables. Logistic regression was used to calculate the odds ratios (ORs) between groups, with a 95% CI. We analyzed the data using SPSS 22 (IBM Corporation) statistical software package.

Ethics

The Regional Ethics Committee of the University of Gothenburg approved the study (DNr 275-11). The study adhered to the rules of the Declaration of Helsinki of ethical principles.

Results

Of the 94 patients in the intervention arm, 37 (39%) chose to use the eHealth tool (PCC + eHealth) and continued to use it at least once, even after discharge from the hospital. The remaining patients (PCC no eHealth, n=57) did not choose to use the eHealth tool (n=39) or did not use the eHealth tool after discharge (n=18) (Figure 1). The majority of patients were male, with a mean age of 60 years (SD 10). There were no significant differences in demographic characteristics, such as age, education, socioeconomic level, diagnosis, or general self-efficacy between patients in the different groups at baseline (Table 3). The majority of patients in the PCC + eHealth group (24/37, 65%) used the mobile app rather than the Web-based app as the primary source of daily self-rating input. Patients used the eHealth tool a mean of 38 times during the first 8 weeks (range 1–18, SD 33) and 64 times over a 6-month period (range 1–597, SD 104).

Table 3. General characteristics of the study population divided into control versus PCC[a]+ eHealth and PCC no eHealth.

Characteristic		Control (n=105)	PCC + eHealth (n=37)	PCC no eHealth (n=57)
Female, n (%)		32 (30.5)	7 (19)	16 (28.1)
Age in years, mean (SD)		61.3 (8.9)	59.8 (10.1)	60.9 (8.7)
Education, n (%)				
	None	1 (1.0)	1 (3)	0 (0)
	Compulsory	21 (20.0)	5 (14)	11 (19)
	Secondary school	28 (26.7)	7 (19)	16 (28)
	Vocational college	14 (13.3)	9 (24)	12 (21)
	University	41 (39.0)	15 (41)	18 (32)
Employed, n (%)		60 (57.1)	24 (65)	30 (53)
Income, n (%)				
	Low	13 (12.4)	5 (14)	10 (18)
	Lower-middle	20 (19.0)	4 (11)	9 (16)
	Upper-middle	30 (28.6)	18 (49)	17 (30)
	High	30 (28.6)	8 (22)	16 (28)
	Missing data	12 (11.4)	2 (5)	5 (9)
Type of acute coronary syndrome, n (%)				
	ST-elevation myocardial infarction	24 (22.9)	9 (24)	15 (26)
	Non-ST-elevation myocardial infarction	51 (48.6)	13 (35)	25 (44)
	Unstable angina	30 (28.5)	15 (41)	17 (30)
General self-efficacy, mean (SD)		30.3 (5.6)	28.8 (6)	30.0 (6)

[a]PCC: person-centered care.

A higher percentage of patients (11/37, 30%) in the PCC + eHealth group improved in the composite score than those in the control group (n=105) over a 6-month period (OR 4.0, 95% CI 1.5–10.5; *P*=.005) (Table 4). There was a significant increase in mean self-efficacy levels, as measured by the GSES, at 6 months in the PCC + eHealth group (n=37) compared with the control group (n=105) (*P*=.01). Patients in the PCC no eHealth group (n=57) showed a nonsignificant improvement in the composite score compared with those in the control group (n=105) (OR 2.0, 95% CI 0.8–5.2; *P*=.14). When comparing the PCC group without eHealth versus the PCC group + eHealth, the PCC + eHealth group (n=37) showed a nonsignificant improvement in the composite score compared with the PCC no eHealth group (n=57) (OR 2.0, 95% CI 0.7–5.3; *P*=.17). In both these comparisons, no significant differences were observed in mean self-efficacy levels at 6 months.

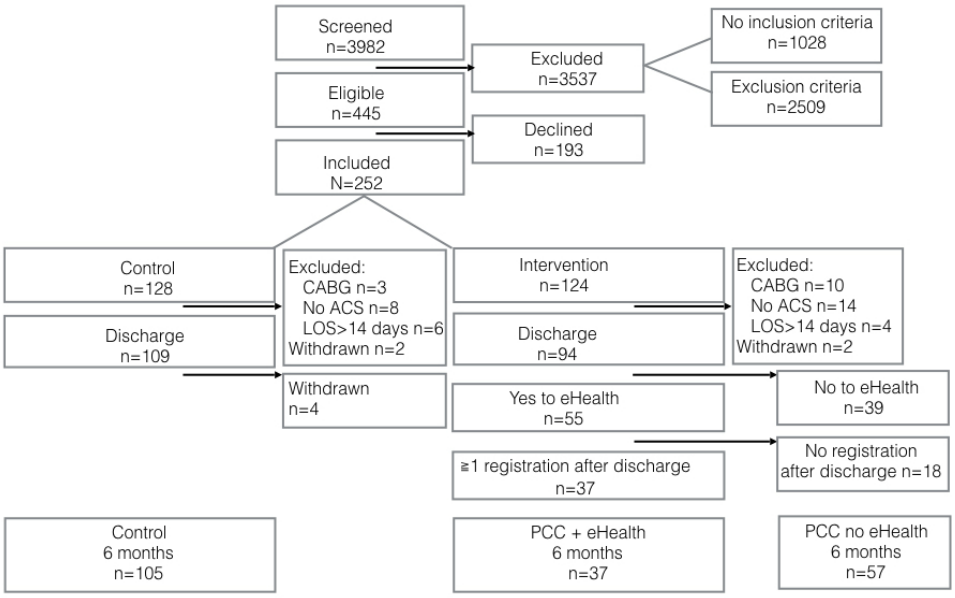
There were 6 events in the PCC + eHealth group (1 death, 5 readmissions), 12 events in the PCC group without eHealth (3 deaths, 9 readmissions), and 16 events in the control group (2 deaths, 14 readmissions). The proportion of patients who returned to work was similar between groups at 6 months (PCC + eHealth 30/34, 88%; PCC no eHealth 47/53, 89%; control 89/98, 91%).

Table 4. Primary end point: change in composite score dichotomized into improved versus unchanged or deteriorated condition in the control group compared with PCC[a]with or without an eHealth intervention.

Change in composite score at 6 months	Control (n=105)	PCC + eHealth (n=37)	PCC no eHealth (n=57)
Improved, n (%)	10 (9.5)	11 (30)	10 (18)
P value vs control		.006	.21
Unchanged or deteriorated, n (%)	95 (90.5)	26 (70)	47 (83)

[a]PCC: person-centered care.

Figure 1. Study profile. ACS, acute coronary syndrome; CABG: coronary artery bypass graft; LOS: length of hospital stay; PCC: person-centered care.



Discussion

We found that patients who used the eHealth tool in combination with PCC had a 4 times higher improvement in the primary end point compared with those receiving usual care. However, fewer than half of the eligible patients used the eHealth tool after discharge, and they preferred the mobile app over the webpage. In comparison with the patients receiving PCC who did not choose or did not use the eHealth tool after the index hospitalization, improvement in the primary end point was less prominent.

eHealth Tool Use Patterns

This study showed feasibility, to a limited extent, for use of an eHealth tool by patients after an ACS event because approximately 40% of the eligible patients used the eHealth intervention after discharge. Patients were offered use of the eHealth tool as a completely optional supplement without any reminders. ACS is an overwhelming event inducing several concerns during hospitalization [26]; therefore, the adherence rate for using the eHealth tool might have been increased if the patients had been asked again if they wanted to use an eHealth tool when their health status had been stabilized, that is, after hospital discharge. The findings from this study are congruent with a systematic review by Munro and coworkers [27] showing use of eHealth programs for targeting patients with different diagnoses of cardiovascular disease, ranging from 36% to 97%. Interestingly, a meta-analysis by Inglis and coworkers [28] in patients with congestive heart failure showed a slightly higher use of eHealth, ranging from 66% to 98%. Nevertheless, because of the design of the study, the use pattern may indicate the present uptake levels for these kinds of self-management tools in the clinical setting. Similar to our findings regarding the use pattern of a mobile app versus a computer-based app, a study with patients with myocardial infarction evaluating uptake of technology-assisted cardiac rehabilitation showed that patients used the mobile app more frequently than a computer-based tool [29]. In this study the eHealth tool had more functions on the Web than on the mobile app, which may have negatively affected the adherence rate.

Clark et al [2] suggested that the duration of the interventions could have a negative effect on eHealth use for patients with ACS because interventions shorter than 2 months involved more users than interventions lasting longer than 2 months. In this study, the average use of the eHealth tool increased during the study period, indicating that patients who used the eHealth app for 2 months or more also used it most often. This finding needs to be further examined in future studies.

Self-Efficacy

Whereas we observed no difference between groups regarding death or rehospitalization, the primary end point was determined by an improvement in the patients' self-efficacy level. Self-efficacy is a person's belief in his or her own ability to execute the behavior required to achieve desired outcomes [14,30]. According to this theory, self-efficacy can be influenced and strengthened, which is probably relevant to patients with chronic conditions. Dickson et al [31] suggested that self-efficacy in patients with congestive heart failure is a dynamic, oscillating resource that is enhanced or diminished by the context and situation. Nevertheless, because health care professionals focus on the medical needs of hospitalized patients, they seldom systematically consider patients' personal resources, independence, and preferences [9]. The essence of PCC is the partnership between the patient and health care professionals. This partnership is based on a shared knowledge and mutual agreement about living with illness (patient) and generic knowledge about the disease (health care professionals). The way in which patients view their illness is as important as the disease itself and an essential factor for improving health outcomes and returning to professional work after an ACS event [32]. The eHealth tool in this study was developed to be used as a self-care device. Increased knowledge about oneself in relation to the illness and disease in question could be an

important step in strengthening patients' role as an expert about their everyday life and an active partner in the interaction with health care professionals.

The eHealth tool also made it possible for patients and health care professionals to develop a partnership through their communication via the chat function on the webpage and by patients presenting their trend graphs during follow-up visits. Since this is a complex intervention it is difficult to differentiate which component of the PCC intervention contributed most to the improvement in general self-efficacy. This study suggested that an eHealth tool in addition to a PCC intervention was associated with even higher improvement levels in the composite score in this selected group of patients than in the control group. The effect was driven by improved general self-efficacy, which suggests that an eHealth tool added to a PCC intervention can improve patients' beliefs in their ability to successfully respond to challenges across a wide range of situations. This in turn was shown to contribute to improved disease management and clinical outcomes, such as health status and health care utilization [33]. The potential of digital technologies to become disruptive innovations in traditional power structures such as health care lies not only in making processes more transparent and easily accessible for the end user. We believe that the disruptive force also could change health care providers' perception of the patients' own view of their capacities to manage different situations. Nevertheless, research shows that most eHealth studies in the field of chronic care management take a professionally driven approach to monitoring signs [16,17], where professionals try to activate patients by pushing content and information that the professionals believe is of importance for the patient. Instead, we propose a more active patient role where the patients themselves seek information and create knowledge that is of importance to them in order to develop a productive interaction that fits the need of both the patients and the health care professionals. Hence, more studies need to investigate the potential in changing the perception of the patient's role as a passive provider of data to an active cocreator of knowledge.

While 94 patients were included in the PCC intervention arm, only 37 (39%) chose the eHealth tool. Nevertheless, 11 patients (30% of the active users, or 12% of the total intervention group) improved even more in the primary end point when they complemented PCC with the eHealth tool in comparison with PCC alone. A comparison of this study outcome with that in the original paper published by Fors et al [18] indicates that the eHealth tool could have an augmenting effect on PCC. The primary end point was a composite score, combining patient experiences with clinical outcomes, which have been shown to be sensitive in differentiating treatment outcomes [34]. We defined improvement very restrictively as requiring no rehospitalization or death in combination with improvement on the GSES by ≥5 units (equivalent to almost 1 SD; in general, 0.5 SD is considered of clinical importance [35]). We also included return to work or previous activity level as a measure of improvement. Our specific definition of improvement might explain why only a minority benefitted from the intervention. For the effects of the intervention to be reflected as a hard outcome, a larger sample and longer follow-up period are needed. In general, there is a low power to evaluate subgroup analyses in clinical trials. Thus, the effects on clinical outcomes need to be studied in larger studies [36].

eHealth was still not considered as a viable support tool by the majority of patients in this study. Qualitative studies in telecare suggest that patients with congestive heart failure emphasize the value of the relationship with their health care professional [37]. Additionally, the patient's primary concern with telecare is that it should not disrupt or compensate for ordinary face-to-face services [38]. Patients' fear that eHealth is a replacement for face-to-face meetings could affect the decision not to choose an eHealth tool. Therefore, future studies should examine how the interaction and communication aimed at improving self-efficacy in people with long-term diseases can be developed through eHealth solutions or other means. In addition, studies need to investigate how patients and their relatives could better understand their own role in PCC. We believe that the interactive communication as manifested *by* the partnership in PCC can provide substantial *support* for eHealth and differentiate this technology from telemedicine. However, this needs to be confirmed in future studies.

Limitations

This study has several limitations. Results should be interpreted based on the limitation that this was a substudy. Only approximately 40% of the patients included in the intervention agreed to participate in this study, which used an eHealth tool at least once after discharge. This group could consist of the most motivated individuals. Additionally, comparing these patients with the entire control group was a limitation of this study. However, there were no significant differences at baseline in demographic variables between the control and intervention groups. Despite this limitation, our study suggests that, for a selected group of people, this type of eHealth tool adds value in combination with PCC. Finally, another limitation is that we did not know whether the patients actively used the eHealth solution as part of the follow-up visits at the outpatient clinic or in primary care. While patients who used the eHealth tool had significantly higher general self-efficacy levels compared with the control group, the effect of using eHealth tools on shared decision making in a PCC setting still needs to be investigated. More studies, also using a qualitative approach, need to evaluate the potential of the intervention in terms of understanding the tool and patients' own role in PCC and among a broader study population.

Conclusion

An eHealth diary and symptom-tracking tool in combination with a structured PCC intervention is associated with improved combined scores, comprising self-efficacy, return to work or prior activity level, rehospitalization, and death, in a selected group of patients with ACS compared with usual care. Future research should address the effects and efficiency of an eHealth tool throughout PCC interventions compared with traditional care.

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Conflicts of Interest

AW is the founder and owner of a company that designs and develops mobile apps, and the mobile app discussed in this article has been developed by that company. Other authors have no conflicts of interest to declare.

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Abbreviations

ACS: acute coronary syndrome
GSES: General Self-Efficacy Scale
OR: odds ratio
PACS: Person-centered Care after Acute Coronary Syndrome
PCC: person-centered care

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Original Paper

Effect of the Web-Based Intervention MyPlan 1.0 on Self-Reported Fruit and Vegetable Intake in Adults Who Visit General Practice: A Quasi-Experimental Trial

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Abstract

Background: Web-based interventions typically have small intervention effects on adults' health behavior because they primarily target processes leading to an intention to change leaving individuals in an intention-behavior gap, they often occur without contact with health care providers, and a limited amount of feedback is provided only at the beginning of these interventions, but not further on in the behavior change process. Therefore, we developed a Web-based intervention ("MyPlan 1.0") to promote healthy behavior in adults. The intervention was based on a self-regulation perspective that also targets postintentional processes and guides individuals during all phases of behavior change.

Objective: The study investigated the effectiveness of MyPlan1.0 on fruit and vegetable intake of Flemish adults visiting general practice (3 groups: control group, intervention group recruited by researchers, and intervention group recruited and guided by general practitioners [GPs]). Second, it examined whether there was a larger intervention effect for the intervention group guided by GPs compared to the intervention group recruited by researchers.

Methods: Adults (≥18 years) were recruited in 19 Flemish general practices. In each general practice, patients were systematically allocated by a researcher either for the intervention group (researchers' intervention group) or the waiting-list control group that received general advice. In a third group, the GP recruited adults for the intervention (GPs intervention group). The two intervention groups filled in evaluation questionnaires and received MyPlan 1.0 for a behavior of choice (fruit, vegetable, or physical activity). The waiting-list control group filled in the evaluation questionnaires and received only general information. Self-reported fruit and vegetable intake were assessed at baseline (T0), 1 week (T1), and 1 month (T2) postbaseline. Three-level (general practice, adults, time) linear regression models were conducted in MLwiN.

Results: A total of 426 adults initially agreed to participate (control group: n=149; GPs' intervention group: n=41; researchers' intervention group: n=236). A high attrition rate was observed in both intervention groups (71.8%, 199/277) and in the control group (59.1%, 88/149). In comparison to no change in the control group, both the GPs' intervention group (fruit: χ^2_1=10.9, *P*=.004; vegetable: χ^2_1=5.3, *P*=.02) and the researchers' intervention group (fruit: χ^2_1=18.0, *P*=.001; vegetable: χ^2_1=12.8, *P*<.001) increased their intake of fruit and vegetables.

Conclusions: A greater increase in fruit and vegetable intake was found when the Web-based intervention MyPlan 1.0 was used compared to usual care of health promotion in general practice (ie, flyers with general information). However, further investigation on which (or combinations of which) behavior change techniques are effective, how to increase response rates, and the influence of delivery mode in routine practice is required.

Trial Registration: ClinicalTrials.gov NCT02211040; https://clinicaltrials.gov/ct2/show/NCT02211040 (Archived by WebCite® at http://www.webcitation.org/6f8yxTRii)

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KEYWORDS

eHealth; Web-based intervention; dietary interventions; fruit and vegetable intake; general practice; self-regulation; health promotion; primary prevention

Introduction

A healthy diet, more specifically a diet rich in fruit and vegetables, can prevent chronic diseases (eg, hypertension, coronary heart disease, diabetes) in adults [1]. Therefore, the World Health Organization recommends adults to consume at least 5 portions or 400 g of fruit and vegetables per day [2]. However, 78% of the adult population worldwide consumes less than 5 portions of vegetables and fruit daily [3]. Western adults (in Belgium, Luxembourg, France, Ireland, The Netherlands, Great Britain) consume, on average, only 129 g of fruit and vegetables per day [1]. In Belgium, adults are recommended to consume 3 portions of fruit and 300 g of vegetables per day. However, only 38% and 47% of Belgian adults fulfill these norms for fruit and vegetable intake [4]. Thus, an effective intervention to promote fruit and vegetable intake is needed.

Web-based interventions are promising to change dietary behavior and allow a personalized approach at a relatively low cost by making use of interactive, computerized technologies [5,6]. They provide several advantages, such as reduced personal demands, consistency over time, increased interactivity, flexibility, automated data collection, and more honest self-reporting. However, the effects of previously conducted Web-based interventions on adults' health behavior are generally small [7,8]. This may be because Web-based interventions target primarily variables that address the adoption of an intention to change (eg, knowledge), hence leaving many individuals in an intention-behavior gap. Interventions based on social cognitive theories primarily address determinants that influence individuals' intention to change. However, intentions do not automatically translate into behavior because of competing demands and unforeseen obstacles. Therefore, to overcome this so-called intention-behavior gap, postintentional factors, such as self-regulation skills and strategic planning, are needed [9]. Self-regulation refers to internal and/or transactional processes that enable individuals to guide their goal-directed activities to translate their intentions into behavior over time and across changing circumstances or contexts [10]. Therefore, a self-regulation perspective can be used to target both pre- and postintentional processes, and to develop interventions that guide individuals during all phases of behavior change [11-13]. The systematic review of Greaves et al [14] showed that increased effectiveness of dietary and physical activity interventions was also associated with using self-regulation behavior change techniques, increased contact frequency, engaging social support, targeting both diet and physical activity, and using well-defined behavior change techniques. The meta-analysis of Michie et al [15] also provides evidence to include behavior change techniques that target both preintentional and postintentional processes, namely prompting intention formation and goal setting, providing feedback on performance, prompting review of goal progress, and self-monitoring. Finally, another meta-analysis of Lara et al [16] showed that barrier identification/problem solving, plan social support, use of follow-up prompts, and goal setting were effective in increasing fruit and vegetable intake.

Another possible reason for the small effects of Web-based interventions may be the limited amount of feedback that is provided at the very beginning of these interventions, but not further on in the process of behavior change. To target this problem, it is recommended to include personal feedback at several moments. This means that participants receive feedback during the actual process of behavioral change [7,14].

A pertinent problem of Web-based interventions is the low percentage of individuals who start with an Internet-delivered intervention and low sustained use of Internet-delivered interventions [17]. Most existing computer-tailored interventions are self-guided without direct contact with an expert or therapist (8). However, enhanced use and larger effects were found in Web-based intervention studies in which personal contact was included [17-20]. Delivery of Web-based interventions in general practice may have advantages. General practitioners (GPs) already play a role in the promotion of healthy nutrition in adults, patients trust their GP as a reliable source of information concerning nutrition [21,22], and Web-based interventions may take over some tasks of the GPs. Web-based interventions can also prompt and guide GPs to further counsel their patients. Furthermore, direct contact with a GP may result in more tenacious goal engagement of the patients and, thus, a more effective intervention [23]. However, several barriers to incorporating health promotion interventions in general practice were also reported: lack of training and skills, lack of time, patient reluctance, other priorities in patient care, and lack of resources [23].

Based on these findings and suggestions, we developed a new Web-based intervention ("MyPlan 1.0") to promote healthy behavior in adults [24]. The intervention was based on self-regulation theory. Barriers to implement the intervention through general practice were taken into account by using a Web-based program and involving GPs in the development process [23,24]. Behavior change techniques that were incorporated were tailored feedback, barrier identification, problem solving, goal setting, implementation intentions, follow-up session with goal evaluation, stimulating social support, and prompting self-monitoring. Preintentional processes were targeted with personal feedback through which awareness was raised [9,13]. Postintentional processes were addressed with action planning, problem solving, prompting to self-monitor behavior, and follow-up modules that provided repeated feedback and guidance based on whether and how individuals changed their behavior and reached their goals. To deliver the Web-based intervention in general practice, tablet computers and flyers were used.

The aim of this study was to test the effectiveness of the Web-based intervention on fruit and vegetable intake in Flemish adults visiting general practice (3 groups: control group, intervention group recruited by researchers in general practice, and intervention group recruited and guided by GPs). A second study aim was to specifically examine whether there was a larger intervention effect on fruit and vegetable intake for the intervention group recruited by GPs compared to the intervention group recruited by researchers.

Methods

Study Design and Participants

A cluster quasi-experimental trial was used to evaluate the effects of the self-regulation Web-based intervention delivered through general practice on adults' fruit and vegetable intake. Potential participants were recruited in general practices in Flanders (Northern part of Belgium). A convenience sample of general practices was recruited by using email messages, telephone calls, and advertisements on association websites of GPs. In total, 19 general practices, of which 6 solo practices (only 1 GP) and 13 group practices (more than 1 GP), agreed to participate in the study. In each general practice, three groups were recruited. In each practice, researchers systematically allocated at least 10 participants to an intervention group (researchers' intervention group, n=190 adults) and at least 10 participants to a waiting-list control group (n=190 adults). That is, alternating between morning and evening consultations, participants were either invited to participate in the intervention group or in the control group. In each practice, the GP also recruited adults for the intervention (GPs' intervention group). Each GP was instructed to recruit at least 10 adults visiting their practice who were age 18 years or older (n=190 adults). Various options of delivering MyPlan 1.0 to the patients were provided, and GPs selected the one that they considered appropriate for the situation or patient. The options were illustrated to GPs using a flowchart (see Multimedia Appendix 1). During the study period, GPs received weekly telephone-call reminders to recruit patients and to evaluate the study procedure.

Both intervention groups filled in evaluation questionnaires on health behavior and received the self-regulation Web-based intervention MyPlan 1.0, which will be further explained in Methods. The waiting-list control group also filled in the evaluation questionnaires on health behavior and received general information about health behavior (general recommendations on fruit and vegetable intake and advantages of achieving the recommendations for fruit and vegetable intake).

Only Dutch-speaking adults who were 18 years or older and had access to the Internet were eligible. Interested and eligible adults could enroll by filling out an informed consent and a short questionnaire in which general information (name, email address, telephone number, and GP's name) was gathered. Data were collected from November 2014 to June 2015. The study protocol was approved by the Ghent University Ethics Committee. The trial protocol of this study is reported at ClinicalTrials.gov (ClinicalTrials.gov: NCT02211040).

MyPlan 1.0: Fruit and Vegetable Components

MyPlan 1.0 is a Web-based intervention [25] developed using self-regulation theory [9,13], and the Health Action Process Approach model [9]. It focuses on two different behaviors: healthy eating (ie, fruit and vegetable intake) and physical activity. Therefore, different intervention modules were developed, including a fruit and vegetable module, the effects of which are reported in this paper.

The intervention content is described in more detail in the study protocol paper of MyPlan 1.0 [24]. In the first module (T0), both preintentional processes that lead to a behavioral intention and postintentional processes that lead to actual behavioral change were addressed. Preintentional processes were addressed by generating personal feedback to raise awareness and to motivate adults to change their behavior. Individuals filled in a questionnaire on a particular health behavior. Based on their answers, personal feedback was provided. The personal level of the health behavior was discussed and compared to health guidelines. Adults were provided with the possibility to read more information about the behavior (eg, relation with diseases and health, benefits). This is akin to previous computer-tailored programs; hence, the content was largely based on previously developed interventions [26,27].

Postintentional processes were addressed by facilitating action planning. Participants were invited to make an action plan to bridge the gap between intentions and behavior. Adults were guided through action planning by answering questions in the tool. Participants were asked how many portions of fruits/vegetables they wanted to eat (eg, eating 2 portions of fruit), on how many days (eg, every day), when (eg, during breakfast and as a snack during the afternoon), and where (eg, at home). Adults were also offered the possibility to identify difficult situations and hindering factors (ie, coping planning). This was achieved by selecting relevant options from a predefined list of hindering factors and barriers. Based on these selections, several solutions were listed and participants could select the solutions that they considered relevant for their situation and wanted to apply. Adults were guided to make an if-then plan (eg, if I'm hungry in the afternoon, then I eat an apple instead of a candy bar). Adults were also advised on how to self-monitor their behavior (eg, using an agenda) and to pursue their health goals as stated in their action plan. The personal action plan was sent via email and adults were offered the possibility to send the action plan to family or friends for social support.

Adults in both intervention groups were informed that they had the opportunity to discuss their feedback or action plan with their GP during their following consultation. That way, patients' personal advice could be used by GPs to talk about patients' health behavior and to discuss attainability of patients' goals. Module 2 (T1) was activated 1 week after finishing module 1. Participants were contacted by email to revisit the website to complete module 2. In this follow-up module, adults received repeated feedback about their behavior change process (eg, ate more or less pieces of fruit compared to last week) and their goals (eg, did or did not reach the goal to eat 3 pieces of fruit every day). Thereafter, adults had the possibility to adapt their

action plan. Adaptations could consist of formulating new goals (eg, more feasible, a further goal if the identified goal was reached), or of reconsidering coping plans based on the experienced difficulties and barriers during goal pursuit. Module 3 (T2) was activated 1 month after finishing module 1, and was identical to module 2. We investigated the change in fruit and vegetable intake from T0 to T2.

Procedure

In general practice, adults were either assigned to the intervention group or to the control group (2:1). Therefore, adults received a flyer with a personal code that gave access to the Web-based program (intervention groups) or questionnaires only (control group) (Figure 1).

Adults in the intervention condition could choose to log in to the computer-tailored program website on a tablet available in at the general practice or take a flyer with a referring link on it and log in to the website elsewhere (eg, on their computer, when back at home or at their workplace). After logging in to the website, adults in the intervention group could choose a behavior of their interest (ie, fruit, vegetables, or physical activity). After participants chose a behavior, they received access to the intervention component of the chosen behavior, filled in the baseline questionnaire on the chosen behavior (T0), and ran the first session of the chosen health behavior. For this study, only adults that chose to focus on fruit and/or vegetable intake and who completed these behavior components of the intervention were included.

Participants in the waiting-list control group were asked to fill in the baseline questionnaire on behavior (T0). After they filled in the questionnaire, they received general feedback on the website. Adults in the control group logged in to the website and filled out the online questionnaire, similar to the participants of the intervention groups. However, they only received nontailored, general information regarding health norms as feedback.

Adults who started on a tablet at the general practice and who were not able to complete the first session (eg, not enough time in the waiting room) could halt the program and resume it at any time by logging in again on the website. Participants who did not start or complete the first session after 1 week received a reminder email.

Figure 1. Study procedure.

<table>
<tr><td colspan="2">GPs select and motivate adults to participate in the intervention

INTERVENTION GROUP 1
(GPs intervention group)</td><td colspan="2">Researchers select and motivate adults to participate in the intervention

INTERVENTION GROUP 2
(Researchers' intervention group)</td><td colspan="2">Researchers select and motivate adults to participate in the study

WAITING LIST CONTROL GROUP</td></tr>
<tr><td colspan="2">Receive flyer with instructions to participate in the study</td><td colspan="2">Receive flyer with instructions to participate in the study</td><td colspan="2">Receive flyer with instructions to fill in the evaluation questionnaire</td></tr>
<tr><td>Start the program on a tablet in general practice</td><td>Start the program on the website (eg, back at home)</td><td>Start the program on a tablet in general practice</td><td>Start the program on the website (eg, back at home)</td><td>Start the questionnaire on a tablet in general practice</td><td>Start the questionnaire on the website (eg, back at home)</td></tr>
<tr><td colspan="4">Choose a behavior
Fill in evaluation questionnaire 1 about fruit or vegetables (T0)
Receive tailored feedback
Use the self-regulation tool (action planning, coping planning)
Receive email with personal action plan</td><td colspan="2">Fill in fill in the baseline questionnaire on behavior (T0)
Receive general feedback</td></tr>
<tr><td colspan="4">Receive invitation email</td><td colspan="2">Receive invitation email</td></tr>
<tr><td colspan="4">Fill in evaluation questionnaire 2 (T1)

Receive tailored feedback on the behavior change process
Maintain or adapt action plan
Receive email with personal action plan</td><td colspan="2">Fill in evaluation questionnaire 2 (T1)</td></tr>
<tr><td colspan="4">Receive invitation email</td><td colspan="2">Receive invitation email</td></tr>
<tr><td colspan="4">Fill in evaluation questionnaire 3 (T2)

Receive tailored feedback on the behavior change process
Maintain or adapt action plan
Email with personal action plan</td><td colspan="2">Fill in evaluation questionnaire 3 (T2)</td></tr>
</table>

Measurements

Demographic variables were assessed in the online questionnaire at baseline (T0) and included age, sex, height, weight, and highest degree of education (primary or secondary education, college, university). Fruit intake was measured via the "fruit test." The reported pieces of fruit per week were multiplied with the correct portion size of the corresponding types of fruit to calculate the mean grams per week. To calculate the mean portion size of fruit per day, mean grams of fruits per week were divided by 7 and 125 (one portion of fruit is equal to 125 g). For participants who selected vegetable intake as the intervention target behavior, the mean grams of vegetables per day were calculated by using the "vegetable test." The reported portions of vegetables were multiplied with the correct portion size of the corresponding vegetable and divided by 7 to calculate the mean grams per day. In both the fruit test and vegetable test, participants reported how many days in the past 7 days they ate fruit/vegetables. If participants ate fruit/vegetables, a list with fruits/vegetables that are frequently eaten in a Western diet was displayed on the screen. For each type of fruit or vegetable, portion sizes and household sizes were described (eg, 1 cherry=4 g, a dessert plate of berries weighs approximately 100 g). Participants were instructed to indicate for each type of fruit or vegetable the number of portions they ate during the past 7 days. The reported portions of fruit/vegetables were multiplied with the portion size of the corresponding types of fruit/vegetables and divided by 7 to calculate the mean grams per day. Criterion validity, assessed against a 7-day diary, was substantial for the fruit test, with a Spearman rho value of .73 and moderate for the vegetable test with a Spearman rho value of .52.

Statistical Analysis

To check normality of the dependent variables (mean portion of fruit and mean portion of vegetables), a Kolmogorov-Smirnov test in SPSS Statistics version 22.0 (SPSS Inc, Chicago, IL, USA) was conducted and showed that the data were not normally distributed. To correct for positive skewness, the mean portion of fruits and mean portion of vegetables were log-transformed. For ease of interpretation, back-transformed mean values are reported in the tables.

Independent sample *t* tests (for quantitative data) and chi-square tests (for qualitative data) in SPSS were used to compare participants' characteristics at baseline between both intervention groups and the control group and to conduct dropout analyses. Little missing completely at random (MCAR) tests were conducted to test whether the missing values were completely at random.

Due to the hierarchical structure of the data, with 496 adults being nested within 19 general practices, we conducted multilevel analyses with three levels (general practice, adults, and time) to investigate the intervention effect on fruit and vegetable intake from T0 to T2. The iterative generalized least squares (IGLS) estimation method in MLwiN (version 2.32) was used to conduct the multilevel regression analyses. Completer analyses were conducted first, followed by intention-to-treat analyses in which missing values at T2 were replaced by mean fruit intake values from T0 or T1 (assuming that patients lost to follow-up at T2 did not change their behavior reported at T0 or T1).

First, a 3-level null model (general practice, adults, time) including the dependent variable only was estimated for fruit intake (null model 1) and vegetable intake (null model 2). The null models were used to show the percentage of the total variance by changes in time (level 1), differences among adults (level 2), and differences among GPs (level 3).

Second, age, gender, educational level, and body mass index (BMI) were inserted in the models as covariates for fruit intake (model 1a) and in the model for vegetable intake (model 2a). Likelihood ratio tests were conducted to compare both models with their respective null model. The model with covariates was considered to have a better fit than the null model, if the likelihood ratio test was statistically significant.

Third, time and condition were included as predictors in both models (model 1b, model 2b). In these models, we also investigated whether changes in fruit intake and vegetable intake over time (before and 1 month after the intervention) differed for adults in the three conditions by exploring the interaction effect between time and condition (time × condition). Likelihood ratio tests were used to determine if the models with predictors were better fits than the models with only covariates.

In the Results section, we first report the null model, model a, and model b conducted with completer analyses; second, we report model b again conducted with intention-to-treat analyses. Statistical significance was set at a level of .05.

Results

Participant Characteristics, Response, and Dropout Analysis

Figure 2 shows the flow of participants. In total, 615 adults agreed to participate by signing the informed consent. Of these participants, 104 adults were in intervention group 1 (GPs' intervention group), 328 in intervention group 2 (researchers' intervention group), and 183 in the control group at baseline (T0). In the intervention groups, fruit intake was initially selected by 211 participants (30 in GPs' intervention group, 181 in researchers' intervention group) and vegetable intake was initially chosen by 66 participants (11 in GPs' intervention group, 55 in researchers' intervention group).

Dropout analyses (at T2) indicated that men (χ^2_1=15.9, P<.001), participants with low education (χ^2_1=11.9, P<.001), and participants who chose more than one behavior (χ^2_1=6.1, P=.01) were more likely to drop out. No significant differences were found for condition, age, fruit/vegetable intake at baseline, meeting health guidelines, and BMI. A Little MCAR test showed that missing values were completely at random for fruit intake (χ^2_2=1.7, P=.42) and for vegetable intake (χ^2_8=12.4, P=.13).

Baseline characteristics are shown in Table 1. Participants in the researchers' intervention group had a significantly lower fruit intake compared to those in the GPs' intervention group (t_{98}=–3.08, P=.002) and compared to those in the control group

(t_{433}=2.93, P=.004). Also, participants' BMI was different between the control group and the GPs' intervention group for fruit intake, with adults in the GPs' intervention group having a higher BMI, but these results were not statistically significant (t_{286}=1.72, P=.09). Furthermore, more participants in the GPs' intervention group for vegetable intake had a higher education than the researchers' intervention group for vegetable intake (χ^2_1=4.0, P=.04).

Table 1. Baseline characteristics of participants (N=314).

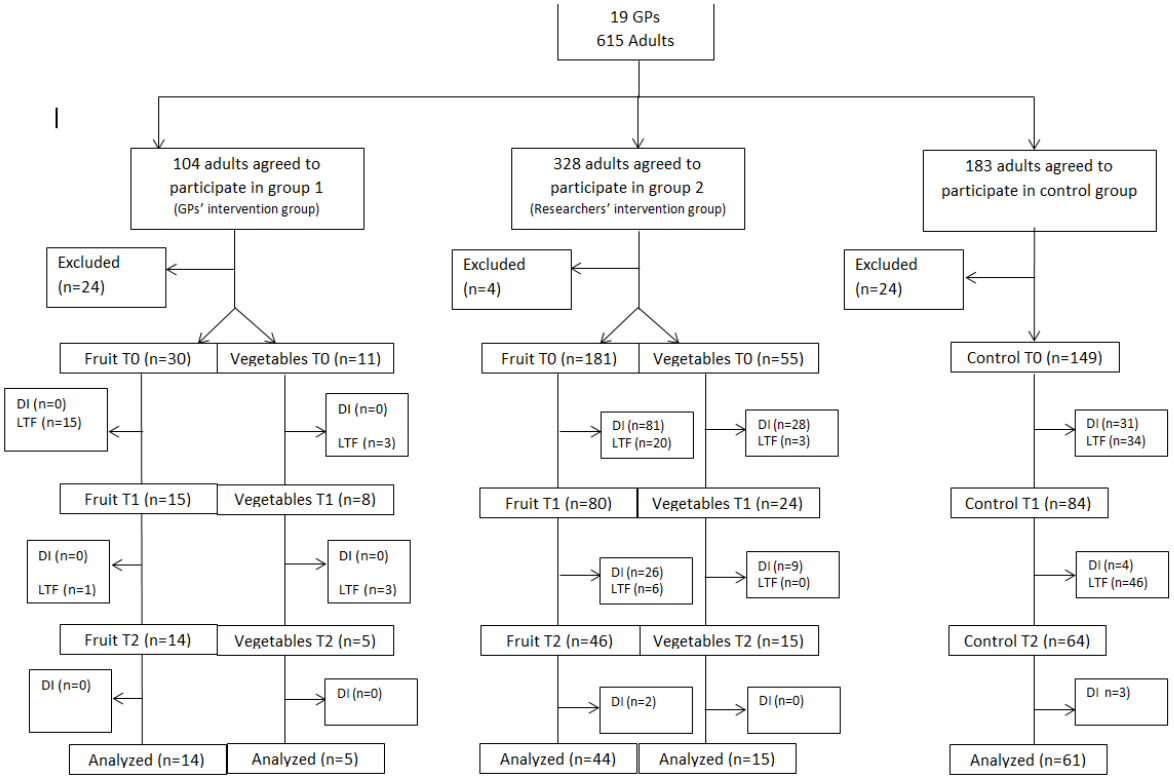
Characteristics	Fruit intake		Vegetable intake		Control group (n=118)
	GPs' intervention (n=30)	Researchers' intervention (n=100)	GPs' intervention (n=11)	Researchers' intervention (n=55)	
Age (years), mean (SD)	43.68 (11.38)	44.20 (13.74)	45.80 (14.95)	43.53 (13.59)	46.14 (14.76)
Gender (male), n (%)	8/30 (27)	31/100 (31.0)	4/11 (36)	36/55 (65)	39/118 (33.1)
Education level (high university or college), n (%)	17/30 (57)	48/100 (48.0)	7/11 (64)[a]	19/55 (35)[a]	58/118 (49.2)
BMI (kg/m^2), mean (SD)	26.50 (5.11)[b]	25.99 (5.65)	25.64 (6.12)	26.51 (6.38)	25.21 (5.10)[b]
Not meeting recommendations, n (%)					
Fruit	28/30 (93)	94/100 (94.0)	—	—	106/118 (89.8)
Vegetables	—	—	10/11 (91)	50/55 (91)	110/118 (93.2)
Fruit intake (portion/day), mean (SD)	1.60 (26.50)[a]	1.13 (1.01)[a,c]	—	—	1.44 (1.20)[c]
Vegetable intake (g/day), mean (SD)	—	—	120.00 (107.34)	153.19 (115.79)	141.63 (86.33)

[a] Significant difference between GPs' intervention group and researchers' intervention group (P<.05).

[b] Significant difference between GPs' intervention group and control group (P<.05).

[c] Significant difference between researchers' intervention group and control group (P<.05).

Figure 2. Participants' flow through study. DI: discontinued intervention; LTF: lost to follow-up.



Reaching Health Guidelines

At T0, only a minority of the participants reached the health norm for fruit intake (7%, 2/30 in the GPs' intervention group; 6.0%, 6/100 in the researchers' intervention group; 10.1%, 12/118 in the control group), but no significant association between the different conditions was found (χ^2_2=2.7, *P*=.26). A significant association between the different conditions and reaching health guidelines for fruit intake at T2 was found (χ^2_2=18.4, *P*<.001). More adults in the intervention groups—57% (8/14) in the GPs' intervention group and 20% (9/44) in the researchers' intervention group—reached the health norm for fruit intake at T2 than adults in the control group (8%, 5/61). For vegetable intake, only a minority reached the health guidelines at T0 (9%, 1/11 in the GPs' intervention group; 9%, 5/55 in the researchers' intervention group; and 6.8%, 8/118 in the control group) and no significant association with condition was found (χ^2_2=0.6, *P*=.73). At T2, a significant association between the different conditions and reaching health guidelines for vegetable intake was reported (χ^2_2=18.5, *P*<.001). More adults in the intervention groups—20% (1/5) in the GPs' intervention group and 60% (9/15) in the researchers' intervention group—reached the health norm for vegetable intake at T2 than adults in the control group (8%, 5/61).

Effects on Fruit Intake

In the completer analyses, the random parts of the null model for fruit intake showed that the variance at both the time level (61%, χ^2_1=61.8, *P*<.001) and adult level (39%, χ^2_1=19.2, *P*<.001) differed significantly from zero. There was no significant between-GP variance in adults' fruit intake. Of the covariates that were included in the model, only age was significantly related to fruit intake. Higher age was related to higher fruit intake (β=0.011, SE 0.005; χ^2_1=4.4, *P*=.04) (see Table 2).

Table 2. Relationship with age, gender, educational level, BMI, time, condition and the interaction of time×condition with fruit intake.

Parameter	Null model 1	Model 1a	Model 1b
Fixed part, β (SE)			
Intercept	1.491 (0.04)	1.494 (0.142)	0.199 (0.148)
Age		0.012 (0.005)[a]	0.011 (0.005)[a]
Gender		0.024 (0.155)	0.043 (0.153)
Educational level		–0.093 (0.145)	–0.142 (0.143)
BMI		–0.038 (0.151)	–0.012 (0.149)
Condition			0.199 (0.148)
Time			0.035 (0.113)
Time×condition			–0.883 (0.268)[b]
Random part, σ^2 (SE)			
Time-level variance	1.063 (0.135)[b]	0.570 (0.077)[b]	0.420 (0.057)[b]
GP-level variance	0.000 (0.000)	0.010 (0.034)	0.000 (0.000)
Adult-level variance	0.692 (0.158)[b]	0.722 (0.123)[b]	0.780 (0.110)[b]
Deviance test model	1211.12	995.81	956.231
χ^2(*df*)		215.3 (4)[b]	254.9 (7)[b]

[a]*P*<.05

[b]*P*<.001.

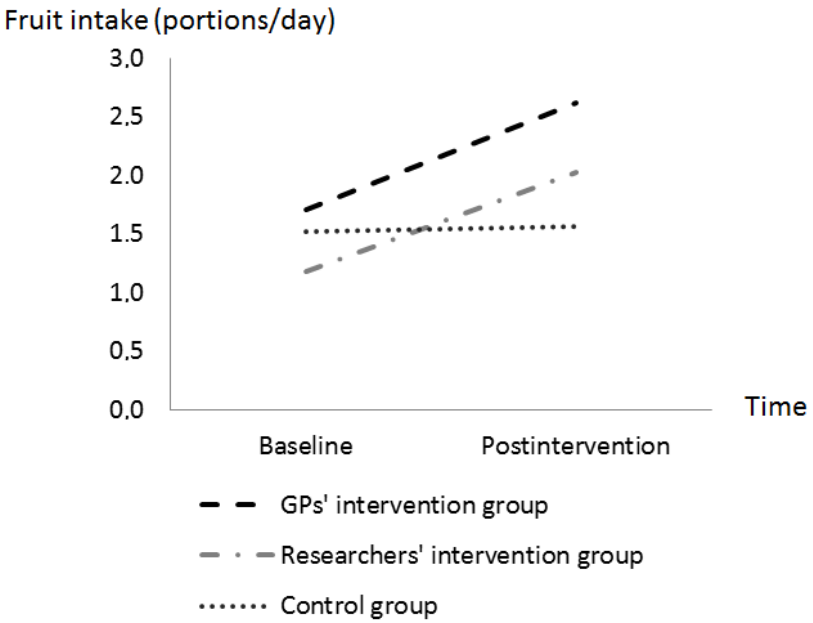
In the completer analyses, a significant interaction effect for fruit intake was found, suggesting that the change in fruit intake over time (from T0 to T2) significantly differed between the control group and the GPs' intervention group (β=–0.883, SE 0.268; χ^2_1=10.9, *P*=.004) and between the control group and the researchers' intervention group (β=–0.802, SE 0.189; χ^2_1=18.0, *P*=.001). Table 3 shows a greater increase in fruit intake from baseline to posttreatment in the researchers' intervention group and in the GPs' intervention group compared to in the control group (see also Figure 3). The change in fruit intake did not significantly differ between both intervention conditions (β=–0.081, SE 0.286; χ^2_1=0.1, *P*=.96).

Table 3. Change in fruit and vegetable intake from baseline (T0) to posttreatment (T2) for the three conditions.

Time	GPs' intervention group	Researchers' intervention group	Control group
Fruit intake (portion/day), mean (SD)			
Baseline	1.70 (0.25)	1.18 (0.17)	1.52 (0.15)
Posttreatment	2.62 (0.30)	2.02 (0.21)	1.56 (0.17)
Vegetable intake (g/day), mean (SD)			
Baseline	115.00 (37.30)	145.43 (19.96)	118.09 (16.09)
Posttreatment	266.88 (50.50)	291.09 (30.24)	143.02 (19.03)

The intention-to-treat analysis showed the same results: the change in fruit intake over time significantly differed between the control group and the GPs' intervention group (β=0.403, SE 0.197; χ^2_1=4.2, *P*=.04) and between the control group and the researchers' intervention group (β=0.328, SE 0.130; χ^2_1=6.4, *P*=.01). The change in fruit intake from baseline to postintervention did not significantly differ between both intervention conditions (β=0.075, SE 0.202; χ^2_1=0.1, *P*=.71).

Figure 3. Changes in fruit intake from baseline (T0) to postintervention (T2) in the three different groups.



Effects on Vegetable Intake

In the completer analyses, the random parts of the null model for vegetable intake showed that the variance at both the time level (72.4%, χ^2_1=44.1, *P*<.001) and adult level (19.3%, χ^2_1=3.3, *P*=.07) differed significantly from zero. There was no significant between-GP variance in adults' vegetable intake. A higher educational level was related to a higher vegetable intake (β=29.039, SE 16.269; χ^2_1=3.2, *P*=.07) and a higher BMI was related to a lower vegetable intake (β=–2.617, SE 1.471; χ^2_1=3.2, *P*=.08), but neither of these were statistically significant (see Table 4).

Table 4. Relationship with age, gender, educational level, BMI, time, condition, and the interaction of time×condition with vegetable intake.

Parameter	Null model 2	Model 2a	Model 2b
Fixed part, β (SE)			
Intercept	160.964 (10.921)	140.072 (15.531)	118.094 (16.093)
Age		0.472 (0.567)	0.437 (0.534)
Gender		19.575 (16.771)	19.349 (15.484)
Educational level		29.039 (16.269)	27.949 (15.484)
BMI		–2.617(1.471)	–2.659 (1.375)
Condition			27.340 (20.262)
Time			24.931 (15.876)
Time × Condition			120.734 (33.730)[a]
Random part, β (SE)			
Time-level variance	10017.922 (1509.309)[a]	9861.971 (1519.984)[a]	8656.535 (1331.062)[a]
GP-level variance	1144.326 (730.174)	1719.047 (920.754)	1388.825 (756.336)
Adult-level variance	2671.313 (1473.540)	2252.752 (1454.147)	1700.278 (1245.686)
Deviance test model	3229.283	3075.562	3036.429
χ^2 (*df*)		153.7 (4)[a]	192.9 (7)[a]

[a]*P*<.001

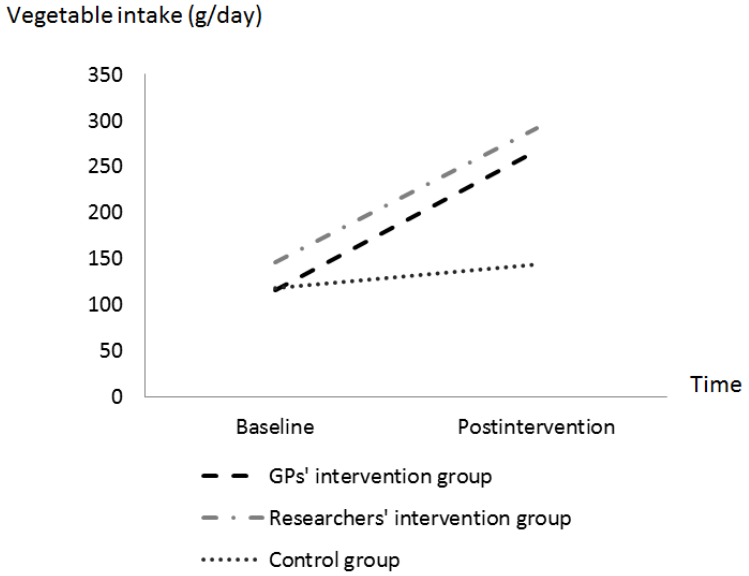
In the completer analyses, there was a significant interaction effect for vegetable intake, suggesting that the change in vegetable intake over time (from T0 to T2) significantly differed between the control group and the GPs' intervention group (β=126.944, SE 55.377; χ^2_1=5.3, *P*=.02) and between the control group and the researchers' intervention group (β=120.734, SE 33.730; χ^2_1=12.8, *P*<.001). Table 3 shows a greater increase in vegetable intake from baseline to posttreatment in the GPs' intervention group and in the researchers' intervention group compared to in the control group (see also Figure 4).

Changes in vegetable intake from baseline to posttreatment did not significantly differ between both intervention conditions (β=–6.210, SE 60.874; χ^2_1=0.0, *P*=.92) in the completer analyses.

The intention-to-treat analysis also showed that changes in vegetable intake over time significantly differed between the control group and the GPs' intervention group (β=93.020, SE 34.954; χ^2_1=7.1, *P*=.008) and a difference was found between the control group and the researchers' intervention group but it was not statistically significant (β=29.648, SE 17.837; χ^2_1=2.8, *P*=.09).

There was also a nonsignificant difference found between both intervention groups for the change in vegetable intake (β=63.372, SE 36.667; χ^2_1=3.0, *P*=.08): a greater increase in vegetable intake from baseline (mean 120.137, SD 38.800 g/day) to posttreatment (mean 220.637, SD 38.800 g/day) was found for adults in the GPs' intervention group than the increase from baseline (mean 152.502, SD 20.830 g/day) to posttreatment (mean 189.630, SD 20.830 g/day) in the researchers' intervention group.

Figure 4. Changes in vegetable intake from baseline (T0) to postintervention (T2) in the three different groups.



Discussion

Principal Findings

This study evaluated the effectiveness of the newly developed Web-based intervention MyPlan 1.0 on the fruit and vegetable intake of adults who visit general practice. The high percentage of adults in our sample who did not reach the guidelines for fruit and vegetable intake at baseline emphasizes the need for effective interventions. MyPlan 1.0 has the potential to increase self-reported fruit and vegetable intake in adults. Greater increases in self-reported fruit and vegetable intake were reported in both intervention groups (received MyPlan 1.0) compared to the control group (received usual care). In most (Flemish) general practices, health promotion involves the provision of flyers and leaflets with general information on dietary behavior [23]. Thus, the findings of our study provide superior effects for the use of self-regulation-based/tailored eHealth dietary interventions. Although MyPlan 1.0 was effective in increasing fruit and vegetable intake of adults, a large part of the participating adults did not reach health guidelines for fruit and vegetable intake after 1 month. This may be because MyPlan 1.0 did not instruct adults to immediately pursue health norms. Rather, adults were stimulated to set personal and attainable health goals (eg, eating one portion of fruit every day) and to reach the health norms over time. Therefore, more research is needed to evaluate the long-term effects of the intervention.

The review of Bhattarai et al [28] showed that interventions that promote healthy diet in primary care have the potential to improve fruit and vegetable intake over 12 months. However, studies included in this review that targeted fruit and vegetable intake made use of face-to-face contacts or motivational phone calls. To our knowledge, no other Web-based interventions based on self-regulation that target fruit and vegetable intake in adults have been evaluated in general practice yet.

In the review of Ball et al [29], it was concluded that effectiveness of dietary interventions implemented in primary care may depend on the theoretical underpinning and content of the intervention. A strength of our study is that MyPlan 1.0 is indeed theory based because it includes several aspects of self-regulation theory and incorporates several self-regulation behavior change techniques. However, further investigation about which (or combinations of which) behavior change techniques are effective is needed. The design of our study did not allow us to examine whether all components were effective and whether a particular combination is necessary. Future research should evaluate the individual impact of the different intervention components.

Ball et al [29] also indicated that intervention effectiveness may be influenced by the way of delivery in primary care. Because GPs have been put forward as a credible and reliable source for health promotion [21,22], it was suggested that GPs' influence may also play an important role in intervention effectiveness of MyPlan 1.0. However, in our study, we did not find significant differences in effect between the GPs' intervention group and the researchers' intervention group. Yet, it has to be noted that due to low reach and high dropout, only a small group completed the intervention in the GPs' intervention group at 1 month, resulting in restricted statistical power. This may explain why no significant differences in effects were found between the two intervention groups. Intention-to-treat analyses were also conducted in which missing values of mean fruit/vegetable intake at T2 were replaced by values reported at T0 (baseline) or T1 (after 1 week). These analyses showed similar results, but also showed a greater increase in vegetable intake in the GPs' intervention group compared to the researchers' intervention group, although this was not statistically significant. These results might indicate that implementing Web-based interventions in routine practice of primary care settings could lead to beneficial effects. However, this needs to be evaluated in further research. The marginally better outcomes in the GPs' intervention group may also be the result of which adults were recruited by the GP (eg patients with more room for improvement). Our results indicated that GPs recruited a different sample of participants. The BMI of participants in the

GPs' intervention group was higher (mean 26.50, SD 5.11 kg/m^2) compared to BMI of participants in the researchers' intervention group (mean 25.99, SD 5.65 kg/m^2), although the difference was not statistically significant. However, in this study, the aim was to use MyPlan 1.0 in the general population and not only for secondary prevention. Therefore, in both intervention conditions, researchers and GPs were instructed to recruit adults that were 18 years or older. The bias selection and the low reach (n=41) in the GP group may indicate that GPs had difficulties recruiting adults as they were instructed. In previous research, several obstacles were also reported by GPs to implement health promotion interventions, such as lack of training and skills, lack of time, difficulties addressing adults with no related complaints, other priorities in patient care, lack of resources, skepticism about efficacy, and GPs perceiving other health professionals as better suited [21,22,30-34]. We tried to overcome these obstacles by involving GPs from the beginning of the developmental process of MyPlan 1.0 (eg, through focus group interviews) [23], by offering different choice options to GPs to implement the intervention, and by providing minimal instructions to GPs. Still, implementing an intervention by GPs seems to be less feasible, which may indicate that GP involvement in recruitment for health promotion interventions is not recommended for future research. Because our results also showed strong effects in the researchers' intervention group, delivery by others in general practice (eg, by a practice assistant) or in other (primary care) settings and contexts (eg, pharmacists, dieticians, work places) could also be considered and evaluated.

Limitations

An unexpectedly high attrition rate was observed in the intervention group (71.8%, 199/277) and in the control group (59.1%, 88/149). Previous studies have also reported high dropout rates and low levels of sustained use of Internet-delivered interventions [17]. Therefore, suggestions of those studies were followed to prevent dropout by providing personal feedback, facilitating goal setting and self-monitoring of behavior, the use of periodic email reminders and incentives, and the provision of counselor support [17,35]. However, the dropout rate in the GPs' intervention group was as high as in the researchers' intervention group. This is in contrast with other studies that showed that the use of GP endorsement resulted in improved response to postal questionnaires in health care research [35,36]. Perhaps GPs in our study were not sufficiently involved in the behavior change process and did not motivate participants enough compared to in other studies in which GPs were involved more extensively. Another reason could be that filling in research questionnaires used for the study required too much time and effort. This may increase dropout rates for the research part, but does not necessarily mean drop out from the intervention.

Our dropout analyses indicated that men and participants with low education were more likely to drop out. This is in line with previous studies that identified participant characteristics related to sustained use. Participants who complete health interventions tend to be female, middle-aged, and higher educated [17,37-39]. So, the fact that more lower educated adults participated in our study can perhaps explain the higher dropout rates. This argues for a further evaluation of strategies to prevent dropout, especially in lower educated adults. Furthermore, we also found that participants who chose more than one health behavior were more likely to drop out. Letting participants choose multiple behaviors was included as a possibility to increase participants choices, based on the principles of the self-regulation perspective. Furthermore, previous studies have shown that interventions that target multiple behavioral changes simultaneously may have a greater impact than single-behavior interventions [36]. However, self-regulation capacity of adults' has been shown to be limited and it might be difficult for adults to make multiple behavior changes at the same time [40]. This may explain higher dropout when choosing multiple behaviors.

A consequence of the high dropout and smaller sample size is that this may lead to nonsignificant results, so further research is needed to verify whether or not there truly is an effect.

A second limitation is the use of a quasi-experimental design, which may have resulted in nonequivalent groups. Therefore, increases in fruit and vegetable intake over time may not only be attributed to the intervention, but also to other differences in variables between the groups. Therefore, analyses were controlled for confounding variables (socioeconomic status, age, sex, reaching health norms). Moreover, no fidelity check procedures were conducted on how GPs motivated participants to participate in the study and how GPs discussed participants' advice/action plans. Another limitation is that we did not track or measure website use and user experience and, therefore, have no information on the impact of website use on the intervention effects. Further, self-reported data can lead to reporting biases, although it is difficult and extremely costly to measure dietary behaviors objectively [41]. Therefore, the use of validated questionnaires was important.

Finally, the short study duration must be taken into account when interpreting the results. It may be that intervention effects decline after intervention completion [41,42]; however, it is also possible that intervention effects increase over time when using a self-regulation approach. To evaluate this, long-term follow-up measurements in future research are necessary.

Conclusions

In conclusion, this study showed a greater increase in fruit and vegetable intake when the Web-based intervention MyPlan 1.0 was used compared to usual care of health promotion in general practice (ie, general information). Thus, the findings of this study add new evidence for the further evaluation and use of Web-based dietary interventions implemented through primary care. However, the short study duration and large dropout rate also implicate that more research is needed on the long-term effects of the intervention and that strategies to prevent dropout should be evaluated. The bias selection and low reach in the GP intervention group also showed that GP involvement in recruitment may not be recommended for future research. Finally, further investigation on which (or combinations of which) self-regulation behavior change techniques are effective is needed.

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Conflicts of Interest

The authors are the developers of the intervention.

Multimedia Appendix 1

Flowchart for GPs.

[PDF File (Adobe PDF File), 89KB - jmir_v18i2e47_app1.pdf]

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Abbreviations

BMI: body mass index
GP: general practitioner
IGLS: iterative generalized least squares
MCAR: missing completely at random

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Original Paper

The Efficacy of Three Modalities of Internet-Based Psychotherapy for Non–Treatment-Seeking Online Problem Gamblers: A Randomized Controlled Trial

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Abstract

Background: Internet-based interventions targeted at the most at-risk gamblers could reduce the treatment gap for addictive disorders. Currently, no clinical trial has included non–treatment-seeking patients who have been recruited directly in their gambling environment. This study was the first exclusively Internet-based randomized controlled trial among non–help-seeking problem gamblers with naturalistic recruitment in their gambling environment.

Objective: The aim of this study was to assess the efficacy of three modalities of Internet-based psychotherapies with or without guidance, compared to a control condition, among problem gamblers who play online poker.

Methods: All active poker gamblers on the Winamax website were systematically offered screening. All problem poker gamblers identified with a Problem Gambling Severity Index (PGSI) score of ≥5 were eligible to be included in the trial. Problem gamblers were randomized into four groups: (1) waiting list (control group), (2) personalized normalized feedback on their gambling status by email, (3) an email containing a self-help book to be downloaded with a Cognitive Behavioral Therapy (CBT) program without guidance, and (4) the same CBT program emailed weekly by a trained psychologist with personalized guidance. Efficacy was assessed based on the change in PGSI between baseline and 6 weeks (end of treatment) or 12 weeks (maintenance) and supported by player account-based gambling data automatically collected at the three time points.

Results: All groups met high attrition rates (83%), but the group with guidance had a significantly higher dropout rate than the other three groups, including the control group. Although all groups showed some improvement, with a mean decrease of 1.35 on the PGSI, no significant difference in efficacy between the groups was observed. One-third of the problem gamblers fell below the problem gambling threshold at 6 weeks.

Conclusions: Guidance could have aversively affected problem gamblers who had not sought help. Despite the lack of significant difference in efficacy between groups, this naturalistic trial provides a basis for the development of future Internet-based trials in individuals with gambling disorders. Comorbidities, natural course of illness, and intrinsic motivation seem to be critical issues to consider in future designs.

Trial Registration: ANSM 2013-A00794-41

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KEYWORDS

internet-based cognitive behavioral therapy; brief intervention; internet-based randomized controlled trial; problem gambling; non-help seeking; poker; guidance

Introduction

Despite guidelines for responsible gambling standards [1], online problem and pathological gambling is a growing challenge to health care providers because of its increasing prevalence [2,3] and the limited treatment-seeking by affected subjects. Self-stigma and unawareness of professional sources of help have been described as barriers to accessing the health care system in those with gambling disorders [4]. Online gambling may be more likely to contribute to problem gambling than offline environments [5]. Poker is one of the most popular gambling activities online [2,6]. Poker gamblers seem to be more susceptible to problem gambling compared with the population of all active gamblers [2]. In research to date, larger populations of video poker gamblers have been included in trials aiming to reduce problem gambling, while table poker gamblers have been poorly represented [7,8].

Targeted Internet-based interventions among the most at-risk online gamblers could enhance the efficacy of existing measures and broaden the range of existing sources of help [9]. Therapeutic interventions still have a demonstrated limited effect size in published trials [10]. Most interventions are motivational interventions, cognitive behavioral therapies, or a combination of both [11]. Further data are needed to prioritize one intervention over another and to propose a tailored minimally efficient intervention. In particular, an 8-week Internet-based cognitive behavioral therapy (CBT) program with minimal therapist contact via email and weekly telephone calls of less than 15 minutes has been shown to be effective at reducing pathological gambling, in a population composed of one quarter poker gamblers [8]. Contradictory data are available on the efficacy of motivational support added to CBT strategies [12,13]. However, very short interventions as personalized feedback have been shown to reduce the number of gambling days [14]. Several methodological issues have limited the relevance of behavioral therapy trials among problem gamblers. It may be difficult, for instance, to generalize the findings from patients recruited via advertisements to patients seeking treatment in real-life settings [11].

A fully Internet-based randomized controlled trial is an emerging design that could be particularly pertinent and acceptable in this population, for whom the Internet is the medium of their addictive behavior [15]. Currently, no study has included non-help-seeking patients who have been recruited directly in their gambling environment. Moreover, the Internet-based therapy offers several advantages over face-to-face interventions, including availability, convenience, accessibility, and cost-effectiveness, which are particularly relevant for subjects who are seeking help for their addictive behavior but are not inclined to use traditional services [16]. This study was the first exclusively Internet-based randomized controlled trial among non-help-seeking problem gamblers with naturalistic recruitment in their gambling environment.

The aim of this study was to assess the efficacy of treating online problem gamblers, in particular poker players, with three Internet-based psychotherapy modalities with or without guidance: (1) personalized normalized feedback on their gambling status by email, (2) a self-help book to be downloaded with a CBT program with no guidance, and (3) the same CBT program emailed weekly by a trained psychologist with personalized guidance. Our first hypothesis was that the three Internet-based modalities would be more efficient than the control condition. Our second hypothesis was that less severe problem gamblers would benefit more than more severe ones from modalities requiring less time investment and with no guidance, that is, the personalized normative feedback and the CBT program with no guidance. Our third hypothesis was that more severe gamblers would benefit more from the heaviest intervention requiring more time investment and with guidance.

Methods

Participants

All active poker gamblers on the poker gambling service provider, Winamax, were offered screening for problem gambling, that is, a score of ≥5 on the Problem Gambling Severity Index (PGSI). Those identified as problem poker gamblers were proposed to be included in an exclusively Internet-based randomized controlled trial.

Subject Recruitment

Subjects were considered for enrollment when they started a poker session during the inclusion period from November 13, 2013, to January 16, 2014 (subjects could be included only once). The additional inclusion criteria were age ≥18, completion of registration (ie, an identification card was sent to Winamax to confirm their age), and registration for ≥30 days. On the day after players first opened a poker session during the inclusion period, they were automatically sent an email with a link that they were invited to click and were redirected to an online survey platform hosted by Winamax, where data were collected and then provided to the investigator. Thus, it was a closed survey. The email presented the research team and the perspectives of the study, namely to help identify problem gamblers and offer them an intervention to control their gambling behavior. Before completing the online process, the subjects read a page that contained clear information about the study phase in which they were to be included. The subjects had to read the page to confirm that they agreed and that they understood the study to proceed to the survey. Gamblers were invited to complete the Canadian Problem Gambling Index's PGSI. If they scored ≥5, they were informed by mail that their scoring could mean they had a gambling problem. They were then invited for inclusion in the randomized control trial with all information on the randomization process and the allocation groups. As a result, the included gamblers were poker gamblers with problem gambling—we use the term "problem poker gamblers" in the paper.

Interventions

The included gamblers were randomized into four groups following a computer-based randomization process: (1) waiting list (control group), (2) personalized normalized feedback on their gambling status by a preprogrammed email with blanks automatically filled based on the PGSI score, (3) email with a self-help book in a PDF file to be downloaded, containing a

CBT program with no guidance, and (4) the same CBT program emailed weekly by a trained psychologist with personalized guidance. The gamblers randomized to the waiting list received an email explaining that they were registered on a waiting list and could contact the research team at the end of the 12-week period if they wanted to benefit from one of the three treatment modalities. The personalized normalized feedback group received an email returning their PGSI score, explaining the corresponding gambling category, and gave prevalence information corresponding to this category, derived from the only available French prevalence data at that time [2]. The therapeutic CBT program was adapted from the Ladouceur self-help book [17], with permission of the author. The program was in accordance with the 6 steps of the self-help program: motivation, financial issues, cognitive distortions, triggers, life reorganization, and relapse prevention. Ladouceur's 6-step CBT program has shown its efficacy in pathological video poker gambling with media other than a self-help book [18]. Video poker is a casino game played on a computerized console and based on five-card draw poker, which is considered the simplest variant of poker. It is quite different from and reputedly less intimidating than playing table poker with others. More recently, the Ladouceur program was also the basis for the development of another program adapted for Internet use that has shown its efficacy along with additional telephone support, as compared to a waiting list, in a population of pathological gamblers, of which 21.2% were poker gamblers [8]. We chose this program because it has shown its efficacy in poker gamblers, whereas the other self-help book that was assessed in randomized controlled trials at the time of the study, had shown its efficacy in samples largely comprising video lottery gamblers [7,12,13,19]. Owing to the behavioral nature of the interventions, no blinding could be applied. No face-to-face contact or contact by phone was established.

All emails regarding screening, recruitment, intervention, and assessment, except for Group 4 intervention (ie, exchange with the therapist) were automatically generated by the Winamax platform.

Ethics

Subject consent was obtained as required by local French laws and regulations. The trial has been prospectively registered to the French Medicine Agency, ANSM (ID No. RCB: 2013-A00794-41). The study was authorized by the Comité de Protection des Personnes, as is required for medical intervention research in France. The subjects did not receive any compensation for their participation in this study. Subject anonymity was established and maintained throughout the course of the study, except for Group 4, who agreed to share their email addresses to be able to benefit from the guidance. Before completing the online process, the subjects read a page that contained clear information about the study. The subjects had to read the page to confirm that they agreed and that they had understood the study to proceed to the survey. The subjects received no incentive to respond.

Sample Size

The sample size for the interventional phase was 992 patients, assuming a standard deviation of PGSI of 8.4, an expected delta of 3 points, and a dropout rate of 50%. We systematically recruited gamblers to be included in the study until we attained the desired sample size for the interventional phase (see Figure 1).

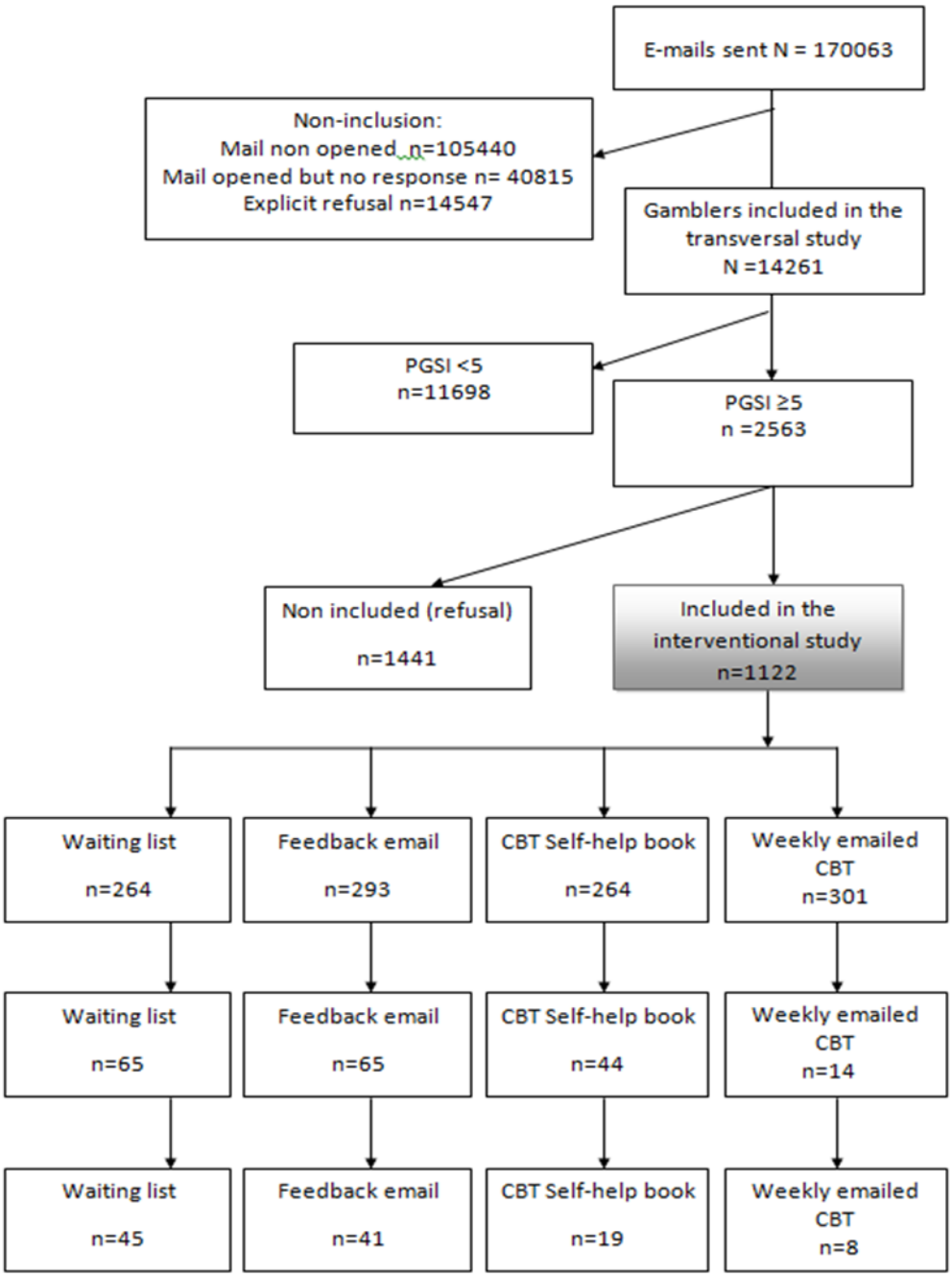
Settings and Data Collection

After gamblers opened a gambling session on the Winamax website, they were automatically emailed an invitation for inclusion in the study. The assessment of enrolled subjects was completed exclusively online. Player account–based gambling data were prospectively collected automatically at baseline, 6 weeks, and 12 weeks by Winamax and were then retrospectively extracted for the 30-day period before the inclusion day, before week 6 and before week 12. We collected the PGSI at the two endpoints by additional email invitations. Data management and analysis were conducted by the authors. Winamax was contractually commissioned to collect the data, but the authors analyzed the data independently of Winamax.

Measures

The only additional data collected online involved the PGSI [20]. Since its publication in 2001, the PGSI has become internationally recognized as a robust measure of gambling behavior and has been used in Canada, Australia, Great Britain, Iceland, and Norway. A new screening threshold for this index has recently been proposed [21]. Currie et al recommended eliminating the low-risk and moderate-risk subtypes in favor of two new mid-level categories consisting of low-risk gamblers, defined as a PGSI score of 1-4, and hazardous gamblers, defined as a PGSI score of 5-7. Gamblers with a score of 3 and 4 were a less homogeneous group. Other authors suggest that the PGSI threshold of 8 is too stringent and recommend that 5 and above should define problem gamblers [22]. We chose a priori to use this new threshold of 5 to be more conservative than the previous threshold of 3 for at-risk problem gambling and to avoid inadequate sensitivity of the instrument. In our study, we chose the term "problem gambler" to have an inclusive meaning, designating at-risk and pathological gamblers, as mentioned by the National Center for Responsible gaming [23]. Moreover, the choice of a conservative threshold was driven by a nested clinical trial proposing a therapeutic intervention for the identified problem gamblers. The PGSI is the only self-reporting instrument that has been validated in French to identify problem gamblers. It is short enough to be acceptable and sufficient to screen a large sample of gamblers. We chose this instrument, although the recall period was 12 months, as no other short self-reporting instrument with a shorter recall period was available to identify problem gamblers. There was no randomization of the item order and only a one-page questionnaire. The PGSI is an unusual choice for a primary follow-up variable but is justified by its short length and its use in the only epidemiological French data at this time [2]. It is needed to calculate the sample size and to formulate the personalized normative feedback (Group 2).

Figure 1. Flow chart.



Basic sociodemographic and routinely recorded data were extracted from the Winamax player account–based dataset at the three time points. The gambling variables used have previously been reported to be good indicators of problem and pathological gambling (7), and this information is routinely recorded by Winamax. We selected the gambling variables based on ease of their extraction from the Winamax player account–based dataset and according to their reproducibility among other online gambling providers. These criteria were multitabling (playing on multiple tables in the same time) in the past 30 days (yes/no), compulsivity (yes/no) (defined by at least 3 deposits in a period of 12 hours), amount of total deposit in the past 30 days (euros) (an initial deposit is required upon opening the gambling account, which implies that some gamblers could have a null deposit during the study period), mean loss per gambling session including the rake (euros), loss in the past 30 days including the rake (euros), total stakes (euros), number of gambling sessions in the past 30 days, number of gambling days in the past 30 days, and time gambled (hours) in the past 30 days. Two criteria could not be correctly assessed because of technical limits related to a lack of automatic disconnection from the app on some wireless devices, particularly smartphones and tablet computers: time gambled (hours) in the past 30 days and number of gambling days in the past 30 days. We therefore excluded these two criteria from the analysis.

Statistical Analysis

Included and non-included gamblers were compared using Student's *t* test for quantitative variables and the chi-square test for qualitative variables. Dropout rates between groups were compared with the chi-square test. The primary outcome was

to assess the efficacy of these fully Internet-based interventions based on a comparison of the change in the total PGSI score between baseline and 6 weeks for the Control Group 1 and Groups 2, 3, and 4. The secondary objectives were to compare the changes in the PGSI and other gambling data between baseline and 6 and 12 weeks among the groups. The primary analysis was an intent-to-treat analysis. As stated in the protocol, dropouts were considered failures (no change in total PGSI score). Primary and secondary outcomes were compared to the control group using an analysis of variance with Dunnett's test for multiple comparisons. To test for a difference in efficacy of the intervention according to the total score at baseline (≥5 and <8 versus >8), an interaction group x total PGSI score at baseline was added to the model. Changes in PGSI and other gambling data within each group were tested with the Wilcoxon signed rank test. The responder rate, defined as the gamblers whose PGSI score decreased by ≥50%, was compared with a chi-square test. To identify potential predictive variables of the response, we performed a multivariate stepwise logistic regression. Variables introduced in the model were demographic and gambling data at inclusion. Finally, as the Ladouceur self-help book emphasizes addressing financial issues, we explored the possibility of a partial efficacy of the interventions on the financial subscore of the PGSI, defined as the sum of the three items of the PGSI regarding financial difficulties (items 1, 4, and 8).

Results

Population

Figure 1 shows the CONSORT flowchart of participants. The interventional study was proposed to the 2563 identified problem poker gamblers. Of the identified gamblers, 43.78% (1122/2563) accepted the invitation to participate, were included, and equally randomized into the 4 groups. The baseline characteristics of the included and the non-included problem gamblers are shown in Table 1. The mean age of the included problem gamblers was 34.7 years; the mean age of all of the gamblers (including non-problem gamblers) included in the first cross-sectional phase was similar (35.8 years). Most of them were male, similar to the "all gamblers screened" group (1033/1122, 92.07% and 12,838/14,261, 90.02%, respectively). The mean PGSI score of the included problem gamblers was 9, which is considered pathological gambling. The included problem gamblers were 2 years older and had a more severe gambling addiction and experienced a greater financial impact than the non-included gamblers (significant differences).

Table 1. Included and non-included screened problem gamblers characteristics and comparison[a].

	Included (n=1122)	Non-included (n=1441)	*P* value
Age in years, mean (SD)	34.7 (10.1)	32.55 (9.6)	<.001
Gender, male, n (%)	1033 (92.07%)	1339 (92.92%)	.4
Deposal €, mean (SD)	293.4 (805.7)	212.9 (638.3)	.01
Total loss in €, mean (SD)	180.6 (740.3)	77.3 (652.7)	.0002
Mean loss per gambling session in €, mean (SD)	4.0 (16.7)	2.7 (13.8)	.04
Total stake in €, mean (SD)	1736.1 (5662.6)	1588.1 (11675.8)	.7
Number of gambling sessions, mean (SD)	61.8 (78.6)	58.7 (73.1)	.3
Multitabling, yes, n (%)	898 (80.04%)	1110 (77.03%)	.06
Compulsivity, yes, n (%)	91 (8.11%)	99 (6.87%)	.23
PGSI total score (on 27), mean (SD)	9 (4.7)	7.73 (3.9)	<.001

[a]Student's *t* test for quantitative variables and chi-square test for qualitative variables.

Acceptability

Very few gamblers completed the PGSI assessment at the end of the interventions (188/1122, 16.76%; see Table 2). Because the other gambling variables were collected automatically, there were no other missing data. Gamblers who completed the assessment at 6 weeks were older (38.8 vs 33.9 years old), but there were no significant differences in the baseline gambling variables, including the PGSI, except for the mean loss per session, which was lower than in those who did not complete the PGSI at the end of the interventions (-0.11 vs -4.73, *P*=.01). The group who received guidance (Group 4) had the highest dropout rate of the 4 groups, including the control group at 6 and 12 weeks (see Table 2).

Table 2. Dropout rate in the randomization groups at 6 and 12 weeks.

Intervention group	Dropout on PGSI at 6 weeks, n (%)	Dropout on PGSI at 12 weeks, n (%)
Waiting list (n=264)	199 (75.4)[a]	219 (83.0)
Feedback email (n=293)	228 (77.8)[a]	252 (86.0)
Self-help CBT book (n=264)	220 (83.3)[a]	245 (92.8) (*P*=.001)
Weekly emailed CBT (n=301)	287 (95.3)[a]	293 (97.3)[a]

[a]*P* value <.001 (chi-square test).

Efficacy

The mean PGSI total score decreased significantly between baseline and 6 weeks in the overall sample and within each group, except in the CBT group with weekly emailed guidance (Group 4): mean change -1.35 points (SD 3.8) for the overall sample (see Table 3). Nearly a third of the included problem gamblers assessed at 6 weeks were no longer considered problem gamblers at 6 weeks (PGSI <5). However, we found no significant difference in the changes in total PGSI score at 6 and 12 weeks between the groups.

Table 3. PGSI variation score between baseline and 6 weeks by intervention group and by severity.

Intervention group	Mean (SD)		
	All	5≤ PGSI <8 (n=98)	8≤ PGSI (n=91)
Waiting list (n=65)	-1.32 (3.1)	-0.75 (2.4)	-2.03 (3.7)
Feedback email (n=65)	-1.06 (4.1)	-0.74 (2.2)	-1.43 (5.5)
Self-help CBT book (n=44)	-1.73 (4.2)	-0.48 (3.3)	-3.1 (4.7)
Weekly emailed CBT (n=14)	-1.64 (3.9)	-1.25 (3.6)	-1.8 (4.2)

No significant difference was found in the other gambling variables between the groups at 6 and 12 weeks (Tables 4 and 5). Although the findings are statistically insignificant, at 6 and 12 weeks in Groups 1, 3, and 4, total loss and mean loss per session increased, whereas they decreased in the control group (difference between groups not significant). The mean total loss increased by €90 to €99 versus a decrease of €20 in the control group at week 6 and increased by €63 to €737 versus an increase of €3 at week 12. Multitabling decreased significantly within each group at 6 weeks, total deposit in the month decreased significantly within Group 2, and number of gambling sessions decreased significantly within Group 3. At 6 weeks, no significant difference was found in the PGSI score between the groups in the less severe problem gamblers subgroup (5≤ PGSI <8) or the more severe pathological gamblers subgroup (PGSI ≥8) (see Table 3).

Table 4. Gambling variables changes at 6 weeks by intervention group (n=1122).

Gambling variables (last 30 days)	Minimum	Median	Maximum	Mean (SD) or %	*P* value within group
Deposit in €					
Waiting list	-5180.00	0.00[b]	1970.00	-9.52 (436.9)	.7
Feedback email	-3206.00	0.00 [b]	2487.00	-69.10 (477.4)	.01
Self-help CBT book	-4774.00	0.00 [b]	9540.00	33.03 (903.8)	.6
Weekly emailed CBT	-3645.00	0.00 [b]	4300.00	-11.99 (474.4)	.70
Total loss in € [a]					
Waiting list	-5210.95	0.48 [b]	3348.89	-18.93 (693.7)	.7
Feedback email	-2377.80	-0.06 [b]	7518.17	89.64 (953.1)	.11
Self-help CBT book	-5727.30	3.26 [b]	13855.52	99.27 (1146.0)	.16
Weekly emailed CBT	-2614.05	0.00 [b]	12285.52	93.83 (988.3)	.1
Mean loss per gambling session [a]					
Waiting list	-206.35	0.01 [b]	91.12	-1.90 (23.1)	.2
Feedback email	-69.02	-0.04 [b]	174.03	1.51 (16.2)	.11
Self-help CBT book	-162.36	0.02 [b]	127.93	1.65 (22.3)	.2
Weekly emailed CBT	-54.54	0.00 [b]	148.02	1.74 (15.8)	.06
Total stake in €					
Waiting list	-15027.92	-10.88 [b]	12126.09	-77.70 (2594.7)	.6
Feedback email	-29009.16	-4.00 [b]	42677.77	-153.72 (4718.2)	.6
Self-help CBT book	-39197.70	-30.50 [b]	129684.50	588.24 (9967.4)	.3
Weekly emailed CBT	-22094.43	-2.00 [b]	55041.05	400.32 (4741.9)	.14
Number of gambling sessions					
Waiting list	-448.00	-3.00 [b]	277.00	-5.18 (70.3)	.23
Feedback email	-255.00	-2.00	221.00	-4.85 (50.9)	.10
Self-help CBT book	-452.00	-5.50	403.00	-9.25 (70.9)	.04
Weekly emailed CBT	-563.00	-3.00	362.00	0.69 (68.3)	.9
Multitabling, yes					
Waiting list	-	-	-	-14%	<.001
Feedback email	-	-	-	-6%	.03
Self-help CBT book	-	-	-	-13%	<.001
Weekly emailed CBT	-	-	-	-9%	.001
Compulsivity, yes					
Waiting list	-	-	-	-0.4%	.83
Feedback email	-	-	-	-2.4%	.2
Self-help CBT book	-	-	-	-1.2%	.6
Weekly emailed CBT	-	-	-	2.3%	.09
PGSI					
Waiting list (n=65)	-13.00	-1.00	6.00	-1.32 (3.1)	<.001
Feedback email (n=65)	-17.00	-1.00	8.00	-1.06 (4.1)	.04

Gambling variables (last 30 days)	Minimum	Median	Maximum	Mean (SD) or %	*P* value within group
Self-help CBT book (n=44)	-17.00	-2.00	8.00	-1.73 (4.2)	.004
Weekly emailed CBT (n=14)	-11.00	-1.00	6.00	-1.64 (3.9)	.11

[a]A negative value is a worsening, and a positive value is an improvement for the participant.

[b]As the variance is huge on the monetary variables, median is more meaningful than the mean.

The self-help book group had the highest responder rate: 15% (10/65), 17% (11/65), 25% (11/44), and 14% (2/14) in Groups 1, 2, 3, and 4, respectively (no significant difference). Age was the only variable predictive of responder status (*P*=.02); the older gamblers were more likely to decrease their PGSI score by ≥50% at 6 weeks than the younger individuals.

We found no significant difference in the financial subscore of the PGSI between the groups at 6 and 12 weeks.

Discussion

Principal Findings

This randomized controlled trial among non–treatment-seeking online problem poker gamblers showed no between-group difference of efficacy of Internet-based interventions compared to placebo. The group with guidance had the highest dropout rate.

Acceptability

Given the low treatment-seeking status in problem gambling, we ambitiously chose to propose accessing the health care system by proactively inviting problem gamblers screened in their gambling environment to participate in exclusively Internet-based interventions. However, we found limits to the acceptability of these interventions. The dropout rate was very high, although Internet-based randomized trials usually have high dropout rates [15]. Fortunately, there were no missing data on the gambling variables owing to their automatic collection. Engagement information regarding opening of mail and downloading of the CBT book were unfortunately not available and could have provided critical further information on acceptability of the modalities. However, a higher required level of therapeutic personal investment was associated with a higher dropout rate. Similar results have been described previously in problem gamblers, namely, reluctance in completing homework [24]. Another trial among pathological gamblers suggested that "more is not necessarily better," finding that participants in a brief booster treatment group showed no greater improvement than brief treatment participants without booster [13]. A similar trial, however, that recruited problem gamblers through advertisements showed efficacy of a CBT self-help book enhanced by weekly guidance on the phone by a psychologist [8]. Even if it is traditionally considered that treatments that include guidance seem to lead to better outcomes than unguided treatments [25], our group that received guidance demonstrated a significantly higher dropout rate than the other three groups, including the placebo group. This result could be explained by an aversive effect of guidance among non-help-seeking problem gamblers, possibly because it is too time consuming or too intrusive and is a commitment to someone they have not chosen instead of a commitment to themselves (as in the other groups). Tailored interventions, that is, asking the gambler to choose the level of guidance they could benefit from, could be an innovative way to avoid the aversive effect of guidance.

The proposed interventions could lack an intrinsic motivational component owing to their non-face-to-face nature. Learning during skills-based psychosocial treatments has been shown to be influenced by the intrinsic motivating properties of the treatment context in mental disorders [26]. Intrinsic motivation is specifically and positively associated with more learning, greater persistence of learning, and greater engagement in learning activities. It is known to play a role in treatment success in other psychiatric diseases [26]. A gamification of the modalities could enhance their efficacy. Complete anonymity, or an anonymous feeling for Group 4, in which gamblers shared only their email address, could have lowered the intrinsic motivational component of the proposed program, particularly in non-help-seeking gamblers. Exclusively Internet-based interventions, with no individual contact or only delayed contact by mail (no chatting), could present a poor intrinsic motivational component (eg, no enjoyment or energy of being in a group, no pleasure in social contact, and poor or no experience of therapeutic alliance).

Some trials have proposed financial compensation to lower the dropout rate, through increasing the extrinsic motivation. However, these methods are questionable in patients with a gambling disorder, for whom a monetary gain could interfere with gambling behavior [27], and do not solve the dropout issue [14].

Accessibility

Khadjesari has already indicated that online trial designs evaluate access to therapeutic material rather than engagement in using it [28]. In regard to increasing accessibility of care, the inclusion rate of almost 50% is high, considering that the problem gamblers screened were not seeking help, and the study showed that proposing a therapeutic intervention to a non-help-seeking problem gambler is realistic. However, the inclusion rate can also be perceived as low if compared to a trial with more traditional recruitment methods. Such care promotion initiatives have been documented to lack efficacy at promoting help-seeking behavior in problem gamblers [29].

Table 5. Gambling variables changes at 12 weeks by intervention group (n=1122).

Gambling variables (last 30 days)	Minimum	Median	Maximum	Mean (SD) or n (%)	*P* value within the group
Deposit in €					
Waiting list	-5180.00	0.00	3000.00	-17.67 (573.55)	.03
Feedback email	-12800.00	-3.00	2150.00	-136.69 (884.45)	<.001
Self-help CBT book	-4058.00	-10.00	9300.00	-33.41 (801.36)	<.001
Weekly emailed CBT	-2600.00	-10.00	2710.00	-54.22 (365.61)	<.001
Total loss in € [a]					
Waiting list	-4990.51	2.31	8333.44	-3.30 (852.54)	.12
Feedback email	-2315.58	0.68	26580.10	193.78 (1792.40)	.10
Self-help CBT book	-4051.70	8.00	181410.22	737.06 (11252.29)	.02
Weekly emailed CBT	-2304.00	2.00	10348.32	63.47 (803.72)	.14
Mean loss per gambling session [a]					
Waiting list	-1062.72	0.00[b]	176.63	-5.64 (70.02)	.9
Feedback email	-87.89	0.01	227.21	0.68 (19.09)	.5
Self-help CBT book	-134.81	0.08	3003.66	11.90 (187.26)	.2
Weekly emailed CBT	-73.15	0.03	96.21	0.72 (14.10)	.3
Total stake in €					
Waiting list	-20160.14	-63.50	90062.29	143.79 (6345.74)	.007
Feedback email	-54205.38	-33.21	26282.27	-318.87 (4284.30)	.002
Self-help CBT book	-62492.55	-36.84	50231.28	-5.36 (7083.45)	.003
Weekly emailed CBT	-20276.97	-46.50	122346.52	576.16 (8490.70)	<.001
Number of gambling sessions					
Waiting list	-448.00	-7.00	285.00	-11.91 (71.56)	.005
Feedback email	-262.00	-8.00	318.00	-5.25 (66.27)	<.001
Self-help CBT book	-381.00	-6.00	356.00	-8.96 (71.42)	.001
Weekly emailed CBT	-501.00	-8.00	365.00	-6.46 (71.46)	.002
Multitabling, yes (%)					
Waiting list				-18%	<.001
Feedback email				-13%	<.001
Self-help CBT book				-18%	<.001
Weekly emailed CBT				-17%	<.001
Compulsivity, yes (%)					
Waiting list				0.0%	1
Feedback email				-3.1%	.07
Self-help CBT book				-0.8%	.7
Weekly emailed CBT				1.7%	.3
PGSI					
Waiting list (n=45)	-10.00	-3.00	0.00	1.00 (12.00)	.02
Feedback email (n=41)	-14.00	-3.00	-1.00	0.00 (6.0)	<.001
Self-help CBT book (n=19)	-9.00	-4.00	-3.00	0.00 (7.0)	.09
Weekly emailed CBT (n=8)	-8.00	-2.50	-1.00	0.50 (5.0)	.4

[a]A negative value is a worsening, and a positive value is an improvement for the participant.

[b]As the variance is huge on the monetary variables, median is more meaningful than the mean.

Efficacy

Even if the sample size has been calculated for the primary outcome (PGSI) for which we endorsed a substantial loss to follow-up, the lack of efficacy is supported by the lack of between-groups difference in the secondary criteria, in a very large sample (three time larger per intervention group than the Hodgins' trial [13]).

There are several explanations for the lack of efficacy of the Internet-based CBT interventions in this trial. First, this trial included non-help-seeking problem gamblers recruited in their gambling environment with no initial involvement in treatment. It has been shown that problem gamblers with higher external motivation for change were less likely to be farther along the stage of change continuum [30]. Low readiness to change could have impacted the efficacy of the interventions. However, in the overall sample, the mean PGSI score at 6 weeks decreased compared with baseline, and one-third of the gamblers were no longer considered problem gamblers at week 6. Another limitation is due to the overlap between the recall periods for the PGSI between the baseline and the two endpoints. This factor could have negatively impacted the sensitivity to change in the assessment. In a future study, an adjusted shortened recall period of the PGSI could prevent that risk of bias. In this particular population of non-help-seeking problem gamblers, a possible therapeutic effect of the inclusion process itself cannot be excluded. The inclusion process required completing the PGSI assessment and receiving an email informing the gambler that their score was above or equal to 5, which defined them as a problem gambler. The email proposed that the individual be included in the study to benefit from therapeutic interventions and thereby recover control of their gambling behavior. The inclusion process was very similar to Group 4, in which gamblers received additional personalized normative feedback. The inclusion process described above is similar to the National Cancer Institute's smoking cessation counseling recommendations (ie, anticipate, ask, advise, assist, and arrange) proposed to non-treatment-seeking patients consulting a general practitioner for another reason and has proven efficacy [31]. However, this result could also be explained by the natural course of the gambling disorder. High spontaneous remission rates have recently been described in a large Swedish cohort [32]. Gambling disorder seems to benefit from more dynamic change than other addictions, possibly because there is no substance involvement. The efficacy of an intervention could therefore be more difficult to demonstrate. Moreover, if the intervention did not target specifically the poker practice but all kinds of gambling behavior, we could not document gambling behavioral data of other possible gambling practices, except with the PGSI.

In regard to the less severe patients, we chose a conservative threshold of 5 for the PGSI, whereas many trials include patients with a threshold of 3. However, the PGSI is a screening instrument and does not provide a clear diagnosis of gambling disorder. This threshold choice could have biased the results because low-risk or low-problem gamblers have few reasons to change their behavior.

It is also possible that the program is not effective in the gambling population selected in this trial. The program itself could present limits if proposed to any problem gambler; the proposed design is deeply naturalistic, and there were no exclusion criteria except for the legal age limit. Additional psychiatric conditions could have limited the impact of the proposed program, namely, depression and anxiety are frequent comorbidities in problem gamblers and could interfere with work on the cognitive distortions as proposed in our program [33]. For instance, the perceived inability to stop gambling, a frequent gambling-related cognition [34], could be more difficult to challenge in gamblers who experience negative cognition due to depression. However, another Internet-based CBT program has shown efficacy among pathological gamblers, even if depressed [35]. Comorbidities should be considered in a future online trial. Another limitation specific to poker gamblers could be the emphasis on financial issues in the CBT program, because many problem poker gamblers have only moderate financial issues. Manuals other than the Ladouceur program could have been adapted to this study, for instance the Hodgins' manual, which has shown its efficacy in other populations of pathological gamblers. Our results should not be generalized to other self-help programs. Unfortunately, qualitative material from chat or operator hotlines has not been collected because of technical limitations; participants' textual feedback could have provided valuable information for better understanding the lack of efficacy of the CBT interventions proposed in this trial [36].

Conclusion

This first Internet-based randomized controlled trial among non–help-seeking online problem poker gamblers showed a lower acceptability of the modality including guidance compared to the other modalities including placebo. This was possibly due to an aversive effect of guidance in this particular population. We found no significant difference in efficacy between the Internet-based CBT modalities, with or without guidance, compared to the control condition. This naturalistic trial provides a basis for developing future Internet-based trials for individuals with gambling disorders. The natural course of gambling disorders is still poorly documented, and spontaneous changes are a challenge for future assessment of therapeutic interventions. Although Internet-based CBT may enhance access to treatment, it should include intrinsic motivational components to increase engagement in treatment.

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Conflicts of Interest

MLT and ML received funds for this study from Winamax. Other authors have no conflicts of interest to declare.

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Abbreviations

CBT: cognitive behavioral therapy
PGSI: Problem Gambling Severity Index

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Original Paper

Examining the Relationship Between Past Orientation and US Suicide Rates: An Analysis Using Big Data-Driven Google Search Queries

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Abstract

Background: Internet search query data reflect the attitudes of the users, using which we can measure the past orientation to commit suicide. Examinations of past orientation often highlight certain predispositions of attitude, many of which can be suicide risk factors.

Objective: To investigate the relationship between past orientation and suicide rate by examining Google search queries.

Methods: We measured the past orientation using Google search query data by comparing the search volumes of the past year and those of the future year, across the 50 US states and the District of Columbia during the period from 2004 to 2012. We constructed a panel dataset with independent variables as control variables; we then undertook an analysis using multiple ordinary least squares regression and methods that leverage the Akaike information criterion and the Bayesian information criterion.

Results: It was found that past orientation had a positive relationship with the suicide rate ($P \leq .001$) and that it improves the goodness-of-fit of the model regarding the suicide rate. Unemployment rate ($P \leq .001$ in Models 3 and 4), Gini coefficient ($P \leq .001$), and population growth rate ($P \leq .001$) had a positive relationship with the suicide rate, whereas the gross state product ($P \leq .001$) showed a negative relationship with the suicide rate.

Conclusions: We empirically identified the positive relationship between the suicide rate and past orientation, which was measured by big data-driven Google search query.

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KEYWORDS

attitude; big data; Google search query; Internet search; past orientation; suicide

Introduction

Recently, the new approach of using big data to find complex or hidden social phenomenon has been trending in different fields of research. In particular, as the Internet is an integral part of the current society, Internet search query data are now considered useful in analyzing consumer behavior [1,2] and disease surveillance [3-5]. In line with this, several studies have examined the relationship between suicide rates and Internet search queries [6-10]. Gunn and Lester [6] found that there is a correlation between search query volume and suicide, using search terms such as “how to suicide” and a cross-sectional study of a US state in 2009. Through time-series data analysis of Japanese data, Hagihara et al [7] found that the number of suicide-related queries tends to increase before the increase in suicide rate. In summary, previous studies have mainly examined the correlation between the suicide rate and Internet

search behavior as a warning sign of suicide by examining time-series or cross-sectional data.

Furthermore, Internet search queries and online social media reflect the collective consciousness of the society [1,11,12]. Google's page rank algorithm is also based on collective consciousness [13]. Preis et al [14] developed the future orientation index of the people of a country by utilizing search query data and calculating the ratio of the future year phrase of the Google search queries index to that of the past year. Through this process, the authors tried to measure a regional preference of future time perspective by quantifying future orientation index. Although we used the orientation index term followed by Preis et al [14] along with time perspective, its mean is the same as the one in this research. This future orientation index has been found to have a positive correlation with the gross domestic product (GDP) of a country [14]. Thus, it is possible to detect the specific attitudes of the populace by examining Internet search query data.

Further, although attitudes are significant reflectors of suicidal tendency among adolescents [15,16], it is difficult to quantify the suicide risk, given the lack of criteria linking personality and suicide [17]. Yufit and colleagues [17,18] insist that distortions of time perspective cause people to commit suicide. Keough et al [19] insist that people categorized their perceptions, events, or plans into the past, present, and future perspectives, and the time perspective was utilized to form memories or goals; thus, it is also possible to predict some behavior such as smoking and drinking by investigating the time perspective. In particular, past orientation was found to create unattained goals [20], and a severe past orientation often related to life regrets [21]. Many depressed persons are troubled by past events and memories, relative to those from the present or aspirations of the future [22]. For these reasons, having a past orientation can be a risk factor for suicide.

However, to the best of our knowledge, no study has considered the regional attitudes—especially the past orientation of residents—and relationship between suicide rate and past orientation using Internet search query. Survey-based measurements of past orientation have limitations. First, it is difficult to collect big-data samples that measure past orientation across various regions over a long-term period, because questionnaire investigations that measure time perspectives tend to be economically infeasible. Second, survey-based measurement can also succumb to social desirability bias. To overcome these limitations, we measured past orientation using Google search query rather than survey data. To be precise, we measured past orientation through the use of modified Preis et al's [14] future orientation index. These data are derived from the Google portal's big search query data, and hence, these are reliable. Further, the nature of the data makes it possible to measure past orientation in various countries or regions and over long-term periods, and thus, to construct panel data. Ultimately, we conducted a study under the assumption that past orientation has a positive relationship with the suicide rate; to this end, we examined the relationship between past orientation and suicide rate among the US states between 2004 and 2012 by using panel ordinary least squares (OLS) regression.

More specifically, we measured the past orientation of residents of the United States annually by state, based on big data-driven Google search queries. Next, we controlled independent variables such as the unemployment rate and Gini coefficient. In addition, we arranged the given data as panel data to improve their reliability. Previous suicide studies that utilized Google search queries mainly used time-series and cross-sectional data. Finally, we examined the relationship between suicide rates and past orientation. Besides, to verify robustness of the past orientation variable and our regression model, we calculated the goodness-of-fit of all possible variable combinations through the Akaike information criterion (AIC) and the Bayesian information criterion (BIC) methodologies.

The remainder of this paper is organized as follows. The "Methods" section outlines the methods and variables used to measure past orientation using Google search queries. This section also presents the research model that we use. In the "Results" section, we present the empirical results regarding past orientation and other independent variables by US state. Finally, in the "Discussion" section, we discuss our results, the implications with respect to past orientation, and this study's limitations.

Methods

Past Orientation, Examined Through Google Search Queries

Wohlford [23] measured the time perspective by examining responses to the Thematic Apperception Test (TAT). In concrete terms, when measuring the time perspective using this test, the participant writes a story that features past, present, or future viewpoints, in accordance with the TAT cards provided. Then, based on the outcome of that story, a score is generated that reflects the participant's degree of preference for the past versus the future [24]. Furthermore, the Zimbardo Time Perspective Inventory (ZTPI), a questionnaire method to improve subjectivity of TAT, was developed to measure time perspective [19]. ZTPI measures the individual's time perspective (future, present, and past) through a questionnaire. In summary, the methods of measuring the time perspective center on finding one's preference vis-à-vis time orientation among the past, present, and future through the questionnaire method.

Similarly, Preis et al [14] quantified the future orientation index of a country by utilizing search query data. To measure the future orientation index, Preis et al [14] calculated the ratio of the future year (eg, ''2010" in 2009) phrase of the Google search queries index to that of the past year (eg, ''2008'' in 2009). We measured the past orientation of state residents each year and calculated the ratio of the past year (eg, ''2008'' in 2009) phrase of the Google search queries index to that of the future year (eg, ''2010'' in 2009) by US state. For each year, "past year" and "future year" phrases were changed according to the base year. For example, past orientation in 2010 is the ratio of the "2009" phrase of the Google search queries index to the "2011" phrase of the Google search queries index. For another example, past orientation in 2006 is the ratio of the "2005" phrase of the Google search queries index to the "2007" phrase of the Google search queries index. In this way, we calculated the past

orientation of residents of the 50 US states and the District of Columbia between 2004 and 2012. While Preis et al [14] conducted an international comparison of 45 countries for 3 years, we performed an intranational analysis of 50 US states and the District of Columbia for 9 years. As a result, although we controlled variables such as gross state product (GSP), other factors that can affect suicide rate (eg, cultural difference) also needed to be controlled. In addition, if we analyze international countries, aggregating different sources of suicide rate data in different countries is unavoidable; however, this can cause a data quality problem. Based on this criterion, we were able to measure past orientation index by using Google search query data and comparing yearly search volumes in past and future years among residents of the 50 US states and the District of Columbia. In addition, although Preis et al [14] excluded countries with population less than 5 million, because of the possible inaccessibility of search query data due to the low number of search queries, search query data in US states are sufficiently accessible without any exception. Also, in the US, Internet penetration and Google market share are sufficiently high to utilize search query data. According to internetlivestats, penetration rates of Internet in the US in 2004 and 2012 are 64.76% and 81.03%, respectively.

Returning to the model, Equation (1) is the formula we used to quantify past orientation. The method for calculating the Google search query index for each numerator and denominator is identical to that with regard to Google Trends.

$$\text{Past orientation}_{it} = 100 \times \{[\text{Number of Google search – queries for “past year”}]_{it}/[\text{Number of Google search – queries for “past year”}]_{\max}\}/\{[\text{Number of Google search – queries for “future year”}]_{it}/[\text{Number of Google search – queries for “future year”}]_{\max}\} \quad (1)$$

The numerator in Equation (1), that is, is the index of Google search queries in the past year for state *i* during the year *t*. Specifically, [Number of Google search queries for “Past year”]$_{\max}$ is the “past year” search volume that is the largest “past year” search volume among the 50 US states and the District of Columbia in the year *t*. We then calculated the standardized relative proportion of search volume for the “past year” phrase by state *i*.

Furthermore, the denominator is a Google search query index for “future year” for state *i* during the year *t*. The rest of the calculation is identical to that of the previous denominator for “*past year*.” In more concrete terms, we utilized Google search query data from Google Trends, which provides Google search query data over time and by region, such as by country or state. Finally, the measured past orientation was found to vary from 0.775 to 1.517 by state during the analysis period from 2004 to 2012. Figure 1 shows state-specific average past orientation and average suicide rates.

In Figure 1, Montana, Maine, and Oregon showed a high past orientation value. By contrast, Maryland, California, and Georgia showed a relatively low past orientation value. We examined the past orientation differences among states to determine how they may affect state-specific suicide rates.

Dependent Variable

Suicide rates for each of the 50 US states and the District of Columbia for the 2004-2012 period were obtained from the Centers for Disease Control and Prevention’s deaths data. The suicide rate unit is the number of suicides per 100,000 population. These data are originally recorded on death certificates and filed on states registration offices, and the suicide statistic is processed by Vital Statistics Cooperative Program of Centers for Disease Control and Prevention [25].

There was some variation among the suicide rates of the US states. Figure 1 shows state-specific average suicide rates. Wyoming, Montana, Nevada, Oregon, and Maine recorded higher average suicide rates; in particular, Montana, Maine, and Oregon had high past orientation values. By contrast, the average recorded suicide rates of Massachusetts, New York, and California were relatively low.

Independent Variables

In this study, we used independent variables that were mainly used in previous studies. These variables also served as control variables in pinpointing the determinants of suicide in the US states. Detailed descriptions of the variables are presented in Table 1.

Gini Coefficient

This variable is an index that indicates the relationship between the population distribution and the distribution obtained, where an index value of 0 signifies complete equality and 1 signifies complete inequality. Gunnell et al [27] used the Gini coefficient variable as an income inequality factor to investigate the determinants of the suicide rate; they found that the Gini coefficient has a statistically significant and positive correlation with the suicide rate. In this study, the Gini coefficient variable was used as a control variable to represent income inequality.

Unemployment Rate

The unemployment rate is taken on an annual basis. Yang [28] analyzed the US suicide rate in the 1940-1984 period by using single-equation regression. In that study, the unemployment rate was found to have a significantly positive correlation with the suicide rate of white men. Neumayer [29] also found that the unemployment rate had a positive correlation with the suicide rate. While we used this as a control variable, we also expected it to affect the suicide rate positively.

Figure 1. Past orientation index and suicide rates by US state.

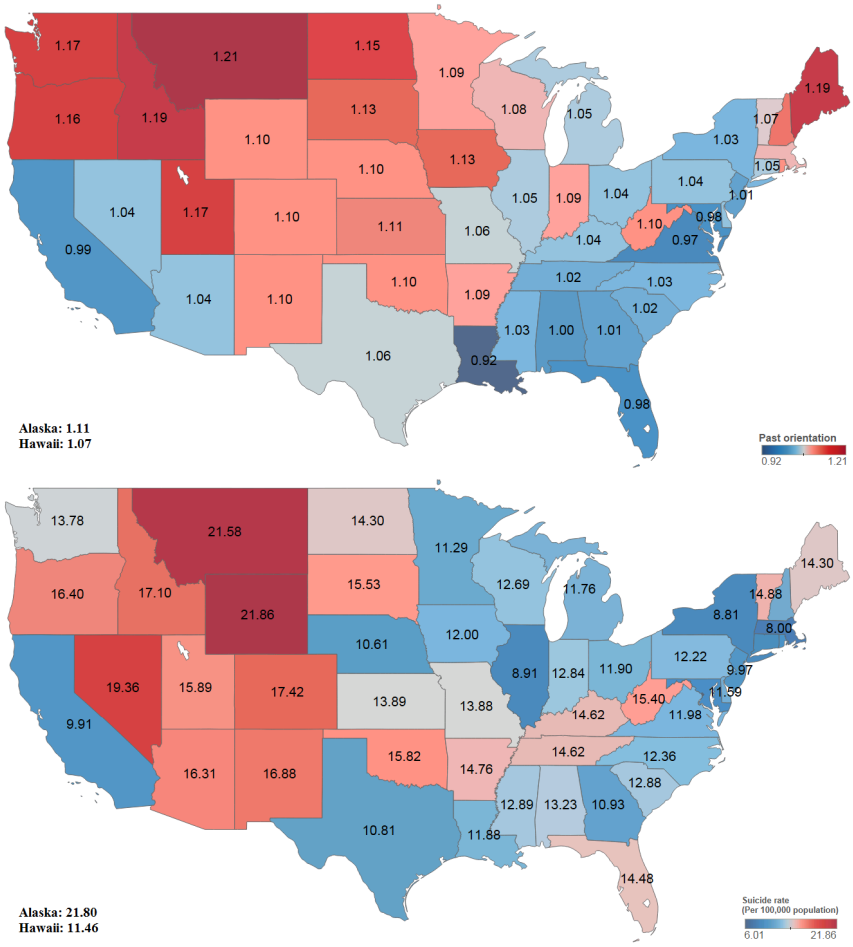


Table 1. Variable descriptions.

Variable	State	Time	Description	Unit	Scale	Source
Suicide rate	O[a]	O	Suicide rate	Per 100,000 population		Centers for Disease Control and Prevention's deaths data
Unemployment rate	O	O	Unemployment rate	Percentage		Bureau of Labor Statistics: local area unemployment statistics
Gini coefficient	O	O	Gini coefficient, an index showing the relationship between the population distribution and the distribution obtained; 0 = completely equal, 1 = completely unequal conditions	Index (0-1)		US state-level income inequality data [26]
GSP	O	O	Gross state production	USD	/10^6	US Department of Commerce/Bureau of Economic Analysis/Regional Income Division
Population growth rate	O	O	Population growth rate	Percentage		US Department of Commerce/Bureau of Economic Analysis/Regional Income Division
Past orientation	O	O	A ratio of "past year" phrase of Google search queries index to "future year" phrase of Google search queries index	Index		Google Trends

[a]O: State specific and/or time specific.

Gross State Product

The GSP refers to the economic outcome of a state. This variable indicates the degree of wealth by state. Similarly, some studies found income or GDP to have a positive correlation with the suicide rate [30-32], whereas others found a negative correlation [29,33-36]. Specifically, Neumayer [29] examined the relationship between GDP per capita and the suicide rate in 68 countries over the 1980-1999 period. In that study, the GDP per capita was found to have a negative correlation with the suicide rate. By contrast, Hintikka et al [32] found that in Finland, the suicide rate increased whenever the economy was on an upswing, and decreased whenever there was an economic recession. We used GSP as a control variable.

Population Growth Rate

A state's population growth rate is its annual rate of population change. Zhang [37] found that among 60 countries in the 1980-1986 period, the population growth rate negatively correlated with the suicide rate. Durkheim [38] asserted that suicide started with modernization, and Zhang [37] interpreted population growth rate as a modernization indicator. In the past, modernized countries were inclined to have a low population growth rate. However, our study examined an already sufficiently modernized period and place and investigated intranational (US states) comparisons, so it is difficult for this study to represent that state's population growth rate to indicate the modernization degree. However, because US states with high population growth rate tend to have high number of immigrants or temporal migrants for employment [39], it can negatively affect suicide rate.

Past Orientation

This variable consists of Google search query values, as described in the "Methods" section. It is calculated as a ratio of the "past year" phrase of a Google search query index value to the "future year" phrase. We conducted this study under the assumption that past orientation has a positive relationship with the suicide rate. Tables 2 and 3 present the summary statistics (including variance inflation factor for multicollinearity check) and correlation matrix of the data, respectively.

Table 2. Summary statistics.

Variable	Number of Observation	Mean	Standard error	Minimum	Maximum	Variance inflation factor
Suicide rate	459	13.350	3.779	4.800	29.700	—
Unemployment rate	459	6.309	2.285	2.500	13.800	1.040
Gini coefficient	459	0.607	0.035	0.536	0.760	1.120
GSP	459	0.281	0.341	0.023	2.100	1.160
Population growth rate	459	0.899	0.887	−5.720	5.290	1.030
Past orientation	459	1.071	0.102	0.775	1.517	1.070

Table 3. Correlation matrix (N=459).[a]

	Suicide rate	Unemployment rate	Gini coefficient	GSP	Population growth rate	Past orientation
Suicide rate	1.000					
Unemployment rate	0.100[b] (.032)	1.000				
Gini coefficient	0.157[c] (.001)	0.082[d] (.081)	1.000			
GSP	−0.336[c] (<.001)	0.134[c] (.004)	0.296[c] (<.001)	1.000		
Population growth rate	0.285[c] (<.001)	−0.128[c] (.006)	0.087[d] (.062)	−0.037 (.434)	1.000	
Past orientation	0.281[c] (<.001)	0.012 (.794)	−0.154[c] (.001)	−0.238[c] (<.001)	0.004 (.924)	1.000

[a]*P* values are provided in parenthesis.

[b]*P*<.05

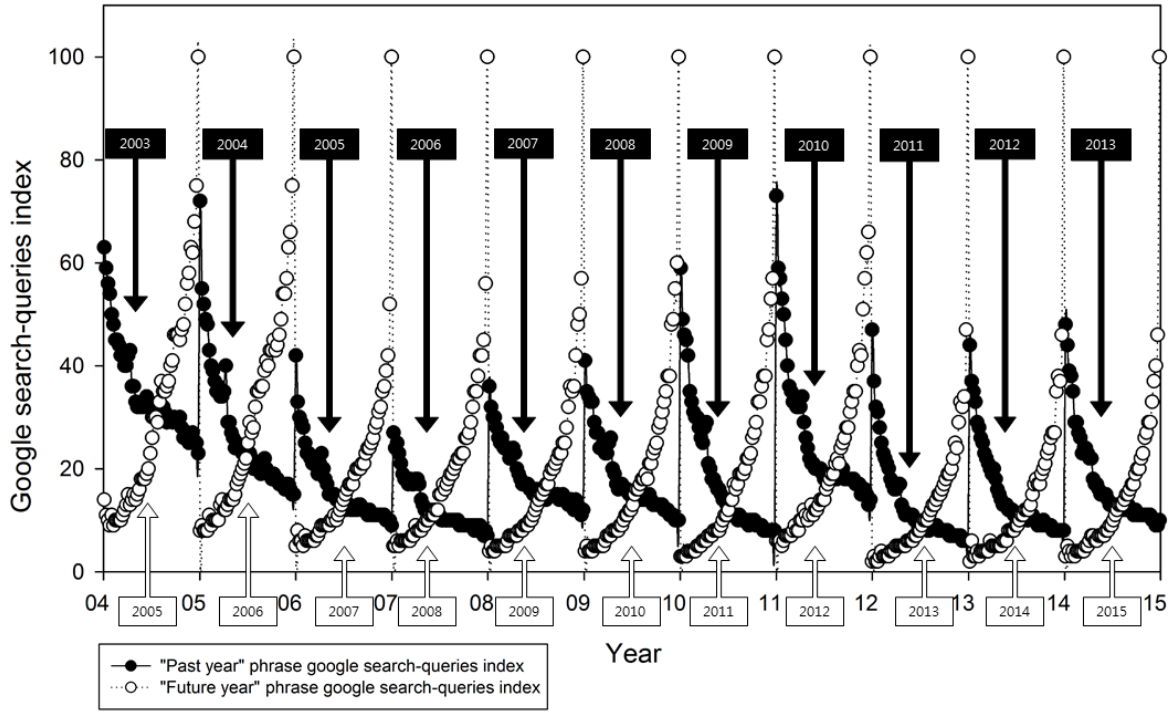
[c]*P*<.01

[d]*P*<.10

Monthly Time Variance in Search Queries

Figure 2 shows the monthly time variance in Google search queries index values of the past year and future year. In Figure 2, the Google search query index values of the past year and future year showed an interesting pattern, depending on the season. The Google search query index for any given past year was highest at the beginning of the year, and it decreased gradually as the year passed. A similar phenomenon was observed in another large-scale big-data study [40]. By contrast, the Google search query index value for the future year showed a gradual increase from the beginning of the year. It then reached its peak when the current year changed to the future year (eg, future search query ["2013"] on December 31, 2012). Additionally, while it can be seen that people gradually change their time perspective focus from the past year to the succeeding year, past-oriented people find it difficult to keep up with a future or present time perspective; indeed, it is not easy for them to depart from the past to which they cling.

Figure 2. Time variance in Google search queries index values of the past year and future year.



Model

Following many previous studies about suicide rate [28,37,41], we utilized a regression model to investigate the relationship between past orientation and suicide rate. In addition, for using the linear model, we already completed the linearity test through scattering variables. We then calculated the AIC, BIC, and R^2 for all possible variable combinations for testing the goodness-of-fit and explanatory power of models and variables. Through this process, we determined whether the past orientation variable increases the goodness-of-fit. As such, we were able to investigate whether past orientation is an important variable of the regression model. The following formula is the multiple OLS regression equation that we used:

$$\text{Suicide rate}_{it} = \alpha_t + \beta_1 (\text{unemployment rate}_{it}) + \beta_2 (\text{Gini coefficient}_{it}) + \beta_3 (\text{GSP}_{it}) + \beta_4 (\text{population growth rate}_{it}) + \beta_5 (\text{past orientation}_{it}) + \in_i \quad (2)$$

where i represents a state, t the year, and $_i$ the error term.

We obtained four regression models by combining independent variables. In Model 1, we used only the unemployment rate and the Gini coefficient. In Model 2, we added past orientation to Model 1. We also investigated changes to the AIC and BIC of Models 1 and 2. Through this process, we were able to examine the degree to which the model vis-à-vis past orientation and the suicide rate improved.

The independent variables in Model 3 consist of the unemployment rate, the Gini coefficient, GSP, and population growth rates. Finally, Model 4 added the past orientation variable to Model 3; we also investigated changes to the AIC and BIC in Models 3 and 4.

Results

Regression Analysis

Table 4 shows our regression results by model. For both Models 2 and 4, we see that past orientation had a positive relationship with the suicide rate whenever we included the past orientation variable ($P \leq .001$). Based on Model 4, when a past orientation value of 1 increases, the suicide rate increases to 8.5 people per 100,000 population ($P \leq .001$). These results are consistent with our assumption that past orientation has a positive relationship with the suicide rate. These results indicate that past orientation is often related to life regrets [21] and that it can be a suicide risk factor. In addition, we looked at improvement in the model's goodness-of-fit with respect to past orientation, and found that

in Model 1, the AIC and BIC are 2513 and 2525, respectively, whereas in Model 2, these values are 2468 and 2485, respectively. The AIC and BIC in Model 2 are smaller than those in Model 1, indicating that Model 2 has better goodness-of-fit than Model 1. The AIC and BIC in Model 4 are 2355 and 2379, respectively, whereas these in Model 3 are 2385 and 2405, respectively. As is the case for Models 1 and 2, the AIC and BIC in Model 4 are lower than those in Model 3. In other words, given our AIC and BIC results, it can be said that the use of the past orientation variable improves the goodness-of-fit.

Table 4. Regression results.

Variables	Suicide rate											
	Model 1			Model 2			Model 3			Model 4		
	Coeff.	SE	*P* > *t*	Coeff.	SE	*P* > *t*	Coeff.	SE	*P* > *t*	Coeff.	SE	*P* > *t*
Unemployment rate	0.146[a]	0.076	.057	0.133[a]	0.073	.068	0.284[b]	0.067	<.001	0.265[b]	0.065	<.001
Gini coefficient	16.097[b]	4.966	.001	21.284[b]	4.782	<.001	26.230[b]	4.528	<.001	28.568[b]	4.395	<.001
GSP							−4.67[b]	0.467	<.001	−4.122[b]	0.462	<.001
Population growth rate							1.151[b]	0.173	<.001	1.140[b]	0.167	<.001
Past orientation				11.476[b]	1.642	<.001				8.501[b]	1.481	<.001
Cons	2.663	3.017	.378	−12.691[b]	3.615	<.001	−4.078	2.713	.133	−14.623[b]	3.201	<.001
AIC	2513			2468			2385			2355		
BIC	2525			2485			2405				2379	
P > *F*	.001			<.001			<.001			<.001		
R^2	.032			.126			.274			.324		
Adjusted R^2	.028			.120			.268			.316		
Number of observations	459			459			459			459		

[a]*P*<.10

[b]*P*<.01

Next, we find that the unemployment rate has a statistically significant positive relationship with the suicide rate in Models 3 and 4 (*P*≤.001 in Models 3 and 4). Based on Model 4, when the unemployment rate increases to 1%, the suicide rate increases by 0.265 people per 100,000 population (*P*≤.001).

In addition, the Gini coefficient has a statistically significant and positive relationship with the suicide rate (*P*≤.001). Based on Model 4, when the Gini coefficient increases to 1, the suicide rate in a state would increase by about 28.5 people per 100,000 population (*P*≤.001).

The GSP variable in Model 3 was found to have a statistically significant and negative relationship with the suicide rate (*P*≤.001). A high GSP state tends to have a statistically significantly lower suicide rate. Based on Model 4, when the GSP increases by 1 million dollars, the suicide rate decreases by 4.122 people per 100,000 population (*P*≤.001).

Next, the population growth rate variable was found to have a statistically significant and positive relationship with the suicide rate (*P*≤.001). Based on Model 4, when the population growth rate increases by 1%, the suicide rate increases by 1.14 people per 100,000 population (*P*≤.001).

Goodness-of-Fit of the Regression Model

Furthermore, we verified the goodness-of-fit and explanation power for all possible variable combinations. Table 5 shows the goodness-of-fit of regression results. Model 4 in Table 4, including past orientation and all independent variables, has the smallest AIC and BIC, and the largest R^2 and adjusted R^2. In addition, R^2 of the model, which only has past orientation, is about .079. Its explanation power ranking is third between the independent variables and it is almost similar to the second ranking explanation power. Thus, past orientation also can be a significant factor in a regression model of suicide rate. Lastly, we verified our regression model again through a stepwise regression test with 1% significance level. To conclude, the result is same as that of the goodness-of-fit test, and hence, Model 4 is the best model, consistently.

Table 5. Goodness-of-fit of the regression model.

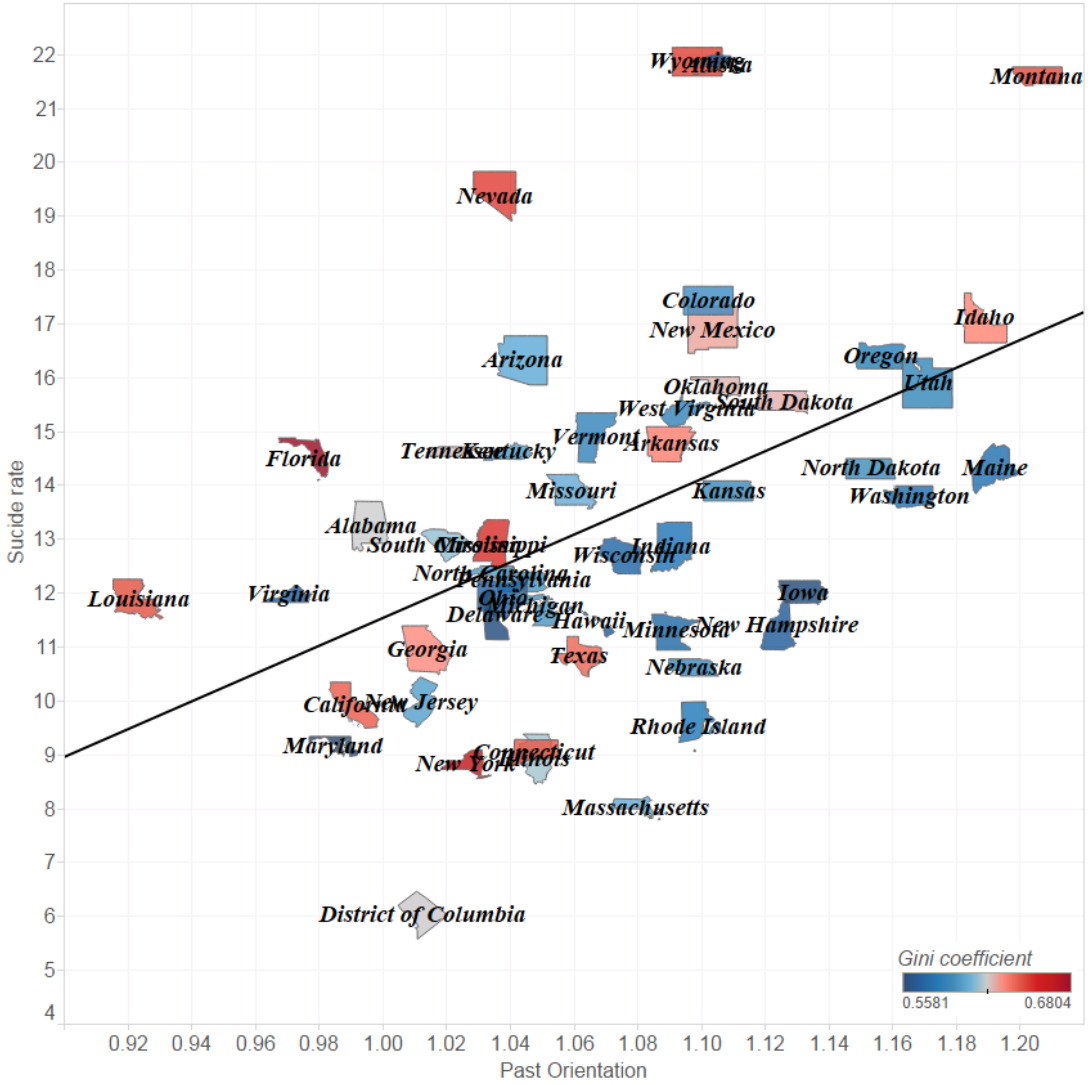
Unemployment rate	Gini coefficient	GSP	Population growth rate	Past orientation	AIC	BIC	$P > F$	R^2	Adjusted R^2
O[a]	O	O	O	O	2354.5	2379.3	<.001	.324	.316
	O	O	O	O	2368.9	2389.6	<.001	.299	.293
O	O	O	O		2384.8	2405.4	<.001	.274	.268
O		O	O	O	2393.5	2414.1	<.001	.261	.254
O	O	O		O	2397.5	2418.1	<.001	.254	.248
	O	O	O		2400.4	2416.9	<.001	.246	.241
	O	O		O	2404.8	2421.3	<.001	.239	.234
		O	O	O	2409.6	2426.1	<.001	.231	.226
O		O	O		2415.5	2432.0	<.001	.221	.216
O	O	O			2425.6	2442.1	<.001	.204	.198
O	O		O	O	2426.8	2447.5	<.001	.205	.198
		O	O		2432.6	2445.0	<.001	.188	.184
	O		O	O	2432.8	2449.3	<.001	.191	.186
	O	O			2434.0	2446.4	<.001	.185	.182
O			O	O	2440.4	2457.0	<.001	.177	.172
O		O		O	2441.9	2458.4	<.001	.175	.169
			O	O	2448.4	2460.8	<.001	.159	.156
		O		O	2450.3	2462.7	<.001	.156	.152
O		O			2461.6	2474.0	<.001	.135	.131
O	O			O	2468.1	2484.6	<.001	.126	.120
	O			O	2469.5	2481.9	<.001	.120	.116
		O			2470.9	2479.2	<.001	.113	.111
O	O		O		2474.1	2490.6	<.001	.115	.109
O			O		2479.5	2491.9	<.001	.100	.096
	O		O		2480.2	2492.6	<.001	.099	.095
O				O	2485.7	2498.1	<.001	.088	.084
			O		2487.1	2495.4	<.001	.081	.079
				O	2488.4	2496.6	<.001	.079	.077
O	O				2512.9	2525.3	.001	.032	.028
	O				2514.6	2522.8	.001	.025	.023
O					2521.4	2529.6	.032	.010	.008

[a]O: Variable utilized in the model.

Past Orientation Versus Suicide Rate

Finally, we mapped the average past orientation and the average suicide rate by state (Figure 3). Although there are many factors that affect a state's suicide rate, we plot between past orientation and suicide rate to focus on past orientation. Notably, the past orientation and suicide rate values vary widely among the US states. As seen in our regression results, there is a tendency where the higher the past orientation of the residents of the state, the higher the state's suicide rate. In particular, many states with high suicide rates (eg, Oregon, Colorado, and New Mexico) have high past orientation; the past orientation of Georgia, California, and Maryland is low, and their suicide rates are also relatively low. As a result, past orientation—including attachment to the past—can be seen as a suicidal risk factor, and it is found to have a positive correlation with the suicide rate.

Figure 3. Past orientation versus suicide rate by US state.



Discussion

Overview

We investigated the potential impact of past orientation on suicide rates; we measured past orientation through the use Google search query data. We also found that suicide rates vary widely by state. We built a yearly panel dataset by considering the categorized control variables for the US states in the 2004-2012 period. We were then able to reveal the relationship between past orientation and the suicide rate through multiple OLS regression: past orientation was found to have a positive relationship with suicide rate in a statistically significant manner ($P \leq .001$). In addition, through AIC and BIC analyses, past orientation was confirmed as being an important variable of suicide rate in the US states. Ultimately, we were able to pinpoint the relationship between suicide rate and its risk factors in the US states.

Principal Findings

We have made three salient contributions to the suicide literature. First, we were able to empirically identify the relationship between past orientation and suicide rate. At the individual level, the risk of suicide tends to increase when one faces a divorce or the death of a loved one, is dismissed from work, or experiences health problems, inter alia. These situations are worse than the aforementioned situations (eg, economic status, job stability, and health status) and are specific to a situation where one has lost a relationship with the people around him or her. When one falls into such a situation, he/she tends to focus on the past and may fall into obsession. These also can be one of reasons why past orientation has a positive relationship with the suicide rates. Second, we were able to measure the past orientation of the residents of US states by applying big data-driven Google search query to the phenomenon of suicide. Finally, we were able to verify clearly that the unemployment rate, Gini coefficient, GSP, and population growth rate are the determinants of the suicide rate in the United States.

More specifically, the unemployment rate finding accords with our expectation that it affects the suicide rate positively. This is consistent with the results of previous studies—such as those of Yang [28] and Neumayer [29], who examined national suicide rate determinants. In particular, vulnerable social groups face unemployment and life hardships whenever the unemployment rate is high; therefore, the unemployment rate has a positive relationship with the suicide rate.

In addition, Gini coefficient was found to have a statistically significant and positive relationship with the suicide rate. This result is consistent with the findings of Gunnell et al [27] in England and Wales. This can be interpreted as follows: deepening wealth inequality has a positive association with the high suicide rate. As a result, not only the GSP but also wealth inequality is an important factor of suicide rate.

By contrast, GSP was found to have a negative relationship vis-à-vis the suicide rate. There are strong links between GSP and suicide rate. While income or GDP variables have been frequently considered in many previous studies [29-36], the results thereof have not been consistent. Our results align with those of previous studies that found GSP to have a negative correlation with the suicide rate [29,33-36]. However, they are inconsistent with some studies that found income or economic boom to have a positive correlation with the suicide rate [30-32]. Although it is possible to explain modernization factor as the reason for income or economic factors affecting the suicide rate in these studies [30-32], our study investigated an already sufficiently modernized region and period, and hence, the results may differ.

Finally, the result of population growth rate can be interpreted as follows: states with a high population growth rate can be more changeable and unstable because immigrants and temporal job opportunities are critical reason of population growth [39]. This instability could contribute to a high suicide rate.

Limitations

Although this study considered many aspects, it nonetheless has some limitations. First, Google search queries data are accessible only from 2004. In addition, the initial stage of Google search queries data, such as data in 2004, is of relatively low reliability because of relatively low Internet users (penetration rate of Internet in the United States is about 64.76% in 2004, but 81.03% in 2012).

In addition, although Google trends provide data only when they have sufficient search query data, a low sample error may occur because of the relatively small population in some states such as Wyoming or Vermont. Finally, Google search query data reflect only the views of people who can access the Internet and Google; for this reason, we cannot reflect on people with no access to the Internet.

Future Research

Future studies need to investigate the causal relationship between past orientation and suicide rate. This can boost our results and bridge the gap of interventions directed at influencing behavior and attitude. Furthermore, next studies will be conducted on the development of tools by which Internet users can request medical help; on the basis of these findings, such tools would leverage past orientation. It can also be valuable to examine how the government can effectively intervene in suicide risk situations using big-data analysis. We will also try to investigate the relationship between suicide or disorders and other specific attitudes by undertaking big-data analysis made possible by the provision of search query or social network data.

Authors' Contributions

DL was responsible for model setup, data analysis, research management, and search query handling. H.L. performed literature review and theoretical back up, and provided medical advice for analysis. M.C. was responsible for research management, provided advise for research, and supported in the manuscript submission process.

Conflicts of Interest

None declared.

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Abbreviations

AIC: Akaike information criterion
BIC: Bayesian information criterion
GDP: gross domestic product
GSP: Gross state product
OLS: Ordinary least squares
TAT: Thematic Apperception Test

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Original Paper

Can Google Searches Predict the Popularity and Harm of Psychoactive Agents?

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Abstract

Background: Predicting the popularity of and harm caused by psychoactive agents is a serious problem that would be difficult to do by a single simple method. However, because of the growing number of drugs it is very important to provide a simple and fast tool for predicting some characteristics of these substances. We were inspired by the Google Flu Trends study on the activity of the influenza virus, which showed that influenza virus activity worldwide can be monitored based on queries entered into the Google search engine.

Objective: Our aim was to propose a fast method for ranking the most popular and most harmful drugs based on easily available data gathered from the Internet.

Methods: We used the Google search engine to acquire data for the ranking lists. Subsequently, using the resulting list and the frequency of hits for the respective psychoactive drugs combined with the word “harm” or “harmful”, we estimated quickly how much harm is associated with each drug.

Results: We ranked the most popular and harmful psychoactive drugs. As we conducted the research over a period of several months, we noted that the relative popularity indexes tended to change depending on when we obtained them. This suggests that the data may be useful in monitoring changes over time in the use of each of these psychoactive agents.

Conclusions: Our data correlate well with the results from a multicriteria decision analysis of drug harms in the United Kingdom. We showed that Google search data can be a valuable source of information to assess the popularity of and harm caused by psychoactive agents and may help in monitoring drug use trends.

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KEYWORDS

drugs; narcotics; Internet; psychoactive agents; forecasting; trends

Introduction

Misuse of psychoactive drugs [1] is one of the most serious social issues [2]. Illegal as they may be, they are readily available on the black market. Exposure to psychoactive drugs in some people may lead to addiction [3], affect the human brain [4], and modify human behavior [5], mood [6], and perception of the outside world. They can also cause death [7].

Harm caused by drug misuse is not easy to measure. The harmfulness of drugs may be approximated based on official statistics on crime, health, deaths, and social problems. On the other hand, questionnaires have been a valuable source of information for determining how harmful or dangerous the use of certain psychoactive drugs is. It is important to select respondents from those in contact with users of psychoactive agents and specialists in psychology, sociology, addiction

therapy, and toxicology. The results of such studies are discussed for example by Nutt et al [8], who determined the harm of such agents using questionnaires distributed among a group of members of the Independent Scientific Committee on Drugs (subsequently renamed DrugScience) in the United Kingdom. They evaluated the agents on a 100-point scale with weighted criteria to include their relative importance. Several other papers and books have addressed the issue of harmful effects and popularity of the agents. Certain reports concluded that when drugs were used sporadically, cognitive functions were largely unaffected [9], while others showed that people who overuse such agents did not realize how harmful they were [10]. It was also confirmed that a method for responding to trends in drug use may be established based on multiyear studies [11]. Relevant books provide information not only about trends in drug use [12], but also about groups of people with a higher tendency to use drugs (by sex, age, or plans for the future) [13].

Laboratory studies of the harmful effects of drugs, most frequently animal studies, may be problematic because they are quite expensive and it is not clear how to translate the results to humans, the actual target. The major issue, however, is the number of agents that may have an impact on the human nervous system and its functions. With the development of chemical tests [14], a significant number of agents with effects similar to those of psychoactive drugs can be produced but have yet to be tested; therefore, they can be legally available even in countries with very restrictive antidrug laws. Designer drugs (novel psychoactive substance) [15,16] are a good example. The United Nations Office on Drugs and Crime (UNODC) [17] and the European Union [18] define a novel psychoactive substance as a new narcotic or psychotropic drug that is not scheduled under the Single Convention on Narcotic Drugs of 1961 or the Convention on Psychotropic Substances of 1971. NPSs may pose a public health threat comparable with that posed by substances listed in those conventions. They tend to be legally available because their ingredients are not included in the lists of illegal substances.

This study was inspired by a study based on Google Flu Trends [19], an investigation into influenza virus activity that showed that the number of persons with influenza worldwide can be monitored using the Google search engine. It was shown that the number of Internet search hits had 95% correlation with the number of persons who actually had influenza. Most important was that influenza virus activity can be determined quickly and updated daily, whereas specialized monitoring agencies provide weekly results based on data acquired with a certain delay.

All of these points led us to use the commonly available Google search engine to predict the popularity and harm of psychoactive agents. Here we describe our methods for obtaining popularity and harm rankings of drugs.

Methods

Based on the report of Nutt et al [8] we decided to study 16 drugs: alcohol, amphetamine, benzodiazepines, buprenorphine, butane, cannabis, cocaine, ecstasy, gamma-hydroxybutyric acid (GHB), heroin, ketamine, khat, lysergic acid diethylamide (LSD), mephedrone, methadone, and methamphetamine. We choose the same substances as Nutt et al because we wanted to compare our results.

Our preliminary results showed a limitation of Google search engine, namely that for substances defined by 2 or more words the frequency of hits was either very small or very high, so we excluded these substances (anabolic steroids and crack cocaine). We also excluded tobacco and mushrooms because those keywords gave results that did not correspond to the subject of this research (information on the biological species rather than the drug substances). We entered the name of each drug between quote marks in Google (so that the exact string was searched for) with the SafeSearch filter off. Initially we considered including colloquial drug names in the list, but these could have had a negative impact on the results, because colloquial names often refer to concepts not related to psychoactive drugs in any way (eg, cocaine is called “snow”, while amphetamine is “speed”). Finally, we obtained the frequency of hits (N_i) for the respective drugs. The relative popularity index for each drug (P_i) was calculated as follows: $P_i=(N_i/\max(N_i))\times100\%$ (1), where $\max(N_i)$ is the drug with the highest frequency of hits (highest number of websites where that keyword is found).

Using the Google search engine with advanced search options may limit the results to websites that were available before a specific date. To generate the harmful effect ranking list, we again entered the agents into Google, but together with the terms “harmful” or “harm” (eg, “alcohol” “harm” OR “harmful”). The OR operator let us determine the frequency of page hits for the drug names *and* “harmful” or “harm” ($N_{i,\ harm}$). Subsequently, we calculated harm indexes (H_i) for the respective drugs as follows: $H_i=(N_{i\ harm}/N_i)\times100\%$ (2).

Results

Table 1 shows the frequency of hits obtained in the Google search and the resulting relative popularity indexes calculated based on equation 1.

Table 1. Frequency of Google search hits for drugs (N_i) and their relative popularity index (P_i)[a], June 20, 2014.

Drug no. (i)	Drug	Frequency of hits (N_i)	Popularity index, % (P_i)
1	Alcohol	389,000,000	100
2	Cannabis	59,100,000	15.2
3	Cocaine	58,600,000	15.1
4	LSD[b]	48,600,000	12.5
5	Heroin	46,800,000	12.0
6	Ecstasy	42,900,000	11.0
7	GHB[c]	23,500,000	6.0
8	Methadone	13,400,000	3.4
9	Butane	11,800,000	3.0
10	Khat	10,600,000	2.7
11	Amphetamine	9,070,000	2.3
12	Methamphetamine	8,780,000	2.3
13	Ketamine	8,400,000	2.2
14	Buprenorphine	6,400,000	1.6
15	Benzodiazepines	4,520,000	1.2
16	Mephedrone	2,050,000	0.5

[a]The relative popularity index was calculated as follows: $P_i=(N_i/\max(N_i))\times100\%$, where $\max(N_i)$ is the drug with the highest frequency of hits.

[b]LSD: lysergic acid diethylamide.

[c]GHB: gamma-hydroxybutyric acid.

Table 1 shows that alcohol was the most popular psychoactive agent with a relative popularity index of 100%, followed by cannabis, 15.2%; cocaine, 15.1%; LSD, 12.5%; heroin, 12.0; ecstasy, 11.0%; GHB, 6.0%; methadone, 3.4%; butane, 3.0%; khat, 2.7%; amphetamine, 2.3%; methamphetamine, 2.3%; ketamine, 2.2%; buprenorphine, 1.6%; benzodiazepines, 1.2%; and mephedrone, 0.5%. It is not surprising in our ranking that alcohol is in first place because similar insights were reported in many papers [20-22] and reports [23,24]. The results change practically every day; therefore, the relative popularity index can be easily updated. It is an easy and fast method for data acquisition; only Internet access is needed.

The popularity indexes we obtained are similar to data from the UNODC *World Drug Report* from 2011 [25]. The UNODC report also documents the number of drug seizures. Most seized drugs were in the amphetamine-type stimulants group, followed by cannabis, cocaine, heroin, and morphine (last 2 are grouped and considered together). Our popularity ranking correlates with the UNODC report data: if we combine the amphetamine-type stimulants we looked at (ecstasy, amphetamine, and methamphetamine) in our ranking, this group is the most popular. Similar to the UNODC report, after amphetamine-type stimulants, the most popular drugs in our ranking were cannabis, cocaine, LSD and heroin.

Popularity indexes as calculated with equation (1) for illegal drugs are similar to those reported in the *European Drug Report 2014: Trends and Developments* [26], which uses the number of seizures of a drug as an indicator of its popularity. This could be a useful proxy, but it also depends on policy changes or the ease of hiding a drug (eg, LSD vs cannabis). Nevertheless, the report shows that the most frequently seized illegal drug is cannabis, second is cocaine, third is heroin, fourth is ecstasy, and then amphetamine, methamphetamine, and LSD. This list is quite similar to our ranking except for LSD, which has a higher popularity index than would be indicated by the number of seizures.

Changes in the frequency of hits for respective agents could be monitored practically daily, making it possible to follow drug use trends. We checked how relative popularity indexes change with the date when results were gathered. We compared data obtained on June 20, 2014 with data available before May 1, 2012, October 1, 2012, January 1, 2013, July 1, 2013, and February 1, 2014. Table 2 shows the resulting relative popularity indexes on different dates.

Table 2. Variation over time of relative popularity indexes (%) for drugs found by Google search, by date.

	May 1, 2012	October 1, 2012	January 1, 2013	July 1, 2013	February 1, 2014	June 20, 2014
max(N_i)[a]	42,600,000	55,800,000	61,900,000	68,400,000	85,600,000	389,000,000
Drug						
Alcohol	100	100	100	100	100	100
Cannabis	6.3	5.9	6.9	7.7	10.1	15.2
Cocaine	10.5	9.4	10.3	10.4	11.4	15.1
LSD[b]	6.4	6.8	7.9	8.8	8.8	12.5
Heroin	8.8	9.1	10.0	10.4	11.0	12.0
Ecstasy	6.2	5.1	5.6	6.1	6.6	11.0
GHB[c]	0.9	1.1	1.3	1.5	1.7	6.0
Methadone	1.8	2.1	2.2	2.0	1.7	3.4
Butane	1.8	2.1	2.3	2.3	2.2	3.0
Khat	1.3	1.2	1.3	1.4	1.6	2.7
Amphetamine	1.2	1.5	2.2	1.6	1.6	2.3
Methamphetamine	1.5	1.6	1.6	1.6	1.6	2.3
Ketamine	2.6	2.3	2.2	1.9	1.6	2.2
Buprenorphine	1.0	0.6	0.6	0.6	0.5	1.6
Benzodiazepines	1.7	1.3	1.3	1.2	1.0	1.2
Mephedrone	0.1	0.1	0.1	0.1	0.1	0.5

[a]max(N_i): drug with the highest frequency of hits (highest number of websites where that keyword is found).

[b]LSD: lysergic acid diethylamide.

[c]GHB: gamma-hydroxybutyric acid.

The most popular psychoactive agent was alcohol on all the studied days. As Table 2 shows, the popularity indexes of heroin, cocaine, cannabis, GHB, ecstasy, and LSD all rose greatly with respect to alcohol over the last 2 years. Changes in popularity of other drugs were not as great, but some of them switched places in the ranking. These data show that between May 1, 2012 and June 20, 2014 cannabis became more popular than cocaine and heroin became less popular than LSD. Similar results are also shown in the UNODC's *World Drug Report* [25]. The *European Drug Report 2014* [26] also showed that heroin become less popular and the number of seizures declined. This report also showed that the quantity of seized cannabis increased every year while that of seized cocaine decreased. Because the Internet data can be captured so fast, it is possible to monitor or maybe even respond to changes in drug popularity, making it possible to identify what psychoactive agents come into fashion and to respond to new trends. Moreover, on the basis of changes in popularity, we can point to which substances may be being used together. According to Table 2, we can assume that many users of different substances may also use cannabis. Changes in the popularity of this drug correlate with changes in the popularity of cocaine, LSD, heroin, ecstasy, khat, GHB, and methamphetamine. Changes in the popularity of cocaine correlate with changes in the popularity of ecstasy, khat, and GHB. Changes in the popularity of ecstasy correlate with changes in the popularity of GHB, khat, and mephedrone. Similarly, changes in the popularity of GHB correlate with changes in popularity of khat, methamphetamine, and mephedrone; methadone with methamphetamine and mephedrone; khat with methamphetamine and mephedrone; and methamphetamine with mephedrone. On the basis of these results, we can assume that these groups of substances may have been used together.

Table 3 presents data assessing how harmful a given drug seems to be based on the crude methods described in the Methods sections.

Table 3. Harmfulness of drugs as assessed by harm index (H_i)[a] (data acquired from Google search on June 20, 2014) and their harm score.

Drug no. (i)	Drug	$N_{i, harm}$[b]	Harm index, % (H_i)	Harm score[c]
1	Alcohol	107,000,000	27.5	72
2	Cocaine	15,000,000	25.6	27
3	Heroin	11,700,000	25.0	55
4	Benzodiazepines	467,000	10.3	15
5	Khat	711,000	6.7	9
6	Buprenorphine	374,000	5.8	7
7	Methamphetamine	513,000	5.8	33
8	Amphetamine	465,000	5.1	23
9	Ketamine	411,000	4.9	15
10	Cannabis	2710,000	4.6	20
11	Mephedrone	92,000	4.5	13
12	Methadone	543,000	4.1	14
13	Butane	386,000	3.3	11
14	Ecstasy	669,000	1.6	9
15	GHB[d]	291,000	1.2	19
16	LSD[e]	580,000	1.2	7

[a]The harm index was calculated as follows: $H_i=(N_{i\ harm}/N_i)\times100\%$, where N_i is the frequency of hits for the drug.

[b]$N_{i\ harm}$ is the frequency of page hits for the drug names *and* the search terms “harmful” OR “harm”.

[c]Data from Nutt et al [8].

[d]GHB: gamma-hydroxybutyric acid.

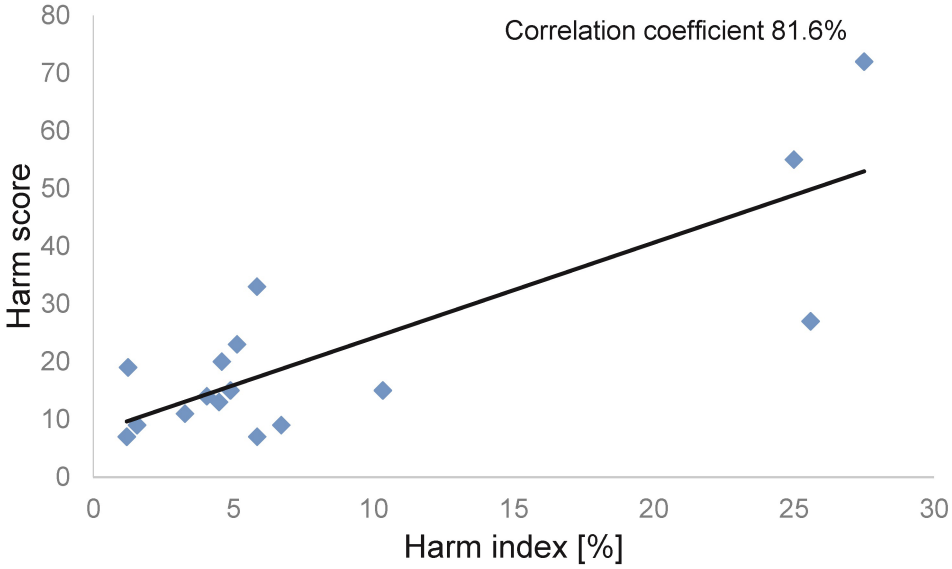
[e]LSD: lysergic acid diethylamide.

Among the studied substances, alcohol had the highest harm index (27.5%), followed by cocaine (25.6%), heroin (25.0%), benzodiazepines (10.3%), khat (6.7%), buprenorphine (5.8%), methamphetamine (5.8%), amphetamine (5.1%), ketamine (4.9%), cannabis (4.6%), mephedrone (4.5%), methadone (4.1%), butane (3.3%) ecstasy (1.6%), GHB (1.2%), LSD (1.2%). We compared our results for the drugs with the results obtained in another study (Nutt et al [8]) in which a different harm ranking list [8] was suggested, with a harm score assigned to agents. They calculated the harm index as a percentage, with the harm score having no unit. Nutt at al [8] assigned 100 points to a theoretical most-harmful substance, which has not been discovered yet. Similar to our ranking, their highest harm score was for alcohol. However, their second-ranking drug was heroin, whereas in our ranking cocaine has the second-highest harm score. The harm score for cocaine is smaller than that for methamphetamine, whereas methamphetamine’s harm index is about 5 times smaller than that for cocaine. Similarly, amphetamine, cannabis, ketamine, benzodiazepines, and GHB have harm scores similar to that for cocaine, but their harm indexes are 5 or 6 times smaller than the harm index for cocaine. Both rankings (except alcohol) also have ketamine, mephedrone, ecstasy, and LSD in the same positions, but in all cases the harm score is bigger than the harm index.

We plotted harm scores from Nutt et al [8] and our harm indexes to visualize the correlation between our studies (Figure 1).

The correlation coefficient between the harm score ranking and the harm index was 81.6%. The calculated *P* value was 0.000143, showing a significant correlation, with the significance level set at 0.01. We should stress that the *P* value does not demonstrate that data from the Independent Scientific Committee on Drugs [8] and our Internet data are correlated because they both address the same topic; however, that they do correlate and the significance of the *P* value indicate that the correlation is unlikely to arise by chance. These results show that a Web search with simple numerical analysis of the results may provide valuable data in a much shorter time frame. The results from using popular names for drugs and the term “harm” as the indicator of adverse effects should, however, be assessed with particular caution, as harmful effects are much more complex. Nevertheless, this method may be viewed as an initial proxy for a concept as complex as harm (which includes social factors, health issues, and mental problems).

Figure 1. Correlation between harm scores obtained by Nutt et al [8] and the proposed harm index for a series of drugs identified by Google search (blue squares).



Discussion

Information derived from the Internet should be assessed with particular caution and always verified against sound data from other sources. Google search data may be and indeed sometimes are misleading. The simplest example is the phrase “cat” OR “dog”. A Google search returns well over 2 billion webpages containing the word “cat” and well over 1 billion websites with the term “dog”. Shockingly, when we combine these 2 words with the OR operator, we obtain less than half a billion webpages. In this case the inclusive disjunction operator does not show results that include both sets.

Nevertheless, the Internet has become a mine of information, which, when verified with other sources of data, may be beneficial. Based on Google Web searches verified against data from the UNODC [25], the European Monitoring Centre for Drugs and Drug Addiction [26], and Nutt et al [8], we have shown that data from Web searches—when treated with caution—may be a valuable source of information on drug use. We obtained popularity and harm ranking lists for selected psychoactive drugs. Furthermore, we recorded changes in drug popularity at various time points over 2 years (2012-2014). The proposed approach may help indicate early changes in drug popularity and may be useful for preventing drug addiction. Interestingly, this crude and simple approach to estimating harm associated with a given drug harm index correlated very well (correlation coefficient 81.6%) with the much more sophisticated method proposed by Nutt et al [8] of calculating harm scores. Our results seem to indicate that, with respect to alcohol, the popularity of psychoactive agents has increased significantly over the 2 years 2012-2014, in particular the popularity of cannabis (from 6% to 15%), cocaine (from 10% to 15%), LSD (from 6% to 12%), and ecstasy (from 6% to 11%).

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Conflicts of Interest

None declared.

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Abbreviations

GHB: gamma-hydroxybutyric acid
LSD: lysergic acid diethylamide
UNODC: United Nations Office on Drugs and Crime

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Original Paper

Garbage in, Garbage Out: Data Collection, Quality Assessment and Reporting Standards for Social Media Data Use in Health Research, Infodemiology and Digital Disease Detection

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Abstract

Background: Social media have transformed the communications landscape. People increasingly obtain news and health information online and via social media. Social media platforms also serve as novel sources of rich observational data for health research (including infodemiology, infoveillance, and digital disease detection detection). While the number of studies using social data is growing rapidly, very few of these studies transparently outline their methods for collecting, filtering, and reporting those data. Keywords and search filters applied to social data form the lens through which researchers may observe what and how people communicate about a given topic. Without a properly focused lens, research conclusions may be biased or misleading. Standards of reporting data sources and quality are needed so that data scientists and consumers of social media research can evaluate and compare methods and findings across studies.

Objective: We aimed to develop and apply a framework of social media data collection and quality assessment and to propose a reporting standard, which researchers and reviewers may use to evaluate and compare the quality of social data across studies.

Methods: We propose a conceptual framework consisting of three major steps in collecting social media data: develop, apply, and validate search filters. This framework is based on two criteria: retrieval precision (how much of retrieved data is relevant) and retrieval recall (how much of the relevant data is retrieved). We then discuss two conditions that estimation of retrieval precision and recall rely on—accurate human coding and full data collection—and how to calculate these statistics in cases that deviate from the two ideal conditions. We then apply the framework on a real-world example using approximately 4 million tobacco-related tweets collected from the Twitter firehose.

Results: We developed and applied a search filter to retrieve e-cigarette–related tweets from the archive based on three keyword categories: devices, brands, and behavior. The search filter retrieved 82,205 e-cigarette–related tweets from the archive and was validated. Retrieval precision was calculated above 95% in all cases. Retrieval recall was 86% assuming ideal conditions (no human coding errors and full data collection), 75% when unretrieved messages could not be archived, 86% assuming no false negative errors by coders, and 93% allowing both false negative and false positive errors by human coders.

Conclusions: This paper sets forth a conceptual framework for the filtering and quality evaluation of social data that addresses several common challenges and moves toward establishing a standard of reporting social data. Researchers should clearly delineate data sources, how data were accessed and collected, and the search filter building process and how retrieval precision and recall were calculated. The proposed framework can be adapted to other public social media platforms.

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KEYWORDS

social media; precision and recall; sensitivity and specificity; search filter; Twitter; standard reporting; infodemiology; infoveillance; digital disease detection

Introduction

Social media have transformed public and interpersonal communications. The Internet and social media have quickly become major sources of health information [1-3], providing both broad and targeted exposure to such information as well as facilitating information-seeking and sharing. As people increasingly turn to social media for news and information [4,5], these platforms can serve as novel sources of observational data for infodemiology, public health surveillance (infoveillance, digital disease detection) [6-11], tracking health attitudes and behavioral intention [6, 7, 9,12-16], and measuring community-level psychological characteristics related to health outcomes [17,18].

While Facebook remains the most commonly used social media platform, varying privacy settings and complex application programming interface (API) streams make the collection and interpretation of Facebook data for observational research extremely challenging. In contrast, Twitter, which is by nature a much more public-facing platform, has millions of active users who provide rich qualitative data in the content of microblog messages (tweets) as well as important quantitative data embedded in the metadata. Metadata fields describe the reach and patterns of the diffusion of a given message, along with some limited characteristics of the users posting messages. Similarly, YouTube has millions of active users who view, post, rate, and comment on its rich video content and advertising. A simple search of any social media platform can provide a tantalizing bounty of information. Yet despite the rich potential of these platforms for research and analysis, methods for collecting, cleaning, and reporting social media data can vary widely, making the evaluation and comparison of studies using those data difficult at best.

Social media data collection in infodemiology is usually defined by the keywords and search filters used to retrieve data from the platform [6]. As such, search filters are the lens through which we can observe what and how people communicate. If our lens is appropriately focused, we can identify content of interest and avoid collecting a lot of irrelevant information. Conversely, if our search is too narrow, we may miss important data and our conclusions may be biased. If it is too broad, we risk collecting a lot of irrelevant and potentially misleading material.

A search filter is a set of keywords integrated with search rules that specify search strategies. While there is an intuitive simplicity in identifying keywords and search rules for a given research question, that seeming simplicity is deceptive. First, keyword selection is not simple. Language and popular culture vary by age, socioeconomic status, race/ethnicity, geographic location, etc. The language used on social media is often colloquial, creative, and varying. Further, users communicate differently across platforms, partly driven by the norms and technical constraints unique to each platform, and partly driven by the social function of each platform [19]. For example, Twitter users are limited to 140 characters and typically post short messages using abbreviations and slang terms. Facebook posts can be longer and thus are more likely to contain multiple, different words for a single construct. YouTube videos are posted with titles and often tagged by the poster with keywords. Instagram posts typically have multiple hashtags that offer some indication of the content. If a researcher is not fluent—or at least familiar—with the language norms of a particular platform, their search filter may be overly broad, too narrow, or simply off-topic.

The keyword is only one part of a filter; without practical rules, an intuitive search term can retrieve a lot of irrelevant information. For example, in tobacco research, the term “smoking” is critically important to any search for relevant content. But without further rules to refine that term, the keyword will retrieve plenty of content about “smoking marijuana,” “smoking ribs,” and “smoking hot girls” [9,12]. A sentiment analysis of data retrieved with the broad “smoking” term would produce different results from data retrieved with a search filter that excluded other key terms that appear in close proximity to “smoking.” Therefore, developing reliable search filters requires a rigorous process to weed out irrelevant content and assure high-quality data collection [20].

While many studies have reported lists of keywords used to retrieve social data [7-10,12-16,21-24], few describe development of search filters [7,9,15,22,23], and fewer yet attempt assessment of search filters by providing what fraction of collected data are relevant [9,15,16,22,23]. One study provided the probabilities of losing possible relevant tweets by removing certain keywords [22] but did not fully assess their search filter.

Because the quality of social data and the interpretation of subsequent analyses depend on the quality of search filters, it is imperative for social media researchers to provide evidence of the quality and scope of their data: face validity is not sufficient. Computer scientists, communication researchers, and librarians, among others, use precision and recall as measures of search filter quality [20,25,26]. Most studies that use social media data, however, do not attempt to objectively assess the

quality of their data. There is often confusion about the meaning of precision and recall because they are used to assess the performance of machine learning classifiers or disease screening tests, which is different from what we aim to assess: the quality of retrieved data. To avoid confusion, we define the precision and recall used to access the quality of retrieved data as the *retrieval precision* and *retrieval recall*. We use the terms precision/recall and retrieval precision/recall interchangeably throughout the paper unless clear distinction is needed.

In studies that do assess validity, search filters are compared against a gold standard that is typically human coding. No studies so far have considered the fact that human coders can make errors. Some errors associated with coding social media contents are inevitable despite well-trained human coders. An imperfect gold standard may cause bias in the validity assessment [27]. While a perfect coding standard may be impractical, it is important that researchers are transparent and consistent about how they report the quality of coding and the strengths and limitations of their benchmark.

In this paper, we describe a framework for the collection and assessment of social media data. The goal is to move toward a reporting standard that researchers and reviewers can use to compare the quality of data retrieved and analyzed across different studies. For illustrative purposes, we use data collection from Twitter to illustrate concepts that can be adapted for other text-based social media platforms open to public. Further, we use electronic cigarette (e-cigarette) content as a working example of a salient public health topic that is rapidly changing, with constantly emerging new brands and new slang [9,12] that challenge researchers' grasp of the language that social media users use to communicate about and market these products.

Below, we first propose a conceptual framework for social media data collection. Within this framework we describe the development of search filters, illustrate the calculation of retrieval precision and recall, and illustrate common challenges and potential workarounds. Next, we apply our framework to a real-world example using data on e-cigarette content: approximately 4 million tweets retrieved from the Twitter firehose. Finally, we discuss the challenges of applying this rigorous approach to data collection and quality assessment and propose a checklist for reporting data preparation.

Methods

Conceptual Framework for Social Data Collection and Quality Assessment

We propose a framework that consists of three major steps to develop and validate search filters (see Table 1). The proposed framework is designed for users who can access partial or full data streams and can be applied to a human-based process that mainly relies on human judgment and coding, and an automated process supported by machine learning techniques and less human judgment [28].

Table 1. A framework for Twitter data collection and validation.

Step	Details
Develop search filter	1. Build a list of search keywords: (a) Generate a list of candidate keywords based on expert knowledge, systematic search of topic-related language, and other resources, (b) Screen the keywords by examining relevance and frequency of posts, (c) Discard keywords that return posts with high proportion of irrelevant contents or relatively low frequency, and (d) Add and screen new keywords when new relevant terms and phrases emerge.
	2. Integrate keywords with search rules (eg, Boolean operators) for a more focused search.
Apply search filter	3. The search filter retrieves and splits data into a retrieved set and an unretrieved set.
Assess search filter	4. Cross-tabulate data by gold standard and search filter: (a) Randomly sample from retrieved and unretrieved data; stratified sampling may be applied, (b) Manually code sampled data to determine relevance in both of retrieved and unretrieved sets, (c) Cross-tabulate sampled data by human-coded relevance (coded relevant vs irrelevant) and search filter retrieval status (retrieved vs unretrieved).
	5. Compute retrieval precision and retrieval recall.

Develop Search Filter

Build a List of Keywords

The first step in developing search filters is keyword selection. Depending on the research topic, keywords should be generated based on expert knowledge and systematic search of topic-related language. It is helpful to brainstorm and categorize keywords into subgroups. In our e-cigarette example, we categorized e-cigarette–related keywords into three subgroups: devices, brands, and behaviors.

Keyword selection also depends on social media platforms from which data are gathered. Twitter data raise unique challenges in keyword selection due to the limited number of characters allowed in a message. Twitter users often shorten messages they post by using hashtags, abbreviations, colloquialisms, and slang terms. For example, the term "square" is slang for cigarettes. A researcher without prior knowledge of this term might create a search filter that does not include the term, likely missing out on many tobacco smoking-related contents. It is therefore crucial for researchers to keep up with current abbreviations, colloquial expressions, and slang terms in their research topics. Resources such as urban dictionary [29] and a diverse team of researchers are essential to generate and understand such keywords.

Despite these efforts, many important terms may still be left out. It is therefore necessary to strategically employ broad search terms rather than highly specific terms/expressions. For example, a tweet like "A girl sitting next to me smokes squares" will be captured using a broad term "smoke" even if one does not know

the term “square.” Although using broad search terms like “smoke” generates many irrelevant tweets, it reduces the probability of omitting relevant content. This is particularly useful when researchers do not have access to historical archives of social media platforms and are collecting data via streaming.

The list of keywords should be further screened and updated iteratively based on relevance and frequency. The keywords that return relatively few tweets (eg, <10 over a month) or that return a small proportion of relevant tweets (eg, <30% precision) may be discarded. That is, the signal (relevant data) to noise (irrelevant data) ratio should be considered [22] and proper thresholds may depend on research questions. New keywords should be added to the list when new relevant terms and phrases emerge (eg, new e-cigarette brands, frequent co-occurring terms). Repeating Steps 1-4 of *Build a list of search keywords* in Table 1 improves the quality of keywords and provides a good understanding of how social media users talk about a specific topic. If the data are collected for surveillance or forecasting, keywords should be updated periodically and related media coverage (if any) should be accounted.

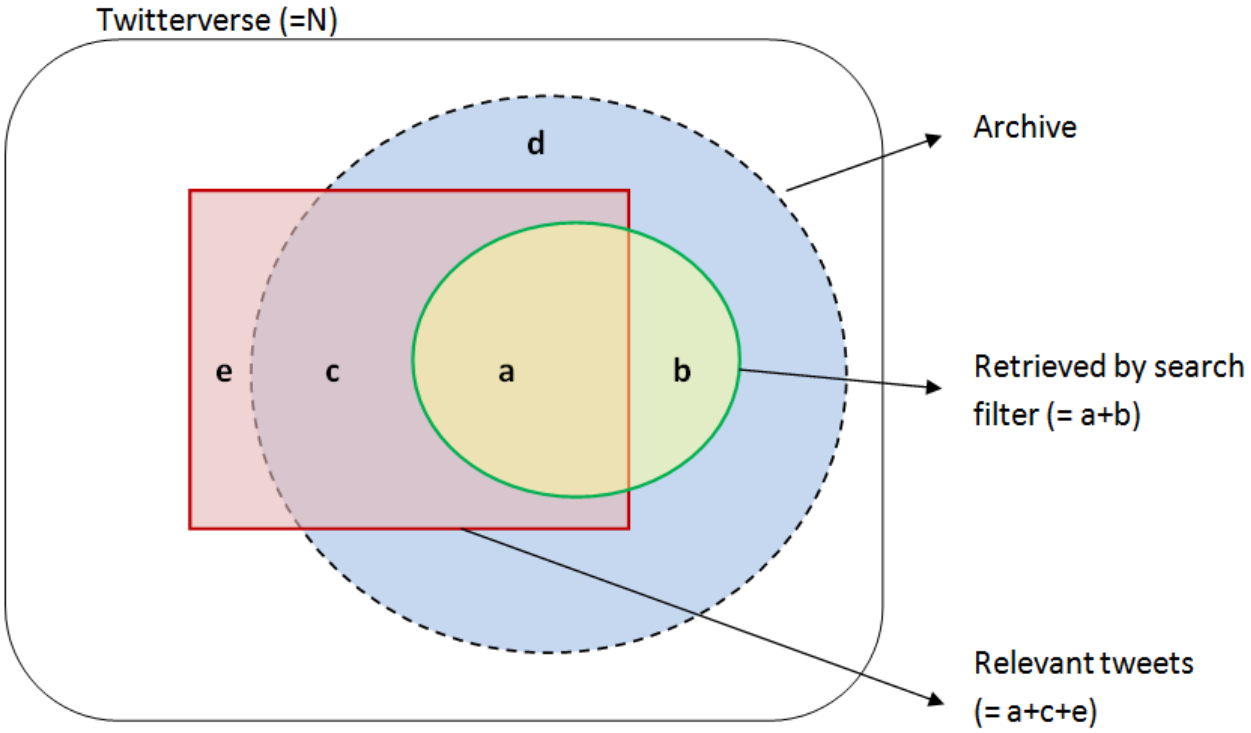
Integrate Keywords With Search Rules

A search filter is a combination of keywords and search rules. Integrating keywords with search rules greatly improves the ability of search filters to retrieve relevant messages. Search rules can be used to weed out irrelevant messages retrieved by broad terms. For example, in tobacco research, irrelevant tweets can be excluded by specifying that terms such as “barbeque” or “marijuana” do not appear in the tweets, while relevant tweets could be kept if a tweet contains both terms “smoke” and “square.” These search rules can be constructed using the Boolean operators (AND, OR, NOT) and data pre-processing techniques such as n-grams or proximity operator.

Apply Search Filter

Figure 1 displays a structure of data archive, search filter, and relevant tweets in the Twitterverse. The archive contains data returned by broad search terms (the blue circle with dotted line indicates the archive, and the red rectangle indicates all tweets relevant to a specific topic). The search filter returns “a + b” tweets. The archive may omit a small fraction of topic-relevant tweets “e” due to unknown terms, misspellings, etc.

Figure 1. The archive (a+b+c+d), retrieved tweets (a+b), and relevant tweets (a+c+e) in Twitterverse.



Assess Search Filter

Quality Measures: Definition

Any search filter should be validated based on its ability to distinguish relevant and irrelevant messages. Two criteria are typically used: *retrieval recall* and *retrieval precision* [25]. Precision measures how much of the retrieved data is not garbage. Recall measures how much of the relevant data is retrieved.

Table 2 is constructed to evaluate a search filter against human coding. Precision is a conditional probability that a particular post is relevant, given that it is retrieved, calculated by a/(a + b). Recall is a conditional probability that a particular post is retrieved given that it is relevant, calculated by a/(a + c). Precision is also called positive predictive value, and recall is often called sensitivity of search filter [30]. There is trade-off: high recall may be achieved at the expense of low precision (or low specificity), and vice versa. The F-score is used to report a single measure combining precision and recall [31], computed by:

$F=(1+\beta^2)(\text{precision})(\text{recall})/(\beta^2\ \text{precision}+\text{recall})$ (1)

Often $\beta=1$ is used and such measurement is called an F1 score. It can be shown that, using the Bayes' theorem [32], the recall can be computed by:

$\text{Recall}=(\text{precision})P(\text{retr})/[(\text{precision})P(\text{retr}) + P(\text{relevant}|\text{unretr})(1\ \ P(\text{retr}))]$ (2)

P(retr) denotes the proportion of tweets retrieved, and P(relevant|unretr) denotes the proportion of unretrieved tweets found to be relevant.

Beyond precision and recall, specificity and negative predictive value (NPV) may be used. Specificity measures how much of the irrelevant tweets is discarded, defined by d/(b + d), and is closely related to precision. NPV is the proportion of unretrieved tweets found to be irrelevant, defined by d/(c + d). Note that P(relevant|unretr)=1 NPV. The proportion of relevant tweets may be obtained by (a + c)/n assuming that the data represent a random sample of the population and human coding is not subject to errors.

Table 2. Assessment of search filter with human coding as a gold standard.

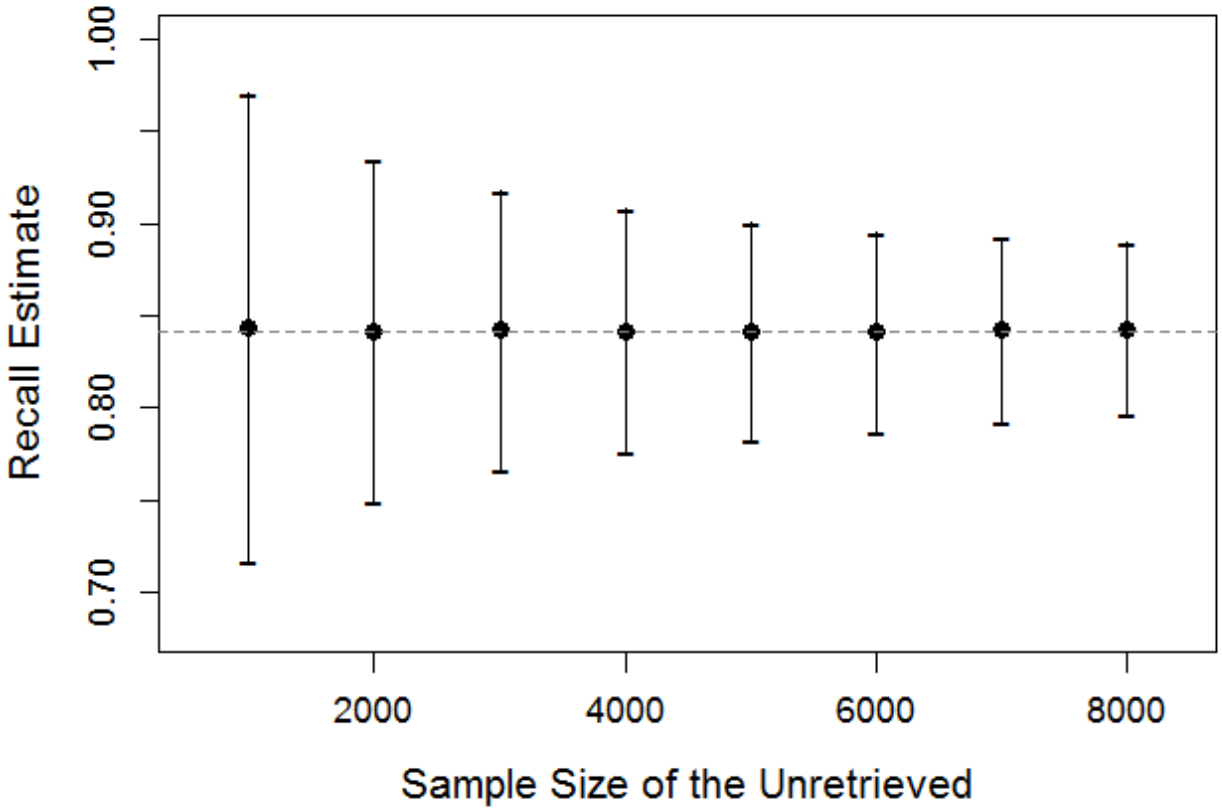
Search filter	Human coding		Total
	Coded relevant	Coded not-relevant	
Retrieved	a (True Positive)	b (False Positive)	$a + b=n_1$
Not retrieved	c (False Negative)	d (True Negative)	$c + d=n_2$
Total	a + c	b + d	n

Sampling Plan for Human Coding

Calculation of retrieval precision and recall depends on the assessment of relevant versus irrelevant content. Typically, trained coders inspect a sample of retrieved data to manually evaluate relevancy as well as a sample of unretrieved data. This poses two important questions: how to sample and how many messages to sample. A practical sample size should be determined because it is labor intensive and time consuming to manually code millions of messages, and the estimates of precision and recall should be precise.

We suggest stratified sampling with retrieval status as strata and oversampling the retrieved messages. This is because typically the size of retrieved messages is small relative to unretrieved messages ($n_1/n_2<0.1$), and oversampling the retrieved messages ensures a desired level of statistical precision. Retrieval recall is more difficult to accurately estimate than retrieval precision because estimating *c* is often similar to finding a needle in a massive haystack of unretrieved messages. Therefore the statistical precision of recall estimate is affected by the sample size. Figure 2 displays how the average length of confidence intervals for retrieval recall estimates decreases as the sample size of unretrieved messages (=k) increases, while the sample size of retrieved message is fixed. The gain in statistical precision diminishes as the number of unretrieved messages increases, and the gain is minimal above a certain sample size. By conducting a simulation or using power analysis tool, a sample size that satisfies the desired level of statistical precision and feasibility can be determined. Multimedia Appendix 1 describes how Figure 2 was generated and discusses more about sample sizes.

Figure 2. The average limits of 95% confidence intervals for recall (vertical axis) as the sample size of unretrieved messages increases (horizontal axis), fixing the sample size of retrieved data at 3000.



Estimation of Retrieval Precision and Retrieval Recall

Calculating retrieval precision and recall is straightforward when (1) human coding performs well as a gold standard and (2) Table 2 is complete. We discuss in detail the cases in which one or both conditions are not satisfied and how to address them.

Assuming Human Coding Has No Error

Ideal Conditions

The definitions of precision and recall are directly used when the two conditions are met. If stratified disproportionate sampling is used, appropriate weights should be applied to calculate recall. Confidence intervals can be estimated based on usual asymptotic methods [33]. If Equation (2) is used to calculate recall, the interval estimate should account for variances of precision and P(relevant|unretr).

Unretrieved Messages Could Not Be Archived

Messages matching search filters may be retrieved directly from a data provider so that only the retrieved messages are archived [11,15,21]. Search filter precision can be estimated, but how do we estimate the recall without knowing *c* and *d*? In this case, the unretrieved total n_2 may be known approximately. Joseph et al used the Bayesian model to estimate recall and specificity when only n_1 and n_2 were given [34]. Bayesian models often provide a feasible solution when insufficient information is contained in data to apply usual methods. Since *a* (thus *b*) can be observed in addition to n_1 and n_2, we slightly modify their method.

Let π be the prevalence of relevant messages, *S* be recall, and *C* be specificity of search filter. The counts of tweets (*a*, *b*, *c*, *d*) in Table 2 have multinomial distribution with respective probabilities forming the likelihood function. Beta prior distributions for π, *S*, and *C* seem sensible because its domain of positive density is bounded in (0,1). Let Beta(α_π, β_π), Beta(α_S, β_S), and Beta(α_C, β_C) denote the prior distributions of π, *S*, and *C* respectively, where Beta(α, β) is beta density function with parameters α and β. Full conditional posterior distributions can be derived for all unknown quantities including *c*, and realized values are sampled from the posterior distributions using a Gibbs sampler. A Gibbs sampler draws from each full conditional posterior distribution sequentially, conditional on all other sampled quantities [32]. It can be shown that the prevalence of relevant messages and recall of search filter have the following posterior distributions: $\pi \sim$ Beta ($a + c + \alpha_\pi$, n a $c + \beta_\pi$), $S \sim$ Beta ($a + \alpha_S$, $c + \beta_S$).

The quantity *c* is obtained in a previous sampling step. The Bayesian credible interval for an unknown quantity can be obtained based on the random draws from posterior distributions. The Gibbs sampling steps for all unknown quantities are provided in Multimedia Appendix 2.

Assuming Human Coding Is Subject to Error

Human Coding Is a Silver Standard

Evaluating search filters using imperfect human coding gives a biased impression of data quality. Recall and precision of a search filter depend on recall and specificity of the gold standard [27]. Staquet et al considered a situation where a gold standard has 100% specificity and unknown recall. It may be relatively unlikely that a trained coder evaluates a given irrelevant tweet as relevant. For example, a coder likely will not determine the message "Come get a *smoking* hot jerk chicken wrap from us" as relevant to tobacco smoking. Thus it may be safe to assume, for a given topic, that the specificity of human coding is (close to) 100%. When this assumption is met, the search filter's recall is unbiased and the bias-corrected equation for precision is given by precision=a/[S_2 (a + b)], where S_2 denotes the recall of human coding. Therefore, when human coding does not have perfect recall (false negative error), the method assuming the ideal conditions underestimates search filter precision.

Human Coding Is Not a Standard Classifier

Although in many cases human coding serves as a gold/silver standard, it may be an inadequate standard classifier for some topics because human language can be ambiguous (eg, "Leo DiCap is smoking"). Language used on Twitter is often colloquial and creative, and it may be difficult (or impossible) to interpret meaning within 140 characters without looking at related conversations (eg, "I can't tell if that's a chocolate Dutch my"; this was a reply to a tweet about Dutch chocolate-flavored cigarillo). Also, coders simply get tired. As a result, coders may falsely determine irrelevant posts to be relevant or vice versa (false positive and false negative error). Joseph et al extended the Bayesian model to the situation where results of two filters, neither of which was a gold standard, were available [34]. We again modify their method to estimate search filter precision and recall.

Similar to Table 2, search filter and human coding results are cross-tabulated. Each cell can be split into truly relevant versus irrelevant contents (see Table 3). Let y_1 be the count of relevant messages out of the *a* messages retrieved by search filter and human-coded relevant; the count of irrelevant messages is a y_1. The rest of the cells can be similarly split.

Table 3. Multinomial likelihood contributions of all possible cases of observed data and unknown quantities (the unknown quantities of truly relevant tweets are denoted by y_1, y_2, y_3, y_4).

Search filter (*j*=1)	Human coding (*j*=2)	
	Coded relevant	Coded not-relevant
Retrieved	$a - y_1$	$b - y_2$
	y_1	y_2
Not retrieved	y_3	y_4
	$c - y_3$	$d - y_4$

Let π be the prevalence of relevant messages, S_1 and C_1 be recall and specificity of search filter, and S_2 and C_2 be recall and specificity of human coding. The eight cells in Table 3 can be expressed as occurrences of multinomial events with probabilities that are functions of the five parameters. Again, a beta distribution can be used to set up prior distribution of each parameter. Denote S_1, S_2, C_1, and C_2 are distributed Beta(α_{S1}, β_{S1}), Beta(α_{S2}, β_{S2}), Beta(α_{C1}, β_{C1}), and Beta(α_{C2}, β_{C2}), respectively. It can be shown that the prevalence of relevant messages and search filter recall and specificity have the following posterior distributions:

$\pi \sim \text{Beta}\ (\sum y_i + \alpha_\pi\ ,\ n \quad \sum y_i + \beta_\pi)$ for i=1,2,3,4

$S_1 \sim \text{Beta}\ (y_1 + y_2 + \alpha_{S1},\ y_3 + y_4 + \beta_{S1})$

$C_1 \sim \text{Beta}\ (c + d \quad y_3 \quad y_4 + \alpha_{C1},\ a + b \quad y_1 \quad y_2 + \beta_{C1})$

The precision and NPV of search filter can be obtained by the equations:

$\text{Precision}_1 = S_1\pi/[S_1\pi + (1 \quad C_1)(1 \quad \pi)]$

$\text{NPV}_1 = C_1(1 \quad \pi)/[C_1(1 \quad \pi) + (1 \quad S_1)\ \pi]$

These are based on the random draws from posterior distributions of π, S_1, and C_1. Multimedia Appendix 3 describes the Gibbs sampling steps to obtain random draws from posterior distributions of all unknown quantities including precision and recall of human coding.

Results

Develop Search Filter

We obtained Twitter data via an API called Firehose from Gnip, Inc., licensed to provide access to the full stream and historic archive of Twitter data. Access to Firehose is not free as opposed to publicly available data streams such as Streaming API. The Twitter Firehose returned 3,954,575 unique tweets that matched broad keywords about tobacco smoking in October 2012, forming an archive. The archive provided a base to construct Table 2.

We developed a search filter to retrieve e-cigarette-related contents, building around three categories of e-cigarette-related tweets: alternative terms and device parts of e-cigarettes, brand names, and related behavior. We tested keywords using the Twitter Search Engine [35] without logging into our Twitter accounts to avoid search bias. We screened and discarded

keywords that returned irrelevant tweets higher than 70% of the time or that returned <10 tweets over a month. When unknown but seemingly relevant terms and phrases that co-occur with our keywords emerged, we checked them in an urban dictionary and other social media platforms, added them to the list, and screened them on Twitter Search. We repeated Steps 1-4 from Table 1 until no more seemingly important keywords were found.

The resulting keyword list included singular and plural forms of e-cigarette terms, different verb forms of behavior terms, and frequent misspellings. We filtered out tweets containing the keywords “atomizer” AND “perfume” as those were likely to describe perfume bottles. Those tweeted by or mentioning @blucigs, an e-cigarette promoting account, were collected. The final list of keywords and rules is presented in Multimedia Appendix 4.

Assess e-Cigarette Search Filter

Sampling Plan for Human Coding

We conducted stratified sampling with retrieval status as strata. A small simulation was performed to determine sample size in each stratum. Data were generated assuming that N was 4 million, retrieval precision was 95%, and retrieval recall was 84%. The simulation details are described in Multimedia Appendix 1 (Case 1). Based on the simulation, we determined that random sampling above 4000 from retrieved tweets and above 6000 from unretrieved tweets would be sufficient.

Assuming Human Coding Has No Error

Ideal Conditions

The e-cigarette search filter retrieved 82,205 tweets from the archive, yielding P(retr)=0.0208. We randomly sampled 4373 from the retrieved set and coded 4176 of those as relevant, resulting in 95.5% retrieval precision (95% CI 94.9-96.1). Table 4 represents number of tweets cross-tabulated by human coding and search filter; the amount of retrieved tweets was adjusted for the disproportionate sampling fraction. Out of 6305 randomly sampled unretrieved tweets, 20 were found relevant, yielding P(relevant|unretr)=0.0032. The retrieval recall was 86.37% (95% CI 81.4-91.9) by Equation (2). The F1 score was 90.7%.

Table 4. Search filter versus human coding on sampled data adjusted for sampling fraction.

Search filter	Human coding		Total
	Coded relevant	Coded not-relevant	
Retrieved	128	6	134
Not retrieved	20	6285	6305
Total	148	6291	6439

Unretrieved Messages Could Not Be Archived

To demonstrate the method, we assumed that the archive contained only the tweets retrieved by the e-cigarette search filter. After assigning initial values (Multimedia Appendix 2), a value of precision was sampled from the uniform distribution with limits equal to the 95% confidence interval of the precision (94.9-96.1). We used n_1=82,205 and n_2=3,872,370 in the subsequent steps. The Gibbs sampler was repeated 100,000 cycles, and the first 10,000 cycles were discarded as burn-in. The prior distribution and posterior inference results are presented in Table 5. Prevalence indicates the proportion of e-cigarette–relevant tweets within the archive. Prior distributions have been set based on our experience: the specificity is usually high due to low prevalence, and we are confident that the search filter captures the majority of e-cigarette tweets. Although rather high uncertainty was reflected in the prior density of recall—as low as 34%. The F1 score values are computed applying the sampled values of recall and precision on Equation (1) at the end of each cycle. The posterior mean of retrieval recall is 75%: between 50% and 98% with 95% probability. Having no information on the amount of false negative tweets caused a wider interval.

Table 5. Prior and posterior means and 95% credible intervals when unretrieved messages cannot be archived.

	Beta prior distribution		Posterior distribution	
	Mean	95% HD[a]	Mean	95% HPD[b]
Prevalence	0.010	1×10^{6}-0.031	0.028	0.020-0.038
Search filter				
Recall	0.667	0.340-0.954	0.752	0.505-0.979
Precision[c]	–	–	0.955	0.949-0.961
Specificity	0.733	0.474-0.962	0.999	0.999-0.999
F1 score[c]	–	–	0.835	0.663-0.968

[a]HD: highest density interval.

[b]HPD: highest posterior density interval. HPD interval gives narrower length than equal-tailed intervals for skewed distribution (computed using R Package BOA [36]).

[c]Prior density functions of precision and F1 score are not specified but determined as a function of other parameters.

Assuming Human Coding Is Subject to Error

Human Coding Is a Silver Standard

We assumed that the coders could accurately evaluate irrelevant contents with 100% specificity although they might falsely determine relevant contents to be irrelevant (<100% recall). When human coders make false negative errors, the method assuming the ideal conditions underestimates retrieval precision of search filter. The bias-corrected equation gave the precision of 95.7%, indicating that precision determined assuming the two conditions was minimally biased.

Human Coding Is Not a Standard Classifier

Finally we assumed that coders could falsely determine irrelevant contents to be relevant and vice versa (<100% recall and <100% specificity). Each cell of Table 4 can be split into truly relevant and irrelevant tweets. Again let y_1 be the count of relevant tweets among those retrieved by search filter and human-coded relevant; the count of irrelevant tweets is 128 y_1. The Gibbs sampler (see Multimedia Appendix 3) was repeated 100,000 cycles, and the first 10,000 cycles were discarded as burn-in. The prior distribution and posterior inference results are presented in Table 6. Our belief that human coding is slightly better than the search filter is reflected in the prior distributions. The posterior mean of prevalence of e-cigarette tweets is 2% in the archive. The posterior mean of retrieval recall is 93% for the search filter and 96% for human coding. Having more information resulted in smaller uncertainty (ie, shorter HPD intervals).

Table 6. Prior and posterior means and 95% credible intervals when human coding is not a standard classifier.

	Beta prior distribution		Posterior distribution	
	Mean	95% HD[a]	Mean	95% HPD[b]
Prevalence	0.019	1×10^{6}-0.031	0.021	0.018-0.025
Search filter				
Recall	0.667	0.340-0.954	0.929	0.862-0.992
Precision[c]	–	–	0.956	0.914-0.994
Specificity	0.733	0.474-0.962	0.999	0.998-1.000
F1 score[c]	–	–	0.942	0.901-0.982
Human coding				
Recall	0.733	0.474-0.962	0.961	0.923-0.995
Precision[c]	–	–	0.897	0.824-0.971
Specificity	0.800	0.616-0.975	0.998	0.996-0.999
F1 score[c]	–	–	0.927	0.883-0.971

[a]HD: highest density interval.

[b]HPD: highest posterior density interval. HPD interval gives narrower length than equal-tailed intervals for skewed density (computed using R package BOA [36]).

[c]Prior density of precision is not specified but implied as a function of other parameters.

Discussion

Principal Findings

While traditional survey data can take years to collect, social media data offer insights into health behavior and public sentiment around health-related topics in a much shorter time frame. They enable researchers to conduct qualitative studies previously only available via focus groups on a large scale. However, a large quantity of data does not assure valid and reliable results. In fact, biases may scale up with the quantity. For example, surveillance systems based on poor data may greatly overpredict or underpredict disease prevalence [37,38]. Without proper search filters, the quality of inferences from social media data will be at best poor, regardless of analytical techniques. Proper filtering and quality assessment are crucial for research with social media data.

Building a search filter is rarely a one-step process, but rather requires significant effort [22]. It is an iterative progression of refining search keywords and rules that capture relevant social data which satisfy pre-specified thresholds for precision and signal to noise ratio. We developed the e-cigarette search filter by monitoring frequency and precision for each keyword. The search filter was refined until no more important new terms were discovered. The keywords were combined with search rules to increase retrieval precision. Wang et al has proposed a method to automatically update the list of keywords by adding the top frequent terms that appear among relevant tweets [28]. We are working toward semi-automating our iterative process by incorporating their method.

We quantified search filter quality by computing retrieval precision and recall in four different cases. Retrieval precision was estimated above 95% in all cases. Retrieval recall was estimated at 86% assuming ideal conditions, 75% when unretrieved messages could not be archived, 86% assuming no false negative errors by coders, and 93% assuming that human coders make both false negative and false positive errors. Researchers should determine which condition is appropriate according to their expert knowledge and experience about the topics and search filters. Regardless of which approach is chosen, the rationale and approach should be clearly reported in any presentation of the data and analyses.

The e-cigarette search filter (see Multimedia Appendix 4) was developed in 2012. Since that time, e-cigarette popularity has increased significantly [39,40], many new brands and various types of vaping devices have entered the market, and e-cigarette-related language and slang terms have evolved. If we were to use the same search filter to study what people say about e-cigarettes on social media in 2015, the retrieval precision and recall would be poor. This underscores the importance of reporting the search filters used, along with their retrieval precision and recall at the time of data collection. When tracking trends of behaviors, attitudes, and beliefs over time, it is crucial to maintain an updated list of keywords/search filters for the given topic.

Filtering Using Machine Classifiers

Machine learning classifiers are often used for content analysis but also can be used to remove irrelevant messages from the data retrieved by search filters [9,22]. A well-developed classifier can reduce human labor. The accuracy of the classifier should be validated on a hold-out sample by computing precision and recall of the classifier. We refer the validation of classifiers to machine learning literature [31,41,42].

The retrieval precision may be approximated by the classifier precision, but the estimation of retrieval recall can be different from the classifier recall. Classifier recall measures the model's ability to correctly identify relevant content among the data retrieved by the search filters, whereas retrieval recall estimates how completely relevant content is captured by the search filters, relative to the universe of possible content (all Twitter messages in our example). The estimation of retrieval recall, therefore, is inherently theoretical because it is arduous and resource-intensive to sample unretrieved messages. In practice, its estimation involves examining unretrieved data from as many sources/repositories as possible. Our team collects and manages Twitter data in multiple archives to cover a broad range of topics related to tobacco products and associated behaviors; thus, we could sample from these other archives to see if they captured any content that is potentially relevant to e-cigarettes. Others may archive the Streaming API of Twitter or design another sampling strategy. The important point is to approximate as best as possible the universe in which relevant content may appear.

Future Research

In addition to data collection and quality assessment, it is important to report data sources, which can affect the validity of inference. Public data on Twitter can be accessed by Firehose, Search API, or Streaming API. The latter two have rate limits, which may prevent retrieval of full data depending on the volume of topics. A small random sample of full stream may contain abundant information about popular topics, for example, a movie star. Some topics may be so scarce in the Twitterverse that rate limit may not be an issue, but sudden spikes in tweet volume induced by, for example, policy change may not be captured due to rate limits. Further research is needed to investigate how the inference is affected by data sources and to provide guidelines. Regardless of data sources, in order to evaluate and compare results across studies, it is critical for researchers using social media data to clearly report how their data were collected and what assumptions were made about unretrieved data, and to provide estimates of the quality of their retrieved data. While strategies may vary by research topic and/or data availability, transparent and thorough reporting is crucial for the credibility of studies as well as the establishment of a rigorous standard for social media research.

Limitations

Our methods have certain limitations. We constructed an archive to store tweets potentially related to tobacco smoking. Such an archive is not a random sample of Twitterverse and thus induces selection bias; it may leave out a small fraction of relevant tweets ("e" in Figure 1). This selection bias affects the recall

estimate via P(retr) and P(relevant|unretr) in Equation (2). First, if the Twitterverse was used instead of the archive, P(retr) would be much smaller than 0.0208 due to a much larger denominator. This implies that the retrieval recall should be lower. On the other hand, the archive has a high chance of containing e-cigarette messages. That is, it is more likely to contain false negative contents than a random sample of the Twitterverse. Accordingly if the Twitterverse was used, P(relevant|unretr) should be lower and is likely to have many leading zeros. This implies that the retrieval recall should be higher. The two components affect recall estimate in opposite directions. Although the archive has selection bias, it helps find false negative contents and refine the search filter. In addition, the ratio of retrieved to unretrieved messages is relatively larger in the archive than in the Twitterverse. Validating the search filter quality when this ratio is about 1/800 or smaller requires coders to evaluate an impractically huge number of tweets for reliable recall estimation (see Case 2 in Multimedia Appendix 1).

Call for Rigorous Research

The number of studies that rely on social media data is increasing [43]. However, few have thoroughly described the search filter building process or fully assessed data quality. In order to assess data collection and quality, research involving social media data should clearly describe data sources, including how data were accessed and collected and how search filters were built, as well as presenting retrieval precision and recall. Data with low recall will poorly represent the target topic, and data with low precision will give misleading information. In light of moving toward a reporting standard, we propose a checklist (see Textbox 1) for reporting social media data preparation. Study findings should be replicable and comparable with clearly described data and methods.

Textbox 1. Checklist for social media data preparation and reporting.

1. Data source
- Social networking site and time frame
- How the data are accessed (eg, Streaming API)
- Why the data source is suitable for the research topics? Is there any limitation with the data source?

2. Development of search filter
- How candidate keywords are generated
- How keywords are refined
- Complete list of final keywords and search rules

3. Assessment of search filter
- Assumptions about human coding
- Sampling frame and sample size for human coding
- Whether all necessary data are available to assess the search filter
- Whether and how retrieval precision and recall are estimated

Conclusions

In this paper, we proposed a framework for social media data collection and validation and discussed how to quantify data quality under different conditions. Our proposed methodology is not limited to Twitter and can be adapted to other public social networking sites (as opposed to online forums or closed online networks). The length limit of posts, different data fields (title, description, tag, comment, etc), main user characteristics, data streaming, or crawling tools may be considered for modification. Our method is primarily useful for text-based social data, but it can be adapted to image-based social media. Instagram users, for instance, post photos with hashtags; we can retrieve potentially relevant contents based on hashtags [44] and remove irrelevant contents by using an image classifier. We hope our proposed framework and methods contribute to more rigorous and transparent health research using social media data.

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Authors' Contributions

All authors contributed to conceptualization, coding the data, and writing the text.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The sample size simulation for human coding.

[PDF File (Adobe PDF File), 324KB - jmir_v18i2e41_app1.pdf]

Multimedia Appendix 2

Precision and recall estimation using only retrieved data.

[PDF File (Adobe PDF File), 360KB - jmir_v18i2e41_app2.pdf]

Multimedia Appendix 3

Precision and recall estimation when human coding is not a standard classifier.

[PDF File (Adobe PDF File), 373KB - jmir_v18i2e41_app3.pdf]

Multimedia Appendix 4

E-cigarette search keywords and rules.

[PDF File (Adobe PDF File), 179KB - jmir_v18i2e41_app4.pdf]

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Abbreviations

API: application program interface
FDA: Food and Drug Administration
HD: highest density
HPD: highest posterior density
NIH: National Institutes of Health
NPV: negative predictive value

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Original Paper

Utilizing Remote Real-Time Videoconferencing to Expand Access to Cancer Genetic Services in Community Practices: A Multicenter Feasibility Study

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Abstract

Background: Videoconferencing has been used to expand medical services to low-access populations and could increase access to genetic services at community sites where in-person visits with genetic providers are not available.

Objective: To evaluate the feasibility of, patient feedback of, and cognitive and affective responses to remote two-way videoconferencing (RVC) telegenetic services at multiple sociodemographically diverse community practices without access to genetic providers.

Methods: Patients at 3 community sites in 2 US states outside the host center completed RVC pretest (visit 1, V1) and post-test (visit 2, V2) genetic counseling for cancer susceptibility. Surveys evaluated patient experiences, knowledge, satisfaction with telegenetic and cancer genetics services, anxiety, depression, and cancer worry.

Results: A total of 82 out of 100 (82.0%) approached patients consented to RVC services. A total of 61 out of 82 patients (74%) completed pretest counseling and 41 out of 61 (67%) proceeded with testing and post-test counseling. A total of 4 out of 41 (10%) mutation carriers were identified: *BRCA2*, *MSH2*, and *PMS2*. Patients reported many advantages (eg, lower travel burden and convenience) and few disadvantages to RVC telegenetic services. Most patients reported feeling comfortable with the video camera—post-V1: 52/57 (91%); post-V2: 39/41 (95%)—and that their privacy was respected—post-V1: 56/57 (98%); post-V2: 40/41 (98%); however, some reported concerns that RVC might increase the risk of a confidentiality breach of their health information—post-V1: 14/57 (25%); post-V2: 12/41 (29%). While the majority of patients reported having no trouble seeing or hearing the genetic counselor—post-V1: 47/57 (82%); post-V2: 39/41 (95%)—51 out of 98 (52%) patients reported technical

difficulties. Nonetheless, all patients reported being satisfied with genetic services. Compared to baseline, knowledge increased significantly after pretest counseling (+1.11 mean score, *P*=.005); satisfaction with telegenetic (+1.74 mean score, *P*=.02) and genetic services (+2.22 mean score, *P*=.001) increased after post-test counseling. General anxiety and depression decreased after pretest (-0.97 mean anxiety score, *P*=.003; -0.37 mean depression score, *P*=.046) and post-test counseling (-1.13 mean anxiety score, *P*=.003; -0.75 mean depression score, *P*=.01); state anxiety and cancer-specific worry did not significantly increase.

Conclusions: Remote videoconferencing telegenetic services are feasible, identify genetic carriers in community practices, and are associated with high patient satisfaction and favorable cognitive and affective outcomes, suggesting an innovative delivery model for further study to improve access to genetic providers and services. Potential barriers to dissemination include technology costs, unclear billing and reimbursement, and state requirements for provider licensure.

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KEYWORDS

health care delivery; dissemination and implementation; cancer genetics; genetic counseling; genetic testing; telemedicine

Introduction

BRCA1/2 testing for predisposition to breast and ovarian cancer is one application of personalized medicine that has become standard practice in cancer prevention [1]. Access to cancer risk assessment and testing when appropriate is now required for the National Accreditation Program for Breast Centers [2]. Cancer genetics services have traditionally included in-person pretest and post-test (ie, result disclosure) counseling with an experienced provider [3]. Given a limited workforce of genetic providers who are generally located in academic and urban centers, this in-person delivery model often requires patients to travel to a potentially distant and unfamiliar medical setting to receive cancer genetic testing with a genetic provider. Some patients proceed with testing without a genetic provider (ie, with their local physician) or they do not proceed with testing at all [3,4]. Thus, there remain significant access, time, and patient cost barriers to in-person genetic services that could contribute to disparities in both uptake and outcomes of genetic services [5,6]. Equally important, genetic testing without genetic providers (ie, with one's primary care physician or other nongenetics provider) has been associated with inappropriate testing and overtesting, which could increase health care costs [7,8]. Thus, as clinically relevant genetic applications increase, innovative delivery models to promote access to cancer genetics specialists are needed [9].

Remote two-way, real-time videoconferencing (RVC) has been increasingly utilized to provide educational, behavioral, and medical services [10,11]. In some areas (eg, education and supportive care, psychotherapy and psychiatric services, and remote monitoring or follow-up care in cardiac and respiratory diseases) there is strong evidence for benefits of remote care, such as RVC, as an alternative to in-person delivery [10,11]. In other areas, there is evidence that RVC is feasible and potentially valuable but further research is needed (eg, stroke rehabilitation, neurologic diseases, genetics, and diabetes care) [10,12-16]. Studies have demonstrated acceptability and feasibility of RVC for delivery of a wide range of medical services in underserved areas, including dermatology [17], stroke, pediatric subspecialties [18-20], obstetrics [21], endocrinology [22], psychiatry [23-27], and neurology [28,29]. Similarly, RVC has been utilized to provide genetic services (ie, telegenetics) to populations where geographic, socioeconomic, or provider factors have limited the use and dissemination of in-person genetic services [30-40]. Of these studies, many have demonstrated high patient satisfaction, but most have been relatively small and reported limited patient-reported outcomes [30,41]. None have been theoretically informed, and few have reported technology disruptions or challenges [40,42]. The largest study of RVC in cancer genetics compared patient experiences, including knowledge and distress, and reported no differences between in-person and RVC genetic services, although this was not a randomized study [12]. Additionally, the clinical geneticist was the provider utilizing RVC with a genetic counselor on site (ie, in-person) with the patient during the consultation. A recently published randomized trial of entirely RVC genetic services versus in-person services provided by a traveling genetic counselor in rural clinics reported no difference in patient satisfaction and lower costs with RVC, but poorer uptake in the RVC arm [40].

In this study, we sought to evaluate a resource-extending model by providing genetic services entirely remotely at community medical facilities with no options for in-person genetic services. In this model, the genetic provider is physically at the host center and services are provided entirely remotely in the patient's local medical facility. Additionally, we utilized communication protocols informed by stakeholders (eg, patient and provider feedback) and all providers were trained for videoconferencing communication. Our primary aim was to evaluate the feasibility of using RVC to provide pre- and post-test counseling by a host center genetic counselor and to evaluate this model at multiple community sites. Second, we sought to evaluate a wide range of patient-reported outcomes, including qualitative advantages, disadvantages, and experiences. We also sought to evaluate cognitive (eg, knowledge) and affective responses (eg, anxiety, depression, cancer worry, and satisfaction) to RVC telegenetic services in geographically and sociodemographically diverse community medical practices.

Methods

Participants

Participants were recruited at 3 community medical sites in New Jersey (NJ) and Delaware (DE), USA, all sites without a genetic provider on staff (see Table 1).

Table 1. Participant characteristics.

Characteristic	Approached (n=100)	Completed V1[a] (pretest counseling) (n=61)	Completed V2[b] (test disclosure) (n=41)
Age in years, mean (SD, range)	54 (14, 23-87)	54 (13, 26-85)	56 (13, 28-85)
Self-reported race/ethnicity, n (%)			
White	74 (74.0)	47 (77)[j]	33 (80)[j]
African American/black	12 (12.0)	8 (13)	4 (10)
Hispanic/Latino/other	14 (14.0)	6 (10)	4 (10)
Gender (female), n (%)	98 (98.0)	60 (98)	40 (98)
Community site, n (%)			
Kennedy Health System (NJ)	26 (26.0)	14 (23)	7 (17)
Community Medical Center (NJ)	47 (47.0)	29 (48)	17 (42)
Bayhealth Medical Center (DE)	27 (27.0)	18 (30)[j]	17 (42)[j]
Education [c], n (%)			
High school or less	18/81 (22)	15 (25)	11 (27)
Some college/associates	25/81 (31)	16 (26)	11 (27)
College graduate	29/81 (36)	24 (39)	16 (39)
Graduate or postgraduate	9/81 (11)	6 (10)	3 (7)
Marital status[d] (married[e]), n (%)	49/80 (61)	39 (64)	25 (61)
Personal history of cancer[c] (yes), n (%)	41/81 (51)	33 (54)[j]	28 (68)[j]
Known mutation in family[c] (yes), n (%)	7/81 (9)	5 (8)	3 (7)
Number of FDRs[f]/SDRs[g] with cancer, mean (SD)	N/A[h]	4.18 (2.74)	3.80 (2.62)
Genetic testing, n (%)			
BRCA1/2	N/A	N/A	38 (93)
Lynch syndrome	N/A	N/A	2 (5)
Both	N/A	N/A	1 (2)
Test result, n (%)			
Uninformative/negative	N/A	N/A	35 (85)
Positive	N/A	N/A	4 (10)
True negative	N/A	N/A	2 (5)
VUS[i]	N/A	N/A	0 (0)

[a]V1: visit 1.

[b]V2: visit 2.

[c]Of the total approached participants, 19 were without available information.

[d]Of the total approached participants, 20 were without available information.

[e]Includes domestic partnership.

[f]FDR: first-degree relative.

[g]SDR: second-degree relative.

[h]N/A: not applicable.

[i]VUS: variant of uncertain significance.

[j]$P<.05$.

Eligible participants were able to communicate in English, were over 20 years old, and were potential candidates for *BRCA1/2* or Lynch syndrome genetic testing as per National Comprehensive Cancer Network (NCCN) guidelines. Hearing-impaired patients were excluded from this study. The study was approved by the University of Pennsylvania (UPENN) Institutional Review Board (IRB); IRB authorization agreements were completed with each of the participating sites. Participants

provided informed consent for study participation and were recruited between April 2013 and June 2014.

Remote Videoconferencing Telegenetic Delivery Model

We adapted previously developed communication protocols for telephone delivery for the purpose of real-time, two-way RVC services [43,44]. Our initial RVC telegenetics protocol was piloted (April-August 2012) at the Fox Chase Cancer Center with a community practice in New Jersey. We utilized patient and provider feedback and review of videorecorded visits (n=10) to refine our protocol for this multicenter study.

RVC and technology support were provided through Mid-Atlantic Gigapop in Philadelphia for Internet 2 (MAGPI). The community sites' and the host's (University of Pennsylvania) central processing units were outfitted with high-definition Web cameras with built-in microphones and Cisco videoconferencing software applications. All connections were at 768 kbps with a minimum connection speed of 384 kbps. Connections between sites were made with a Codian bridge utilizing Advanced Encryption Standard approaches for security.

Patients completed RVC pretest counseling visits with a genetic counselor who was at the University of Pennsylvania. Community clinical staff were available on-site during RVC study visits to assist patients with technology challenges, address questions, and facilitate clinical genetic testing. Patients who proceeded with testing were scheduled for RVC post-test counseling with a genetic counselor. A total of 26 out of 41 patients (63%) met with a community site physician to discuss medical recommendations at the time of the post-test counseling session with the genetic counselor. Others had medical follow-up separate from their post-test counseling session.

Similar to our other studies evaluating adaptations to traditional face-to-face counseling [43,44], we developed standardized counseling topic checklists—15 pretest and 12 post-test counseling topics. Other key components of the RVC telegenetic protocol included visual aids, standardized provider probes to evaluate patient understanding and emotional responses, and situational probes to address technology disruptions and other challenges specific to RVC. All board-certified genetic counselors (n=4) were licensed in outside states according to state laws and completed RVC telegenetic communication training, including a mock visit with individualized feedback from a clinical health psychologist with expertise in health communication, also one of the study authors (LPM). Genetic counselors completed pre- and post-test counseling checklists and all RVC telegenetic visits were recorded to assess fidelity to the protocol.

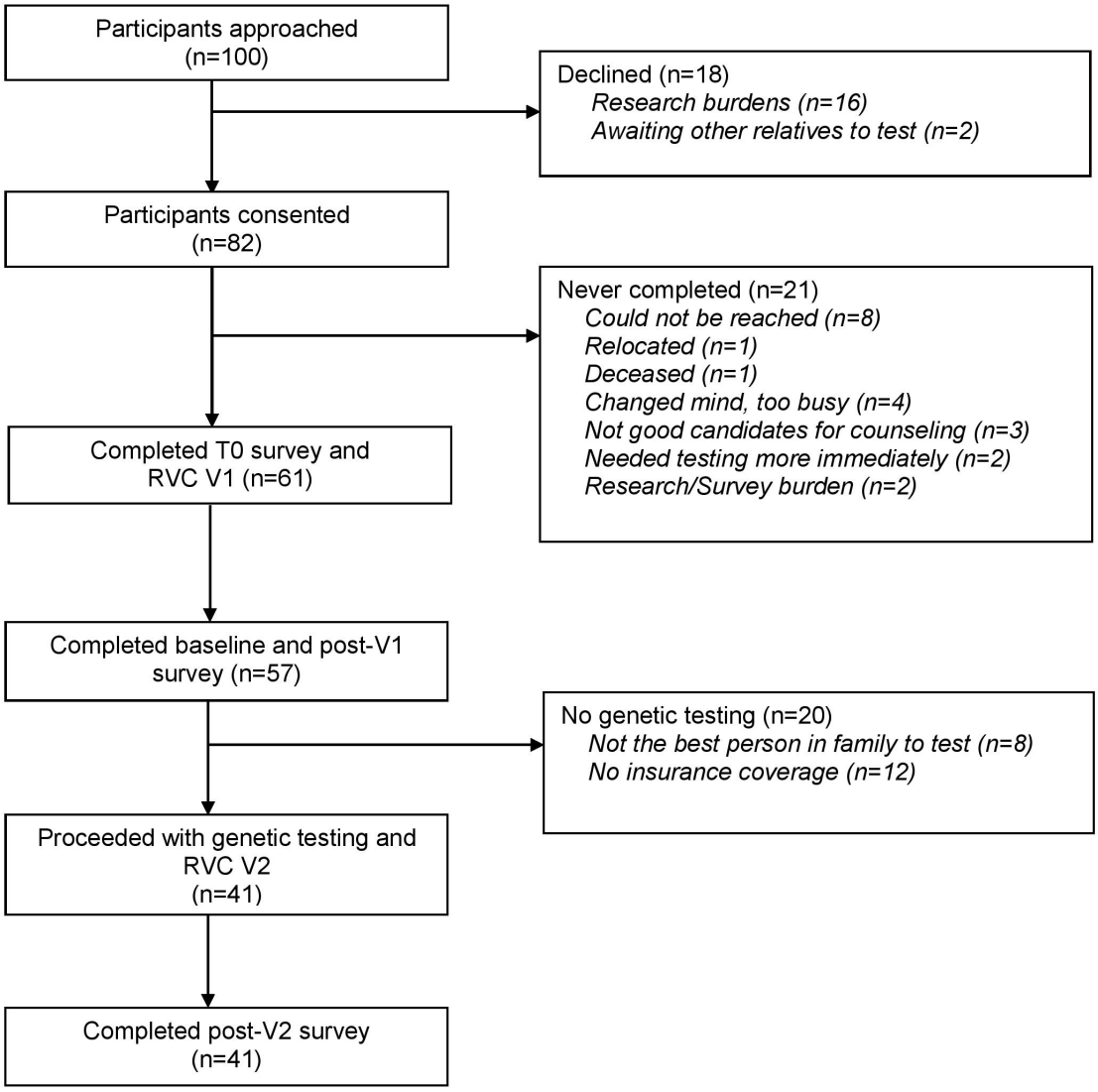
Counseling checklists revealed good fidelity to pretest (mean 83%) and post-test (mean 87%) counseling topics. A total of 20% of recorded visits were reviewed to ensure that provided completed counseling checklists reflected completion of the counseling topics. This audiotape fidelity review revealed very good consistency with provider-completed checklists (89%). Most discrepancies were clerical rather than counseling omissions.

Outcome Variables

Overview

As the successful translation of personalized medicine into improvements in population health requires understanding behavioral change at patient, provider, and organizational levels, we employed our overarching conceptual model integrating the Self-Regulation Theory of Health Behavior and the Diffusion of Innovation Theory. The Diffusion of Innovation Theory has been successfully applied in numerous studies of systems adoption and implementation of innovative information technology [45-48]. The Self-Regulation Theory of Health Behavior [49] has been utilized in descriptive and intervention-based research of individuals' responses to health threats, including genetic predisposition to disease. Our conceptualization of the Self-Regulation Theory of Health Behavior and the Diffusion of Innovation Theory informs the evaluation of the immediate (<72 hours) and delayed responses to our novel delivery model for genetic services [13]. Participants completed self-administered surveys online or by pen and paper at baseline (T0), and after pretest (T1) and post-test (T2) RVC telegenetic visits. Study data were collected and managed using Research Electronic Data Capture (REDCap) [50], a secure, Web-based application for data capture in research studies. All REDCap surveys were IRB approved, closed, and tested for usability, and they utilized adaptive questioning [51]. Completion rates are shown in Figure 1.

Figure 1. Study schema. RVC: remote videoconferencing; V1: visit 1, pretest counseling visit; V2: visit 2, test disclosure visit.



Opinions and Experiences With Real-Time Videoconferencing Telegenetics (T1, T2)

Open-ended items adapted from related research [43,44] were utilized to elicit patient experiences with, perceptions of, and suggestions for, improving RVC telegenetic visits.

Satisfaction With Genetic Services (T1, T2)

Satisfaction with genetic services (T1, T2) was measured with a 9-item scale evaluating satisfaction with health communication and utilized in related research [52,53] (Cronbach alpha=.80).

Satisfaction With Telemedicine Delivery (T1, T2)

Satisfaction with telemedicine delivery (T1, T2) was assessed with 13 items adapted for genetic counseling to evaluate patient-perceived provider comfort, patient satisfaction with privacy, and patient comfort with audio/visual technology [54] (Cronbach alpha=.76).

Knowledge of Genetic Disease (T0-T2)

Participants completed 6 selected items utilized in related research [43,44,55]. This scale included items evaluating cancer inheritance (one item), the meaning of positive results (2 items), and the meaning of negative results (3 items). Internal consistency in this study was good (Cronbach alpha=.62).

Psychosocial Adjustment (T0-T2)

Psychosocial adjustment was evaluated with the following three measures (T0-T2):

1. State anxiety was measured with the 20-item State Inventory of the State-Trait Anxiety Inventory (Cronbach alpha=.96) [56,57].

2. General anxiety and depression were assessed with the Hospital Anxiety and Depression Scale (HADS), anxiety and depression subscales (Cronbach alpha=.86 and .84, respectively) [58,59].

3. Cancer worry was evaluated with the Impact of Events Scale (Cronbach alpha=.89) [60,61].

Statistical Analyses

We used descriptive statistics to describe participant and nonparticipant characteristics. Our primary outcome was feasibility, defined as both adequate uptake (eg, patient

willingness) and successful completion of telegenetic visits. Adequate uptake was defined as at least 50% of patients agreeing to RVC telegenetic visits and at least 50% of those who proceeded with testing agreeing to receive their results by RVC. The decision rule was determined to provide sufficient power. With promising uptake and proceeding rates of 60% each, we would have 93% power to declare a future study feasible. With discouraging uptake and proceeding rates of 45%, we would have a 4.7% type I error rate of declaring a future study feasible. The power and type I error rates were calculated using exact binomial inference. We calculated means, standard deviations, and proportions for all constructs in the dataset and evaluated changes in theoretically informed secondary outcomes from baseline to after pretest counseling, and baseline to postdisclosure of test results. We used Fisher's exact tests, paired *t* tests, and simple linear regressions for hypothesis testing. *P* values of less than .05 based on two-sided hypothesis tests were considered statistically significant.

Framework analysis was utilized to analyze open-ended responses [62,63]. Two research staff members (DH and ES) independently reviewed responses, utilizing thematic analysis to record primary and secondary themes for each item. Disagreements in coding assignments were resolved by a third reviewer (AB).

Results

Participant Characteristics

Participant characteristics are described in Table 1. Participants at Bayhealth Medical Center (BMC) in Delaware and Kennedy Health System (KHS) in New Jersey were more likely to be nonwhite and less likely to have graduated college. Patients recruited at BMC were more likely to have had a personal history of cancer. A total of 82 out of 100 (82.0%) approached patients consented to the study (see Figure 1). None reported declining participation in the study due to discomfort with videoconferencing.

Uptake and Successful Completion of Telegenetic Services

A total of 61 out of 100 (61.0%) approached patients ultimately completed pretest counseling (see Figure 1). There were no differences between those who did and did not complete pretest counseling. A total of 41 of 61 (67%) patients who completed pretest counseling proceeded with genetic testing and received results by RVC. Participants who did not proceed with testing were either not the best candidate in the family for testing (ie, they were unaffected and another family member was the most informative and better candidate for genetic testing) and/or they did not meet payer criteria for insurance coverage for testing. Patients who proceeded with testing were more likely to have a history of cancer (see Table 1). A total of 4 unrelated patients out of 41 (10%) received a positive genetic test result—2 *BRCA2* carriers, 1 *MSH2* carrier, and 1 *PMS2* carrier.

Among 102 completed RVC visits—61 pretest and 41 post-test—only 4 (3.9%) were aborted due to technology failures (ie, lost connections that could not be resolved with multiple attempts). These were believed to be secondary to severe weather (1/102, 1.0%) or connectivity issues at one of the 2 participating sites (ie, the community site or host site). A total of 2 pretest visits were rescheduled for another day and 2 aborted post-test visits were completed by phone. A total of 31 out of 102 (30.4%) visits had disconnections but were resumed and completed during the scheduled appointment. Pretest and post-test visits lasted an average of 61 minutes (range 22-115) and 25 minutes (range 6-63), respectively.

Patient-Reported Advantages, Disadvantages, and Satisfaction With Real-Time Videoconferencing Telegenetic Services

As shown in Table 2, the most frequently reported advantages of RVC telegenetic services were reducing the burden of traveling (pretest 31/51, 61%; post-test 22/36, 61%), and the convenience and ease of local services during pretest (23/51, 45%) and post-test (8/36, 22%) visits. Other patient-reported advantages included informational value, efficiency, and the benefit of services in their local and familiar medical facility. The majority of participants reported no disadvantages (pretest 36/46, 78%; post-test 28/35, 80%) and had no recommendations for improvement (pretest 43/47, 91%; post-test 35/36, 97%). Some reported technical challenges and that visits felt less personal.

Table 2. Patient-reported advantages and disadvantages of remote telegenetic services.

Coded themes[a]	Representative quotes	After pretest counseling (V1[b]), n (%)	Post-disclosure (V2[c]), n (%)
What did you like about receiving your GC [d] by telemedicine? (V1 n=51; V2 n=36) [e]			
Reduced travel burden	"Telemedicine made it easier to consider genetic testing. I would not have made the effort to travel to another city for testing." "I could not have physically traveled to speak to a genetic counselor in person due to my present condition, so for me the telemedicine made genetic counseling possible."	31 (61)	22 (61)
Convenience/ease	"I was able to combine with my hospital visit." "It was easy, convenient, and stress free."	23 (45)	8 (22)
Informative	"The genetic counselor was very helpful, informative, and thorough."	7 (14)	5 (14)
Efficient	"I didn't have to wait like I would in a doctor's office."	4 (8)	5 (14)
Personalized	"I enjoyed the one-on-one session. It felt personal and all about me."	3 (6)	0 (0)
Good experience	"It was my first time utilizing telemedicine. It was a good experience."	2 (4)	4 (11)
Ability to receive services in local facility	"Being able to receive all information locally with my physician present was much better."	0 (0)	3 (8)
What did you dislike about receiving your genetic counseling by telemedicine? (V1 n=46; V2 n=32) [f]			
No dislikes		36 (78)	28 (88)
Technical difficulties	"It was a little hard to hear...my voice would echo so it made it a little difficult to answer the questions." "There was a tech glitch in the beginning but it was fixed. I was concerned that it wouldn't be resolved."	8 (17)	3 (9)
Less personal	"It was strange not being able to make actual eye contact." "It was uncomfortable and not personable."	2 (4)	2 (6)
Is there anything you would have changed about receiving your genetic counseling by telemedicine? (V1 n=47; V2 n=36) [g]			
No changes		43 (91)	35 (97)
Improve technology	"Better sound and eye contact from the counselor." "Better technology."	2 (4)	0 (0)
Improve visual illustrations	"Make sure the items on the slides are in view."	3 (6)	1 (3)

[a]Responses could be coded for multiple reasons. Themes reported <2 times are not shown.

[b]V1: visit 1.

[c]V2: visit 2.

[d]GC: genetic counseling.

[e]There were 6 and 5 nonrespondents post-V1 and post-V2, respectively (original V1 n=57; V2 n=41).

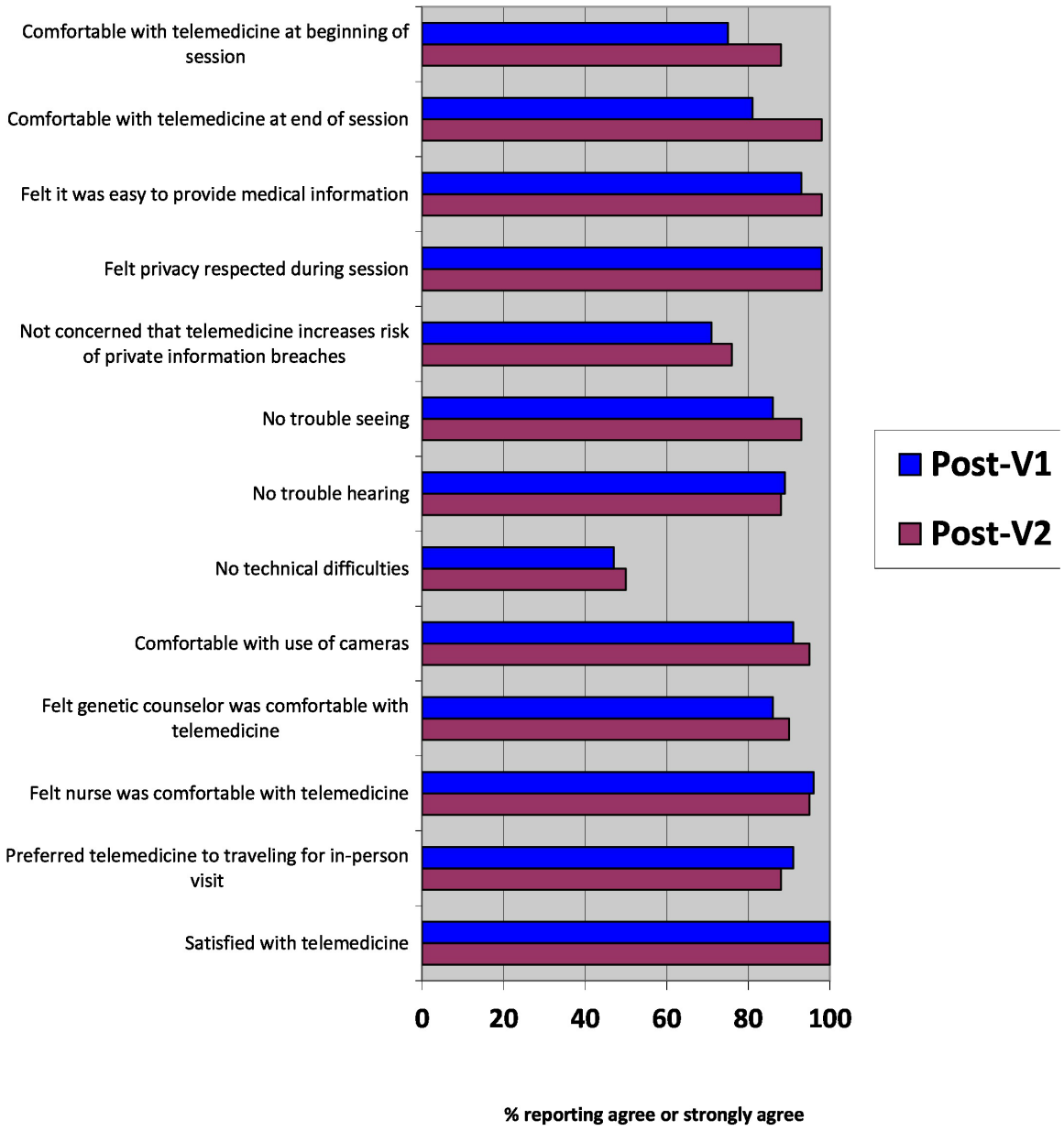
[f]There were 11 and 9 nonrespondents post-V1 and post-V2, respectively (original V1 n=57; V2 n=41).

[g]There were 10 and 5 nonrespondents post-V1 and post-V2, respectively (original V1 n=57; V2 n=41).

Patient-reported satisfaction with genetic services and telemedicine services was high, both overall and on specific items (see Figure 2 and Table 3). Most patients reported feeling comfortable with the video camera—post-V1: 52/57 (91%); post-V2: 39/41 (95%)—and that their privacy was respected—post-V1: 56/57 (98%); post-V2: 40/41 (98%)—although some reported concerns that RVC might increase the risk of breach of confidentiality of their health information—post-V1: 14/57 (25%); post-V2: 12/41 (29%). While the majority of patients reported having no trouble seeing

or hearing the genetic counselor—post-V1: 47/57 (82%); post-V2: 39/41 (95%)—51 out of 98 (52%) patients reported technical difficulties. Nonetheless, all patients reported being satisfied with genetic services (see Figure 2).

Figure 2. Satisfaction with telemedicine services. V1: visit 1; V2: visit 2.



Cognitive and Affective Outcomes With Telegenetic Services

Among those who completed pretest visits, knowledge increased and general anxiety and depression declined significantly after pretest counseling (see Table 3). State anxiety and cancer worry did not change significantly after pretest visits. Among those who proceeded with genetic testing, satisfaction with genetic services and telemedicine increased significantly after post-test counseling, and depression and anxiety decreased significantly.

Table 3. Change in cognitive and affective outcomes with telemedicine delivery of genetic services.[a]

Outcome	Baseline (n=61), mean (SD)	Completed V1[b] (n=57), mean (SD)	Completed V2[c] (n=41), mean (SD)	*P*
General anxiety (range 0-21)				
Completed V1	7.34 (4.00)	6.37 (3.99)	N/A[d]	.003
Completed V1 and V2	6.67 (3.82)	5.59 (3.77)	5.54 (3.50)	.003
General depression (range 0-21)				
Completed V1	3.70 (3.77)	3.33 (3.26)	N/A	.046
Completed V1 and V2	3.33 (3.43)	3.18 (3.22)	2.58 (3.23)	.01
Cancer worry (range 0-70)				
Completed V1	17.93 (13.06)	16.63 (13.21)	N/A	.36
Completed V1 and V2	17.10 (13.29)	14.76 (12.06)	16.88 (13.71)	.25
State anxiety (range 20-80)				
Completed V1	37.49 (13.82)	36.49 (12.71)	N/A	.32
Completed V1 and V2	35.32 (12.97)	34.42 (12.26)	33.29 (11.10)	.27
Knowledge (range 6-28)				
Completed V1	20.96 (2.74)	22.07 (2.99)	N/A	.005
Completed V1 and V2	21.10 (3.16)	22.14 (3.16)	21.61 (3.16)	.08
Satisfaction with genetic services (range 9-45)				
Completed V1 and V2	N/A	40.36 (3.92)	42.58 (3.25)	.001
Satisfaction with telemedicine (range 13-65)				
Completed V1 and V2	N/A	52.25 (5.26)	53.99 (4.96)	.02

[a]Paired *t* tests were performed for changes between two time points; linear regression was estimated by generalized estimating equations to compare time trends for three time points. Time was entered via the use of dummy indicators for each time point in the regressions.

[b]V1: visit 1, pretest counseling.

[c]V2: visit 2, test disclosure.

[d]N/A: not applicable.

We also conducted exploratory stepwise regression analyses to evaluate potential patient factors associated with less favorable select outcomes (eg, less gain in knowledge or greater increase in distress). Older age was significantly associated with lower general anxiety (*P*=.01) at baseline. Being white was associated with greater increases in state anxiety (*P*=.02) after pretest counseling. Being nonwhite was associated with greater increases in state anxiety (*P*=.02) and less satisfaction with genetic services (*P*=.01) after receipt of results. Having a graduate education was associated with greater increases in general anxiety (*P*=.001) after pretest counseling and lower satisfaction with genetic services (*P*=.02). Having more relatives with cancer was associated with lower satisfaction with telemedicine services (*P*=.02), but larger increases in knowledge among those who proceeded with testing (*P*=.001).

Discussion

Principal Findings

In this study, we evaluated a resource-extending model by providing genetic services entirely remotely at 3 community medical facilities with no options for in-person genetic services; we found that real-time videoconferencing telegenetic services are feasible, identify genetic carriers in community practices, and are associated with high patient satisfaction and favorable cognitive and affective outcomes. Various videoconferencing extension models have been used to provide telegenetic services. In our study, the genetic provider is physically at the host center. Services are provided entirely remotely in the patient's local medical facility. Although this is a feasibility study without a comparison arm, to our knowledge it is the largest multicenter study—including 3 community sites in 2 US states outside the host site state—to evaluate the feasibility of offering an entirely remote cancer genetics service by RVC at sites where in-person services are not an option. While the only randomized study of RVC versus in-person genetic services suggests lower uptake of counseling and preferences for in-person services among 32% of participants receiving RVC, traveling of providers to remote sites is more costly and is not feasible in most areas [40]. With increasing attention to medical practice plans and metrics, traveling genetic counselors are diminishing in use, leaving many remote sites entirely without access to genetic providers.

Thus, providing specialized services entirely remotely, either by RVC or phone, has the potential to further extend the reach of genetic services. This model also includes collaborative local physician care, which maintains local provider-patient relationships while facilitating cancer susceptibility testing with genetic provider expertise.

Advantages of Real-Time Videoconferencing Telegenetic Services

Consistent with other studies, this delivery model provides several potential advantages to various stakeholders [17,21,32]. Patients with local providers reported less travel time, fewer travel burdens, and increased informational value by remaining in their local settings. Local providers and practices have access to genetic specialists, while maintaining their local patient-provider relationship. Additionally, studies have suggested that nongenetic physicians are more likely to order unnecessary tests, potentially escalating health care costs [7,8]. In our study, some referred patients were not the best candidate in the family for testing and, thus, testing was not recommended. Thus, RVC telegenetic services might reduce unnecessary testing, providing advantages for payers and the health care system. Equally important, pretest counseling with genetic specialists is one way to facilitate informed decision making for genetic testing, which is becoming increasingly important given the increasing range of testing options (ie, targeted vs multiplex) with variable utility and risk for uncertainty [64]. Providing remote access to the limited workforce of genetic specialists is one way to limit the potential risks of genetic testing as we transition from targeted to broader genetic testing.

Although RVC is technically feasible, technical disruptions or challenges were reported by patients in 52% (51/98) of RVC visits and some patients reported concerns about privacy. Nonetheless, patients were highly satisfied with RVC for cancer genetics services. Many patients indicated that they would not have otherwise received genetic counseling or testing were it not for remote delivery. There were increases in patient knowledge, decreases in depression and anxiety, and no increase in state anxiety or cancer worry. Although this feasibility study did not include a comparison arm, these findings are consistent with published outcomes of telephone and in-person genetic counseling and testing [65,66]. Furthermore, all participants received specialized cancer risk assessment, and 4 families with a genetic predisposition to cancer were identified. While there were technology challenges and disconnections, failure rates were low (and may not be worse than reschedule rates in traditional face-to-face clinic settings). Further, despite technology challenges, patients reported high satisfaction with telegenetic communication and services. Thus, RVC telegenetics provides a feasible alternative model to extend genetic services and identify patients at genetic risk for cancer in communities without local access to genetic services.

To date, there are few studies evaluating RVC for remote clinical delivery of specifically genetic services. There has been only one randomized study that compared RVC to in-person services provided by a traveling genetic counselor. This study reported significant cost savings with RVC. This is consistent with the experience in cancer genetics, as cancer genetics programs have significantly reduced the provision of genetic counselors to satellites given costs. Therefore, while some studies have utilized in-person services as the nonrandomized comparison arm, we propose that the appropriate comparison is usual care, which in these communities typically means patients travel to a regional expertise center or receive testing through their local physician without genetic providers. An example of this design is the randomized study by Myers et al where remote RVC delivery of attention deficit hyperactivity disorder (ADHD) therapy provided by ADHD specialists was compared to ADHD care provided by their primary care providers with a single supplementary RVC specialist visit [16]. Given the limited genetic provider workforce and costs, in-person visits with a genetic provider are not likely to be available in these communities and therefore comparison to in-person visits is not a clinically meaningful, feasible, or real-world comparison. Telephone delivery is a potential alternative delivery model in these settings [43,44,65,66]. In contrast to telephone delivery, RVC has the advantage of maintaining visual communication cues and “face-to-face” communication. To our knowledge, there are no published studies comparing telephone to RVC telegenetic services, but such studies would be valuable to identify the optimal resource-extending model for populations without access to genetic providers. Additionally, given a limited genetic provider workforce, additional models (eg, triaging patients and/or utilizing alternative providers) may be beneficial, but would benefit from evaluation of cognitive, affective, behavioral, and medical outcomes.

Limitations

We acknowledge several limitations to this study. These centers and patients may be early adopters and larger studies are needed. The number of participants remains relatively small and differences by patient factors (eg, race/ethnicity and education) need to be confirmed in larger studies. Our providers utilized stakeholder-informed communication protocols with training for videoconferencing communication. Outcomes could differ without these features. There was no comparison arm and we cannot comment on the value of RVC telegenetics compared to usual care or telephone delivery, and provider experiences were not assessed. While risk reduction and prevention recommendations presented by the genetic counselor in RVC post-test counseling were reviewed with a physician with expertise in cancer genetics and cancer prevention, in this collaborative telegenetics model post-test medical follow-up occurred with local providers. The uptake of important risk reduction and prevention behaviors (eg, prophylactic oophorectomy and breast magnetic resonance imaging [MRI]) in this delivery model is not yet known. Importantly, there remain many practical challenges to implementing RVC services both in and beyond telegenetics. While many third-party payers do pay for telemedicine services, it can vary by payer and state and has not been tested for genetic counseling [67-69]. Nonetheless, barriers to billing for telegenetic visits may be secondary to the challenges of billing for genetic counseling in general, rather than billing for telehealth; further data regarding payer willingness to pay and reimbursement will be useful. While technology costs are dropping quickly, there are technology costs that could impact the cost and benefit

comparison to other remote delivery models (eg, telephone). We utilized a high-quality platform with real-time technical support. Patient and provider experiences could be different with different technology platforms or if extended to the home [39,70]. Lastly, using videoconferencing services and other electronic means of communicating with patients residing in other states may qualify as the practice of medicine in that state, particularly if care has not already been established with a face-to-face visit (ie, providing a new service versus follow-up care). Thus, providers may need to obtain licensure in the state where the patient is located [67]. Additionally, if RVC telegenetic services (ie, phone or videoconferencing) are being provided to inpatients in another state, there may be hospital-credentialing requirements. The legal landscape and the requirements are variable depending on the type of service provided and continue to evolve as new technology evolves. Therefore, until remote services become standard or unified regulations are in place, legal review and oversight is encouraged to ensure compliance with state medical practice laws.

Conclusions

With expanding testing options in inherited cancer genetics, there is an increasing need to provide access to genetic providers and pretest counseling. Remote real-time videoconferencing is feasible, identifies genetic carriers in community practices, and is associated with high patient satisfaction and favorable cognitive and affective outcomes. Remote videoconferencing provides an innovative delivery model for further study in community practices that lack access to genetic providers, providing the potential to help realize the benefits of genetic medicine across sociodemographically diverse populations.

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Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention deficit hyperactivity disorder
BMC: Bayhealth Medical Center
DE: Delaware
FDR: first-degree relative
GC: genetic counseling
HADS: Hospital Anxiety and Depression Scale
IRB: Institutional Review Board
KHS: Kennedy Health System
MAGPI: Mid-Atlantic Gigapop in Philadelphia for Internet 2
MRI: magnetic resonance imaging
N/A: not applicable
NCCN: National Comprehensive Cancer Network
NJ: New Jersey
RVC: remote videoconferencing
SDR: second-degree relative
T0: baseline
T1: pretest
T2: post-test
UPENN: University of Pennsylvania

V1: visit 1
V2: visit 2
VUS: variant of uncertain significance

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Original Paper

Positive Clinical Outcomes Are Synergistic With Positive Educational Outcomes When Using Telehealth Consulting in General Practice: A Mixed-Methods Study

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Abstract

Background: The use of telehealth technology to enable real-time consultations between patients and specialist services (to whom travel may be an impediment to the patient's care) has recently been encouraged in Australia through financial incentives. However, the uptake has been both fragmented and inconsistent. The potential benefits for patients include access to a broader range of specialist referral services, cost and time saving, and more rapid access to specialist services and a continuum of care through the triangulation of interaction between patient, primary health care providers (general practitioners and nurses), and specialists. Enhanced broadband connectivity and higher-grade encryption present an opportunity to trial the use of telehealth consulting as an intrinsic element of medical education for both medical students and doctors-in-training within rural practices and Aboriginal Medical Services.

Objective: This paper discusses the reported, and varied, benefits of telehealth consulting arising from a multisite trial in New South Wales, Australia. The purpose of this study is to encourage the use of selected telehealth consultations between patients in a primary care setting with a specialist service as an integral aspect of medical education.

Methods: The trial closely followed the protocol developed for this complex and multiaspect intervention. This paper discuses one aspect of the research protocol—using telehealth consultations for medical education—in detail.

Results: Qualitative and quantitative analyses were conducted. In the quantitative analysis, free-text comments were made on aspects of Telehealth Consulting for the patient, concerning the quality of the interactions, and the time and cost saving, and also on the leaning opportunities. Students commented that their involvement enhanced their learning. All respondents agreed or strongly agreed that that the interpersonal aspects were satisfactory, with some brief comments supporting their views. In the analysis of the qualitative data, five themes emerged from the analyses concerning the educational benefits of Telehealth Consulting for different levels of learners, while three themes were identified concerning clinical benefits.

Conclusions: The results demonstrated strong synergies between the learning derived from the telehealth consulting and the clinical benefits to the patient and clinicians involved.

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KEYWORDS

telehealth; medical education; patient benefits

Introduction

The use of telehealth technology to enable direct, real-time consultations between patients and specialist services located at a distance from each other has recently been encouraged in Australia through financial incentives [1]. Although the uptake has been fragmented and inconsistent [2,3], potential benefits for patients are in a range of enhancements across the continuum of their care. These include improved access to a broader range of specialist services, cost and time saving, more rapid access to specialist services, and a better continuum of care through the triangulation of interaction between patient, primary health care providers (general practitioners [GPs] and nurses), and specialists, who may be based distally from the patient, often in metropolitan areas [4]. A recent Australian study demonstrated that telehealth consulting reduced patients' traveling time by a mean of 50 minutes (from median 80 mins to 30 mins) [5]. However, travel times for those living in rural or remote Australia may be considerably greater than this.

The practice of telehealth consultations, supported by health care staff (doctors, nurses, and allied health workers) in general practice, has been incentivized in the last 4 years in Australia, which has led to an increase in usage rates [1]. However, the rate of uptake has been fragmented for multiple reasons with the current rate being only 0.24% of all consultations conducted via telehealth consultations [1]. Medicare rebate records indicate there are 6000 specialist telehealth consultations per month in Australia [1] .The incentives were provided for telehealth consultations between patients and specialists through GPs, nurses, Aboriginal health workers, and aged care facilities, and they were limited to nonmetropolitan areas (with exceptions for Aboriginal Health Services and aged care facilities).

Technological advances, resulting in enhanced broadband connectivity and higher-grade encryption, presented the opportunity to trial the use of telehealth consulting from general practices to remote or distant specialist services as an intrinsic element of medical education. This was for medical students on longitudinal rural placements, doctors-in-training primarily in rural practices, and places where supportive Medicare payments were available for Aboriginal Medical Services. There is a paucity of data describing potential educational benefits of telehealth consulting for those working within or on placement in primary care.

Because telehealth consulting is a dynamic and developing aspect of patient care, it is imperative that potential users are aware of current and evolving technological developments to potentially incorporate them into regular practice. This is particularly relevant to new applications, which may benefit patient care, specialist accessibility, and medical education where service provision may be difficult to access.

This paper discusses the reported benefits, both educational and to patient, of telehealth consulting from a multisite trail in New South Wales, Australia. This trial was funded through the Federal Department of Education and Training's Broadband Enabled Education Skills and Services Programme, which ran from 2013 until December 2014. The project was led by the University of Wollongong team working in a collaboration with several other medical schools (University of New England, University of Newcastle, Deakin University, and University of Notre Dame, Sydney) and 2 vocational training organizations (Coast City Country General Practice Training and GP Synergy).

The trial closely followed the protocol developed for this complex and multiaspect intervention [6]. This paper discusses the results, in terms of reported benefits, that have been derived from real-life patient telehealth consultations. It is limited to this aspect of the research.

It is important to define telehealth consultations in this context because this term has evolved from the earlier term "telemedicine" [7]. The International Organization of Standardization defines *telehealth* as "the use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over a distance," which encapsulates the objectives of this study [3].

In the health professions, learning by use of telehealth consultations, although an emerging issue, has had limited research. A systematic review revealed that there were few randomized controlled trials comparing traditional face-to-face learning with telehealth learning [8]. However, the authors of the systematic review concluded that the use of telelearning does enable equivalent opportunities for learning compared to face-to-face within medical education, particularly for rurally based services. There are advantages for rural doctors in using telehealth, through both reduction in isolation and enabling peer communications [9]. This can facilitate retention of rural doctors by reducing their perceptions of isolation from peers and face-to-face learning opportunities [4]. In spite of these advantages, a study from the United Kingdom reported concerns about the introduction of new technology, how patients would cope with using it, and of perceived changed standards of care associated with the use of e-technology [10].

Can Telehealth Consultations Contribute to Medical Learning?

Based on adult learning theory, the University of Wollongong has a longitudinal integrated placement or clerkship for all their postgraduate medical students after 2.5 years of their 4-year degree course. The rural integrated clerkships are based on a model pioneered and extensively evaluated in Australia by Flinders University [11]. The evaluations have demonstrated that long-term integrated clerkships excel in exposure to patient experiences and interdisciplinary working (ie, experiential learning through learners working alongside and with colleagues across a range of health care disciplines), but may lack exposure to specialists [11]. The majority of University of Wollongong students are placed in rural areas and their involvement within this unfamiliar community where their 38-week placement occurs is encouraged both professionally and socially. The students spend 2 days working in general practices, primarily consulting with patients in parallel with and under the guidance of their supervising doctors [12]. Students have access to undifferentiated patients and learn through the skills, expertise, and teaching of their GP preceptors, and from the patients themselves [12]. Additionally, the students spend time in hospitals and with community-based services within the area of their placement.

The purpose of this study was to encourage the use of selected telehealth consultations between patients in a primary care setting with a specialist service for medical education and to evaluate the clinical and educational outcomes of this experiential learning by a medical student or doctor-in-training involved in the live telehealth consultation.

Ethics Approval

Ethics approval for the research was obtained through the University of Wollongong's Human Research Ethics Committee (reference HE13/238).

Methods

The study commenced in late 2013 and concluded in December 2014. A total of 10 medical practices were recruited across 2 study groups based at the University of Wollongong and the University of New England in Armidale. Nine were from rural areas and the other was an urban-based Aboriginal medical center's 2 practices. A series of telehealth consultations, from general practices to a distant medical specialist, were evaluated. For these, the patient and specialist consented to the student or doctor-in-training's involvement and participation in the consultation.

Practice staff and clinicians from practices, which had little or no previous experience with telehealth consultations, completed a skills training module on implementing telehealth consultations in early 2014. Additionally, all University of Wollongong students completed a similar training module before starting their integrated placements. The training included 2 cohorts of students. The first completed the module in May 2013 (n=74) and the second cohort in July 2014 (n=76).

Two methods of data collection were employed. Quantitative data (the first data collection method) were derived from written evaluations of telehealth consultations. The written evaluations contained 5 questions, with a Likert scale answer, and also invited open comments. There were questions on the educational and clinical benefits, the technical quality, and the interpersonal aspects of the consultation. These, along with the appropriate consent forms, were returned to the research team and analyzed at the conclusion of the trial.

The second data collection method included qualitative data, which were obtained from semistructured interviews conducted with GPs, practice managers, nurses, patients, and learners (students or doctors-in-training) associated with each of the participating practices. The interviews were conducted at the 10 participating medical practices by different members of the research team. Interviews were conducted at baseline, when the practice joined the research, during the trial, and at the end of the trial. Student interviews were conducted for the first cohort of students at the end of their placement and for the second cohort at the start of their placement and at the end of 2014. The interviews from each practice were grouped to form a multisite case study. Five practices were selected for analysis of this aspect of the study, aiming for a range of practice locations and distances from the major metropolitan center of Sydney. Characteristics of these practices are described in Table 1 and a description of the structure of Rural, Remote and Metropolitan Areas (RRMA) classification are presented in Table 2.

Table 1. Characteristics of the 5 case study sites.

Site	Rural area	Distance from Sydney (km)	Total interviews, n	Interviewees
Site 1	RA2	617	14	GPs, practice manager, nurse manager, mental health nurses, practice nurses, students
Site 2	RA2	112	7	GPs, practice manager, Prevocational General Practice Placement Program (PGPPP), students
Site 3	M2; Aboriginal Medical Services, Urban	88	7	GPs, practice manager, practice nurses student
Site 4	RA2	219	6	GPs, practice manager, students
Site 9	RA2	476	7	GPs, practice manager, PGPPP

Table 2. Structure of the Rural, Remote and Metropolitan Areas (RRMA) classification.

Zone	Category
Metropolitan zone	
M1	Capital cities
M2	Other metropolitan centers (urban center population >100,000)
Rural zone	
R1	Large rural centers (urban center population 25,000-99,999)
R2	Small rural centers (urban center population 10,000-24,999)
R3	Other rural areas (urban center population <10,000)
Remote zone	
Rem1	Remote centers (urban center population >4999)
Rem2	Other remote areas (urban center population <5000)

Within the participating practices, telehealth consultations were selected by the GP preceptor to be suitable as potential learning experiences.

The interviews were conducted by 4 experienced members of the research team (PKB, GT, DL, and JB). Participant selection was purposeful, selecting those within the practice who were involved in the project's implementation. A total of 81interviews were conducted, face-to-face, in the participating practices. There were no refusals to participate. Because the participants were interviewed at the beginning, during, and after the trial period, reference was made to individual perspectives to establish if changes had occurred.

All interviews were recorded and transcribed verbatim by an independent transcriber and checked for accuracy by a member of the research team. After a review of all data collected, the analytical approach was based on case studies, which consisted of all the interview data from a particular participating practice analyzed as a case study site.

At the completion of analysis of all interviews from the 5 selected practices, it was considered that data saturation had been met and no "new" or novel themes were emerging from the data. Three coders worked independently on the data, with at least 2 researchers independently coding each case study (ie, all interviews associated with one particular general practice). Based on the grounded theory approach, emergent themes were tabulated by the 3 researchers and discussed to confirm concurrence of perception [13].These emergent themes were then confirmed by other members of the research team. The rigor was compared with the standards expressed as consolidated reporting criteria qualitative research [13], which covers the range of criteria, including study context, findings, methods, and research team.

This dual evaluation process, using qualitative and quantitative methodologies, enabled a mixed-methods presentation of the findings.

Results

Quantitative

The quantitative analysis questions and responses are presented in Table 3. There was additional space for comments.

Table 3. Quantitative evaluation results of telehealth consultations from participating medical practices (total evaluations completed: n=38).

Question: Thinking about the telehealth consultation in which you were just involved, to what extent do you agree with the following statements?	Response, n (%)				
	Strongly disagree	Disagree	Neither	Agree	Strongly agree
I think the technological aspects of the telehealth consultation (image, sound quality, or reliability) were satisfactory for its purpose.			2 (5)	17 (45)	19 (50)
I think the clinical aspects of the telehealth consultation (history taking, examination, or discussion of management plan by video consultation) were satisfactory for its purpose.		2 (5)	1 (3)	23 (60)	12 (32)
I think the interpersonal aspects of the telehealth consultation (interaction between doctors and patient via video consultation) were satisfactory for its purpose.				23 (60)	15 (40)
I think the telehealth consultation was valuable as a student/registrar learning experience.		1 (3)	2 (5)	21 (55)	14 (37)

There were free-text comments made on aspects of telehealth consulting for the patient, concerning the quality of the

interactions, the time and cost savings, and also on the leaning opportunities. Students commented that their involvement enhanced their learning.

One GP commented, on his first involvement in telehealth consulting:

> *Excellent. Screen "melted away" [and was] no barrier* [GP, site 2]

The technical aspects were rated as "neither satisfactory or not satisfactory" (ie, neutral) by one student due to poor picture quality and one GP due to sound quality issues, which also impacted patients with hearing difficulties. For the 3 responses that were either neutral or not satisfactory, 2 were related to the same consultation and the student and GP both felt the examination was difficult; however the student described it as "good rapport, in a short consultation, and to be an effective use of time" and a similar comment was made by the other student whose experience was neutral.

All respondents agreed or strongly agreed that that the interpersonal aspects were satisfactory, with some brief comments supporting their views.

Three evaluations, all by students, rated their experiences in terms of learning as either "not valuable" (n=1) or "neither valuable nor not valuable" (n=2). Their comments demonstrated that the consistent issue with the 3 consultations that were considered less valuable was the shortness of the consultation.

Qualitative

In the analysis of the qualitative data, 5 themes emerged from the analyses concerning the educational benefits of telehealth consulting for different levels of learners:

1. Investment and support
2. Patients as educators
3. Evolving real patient learning
4. Mental health learning
5. Job readiness

Three themes were identified concerning clinical benefits:

1. Continuity of care
2. Timeliness
3. Normalization

Administrative Investment Within the Practices and Practice-Wide Support Enhances Educational Outcomes

Having a designated telehealth "organizer" was seen as a worthwhile investment in practices. An administrator with responsibility and appropriate support to organize telehealth consultations was frequently seen as the foundation for efficient implementation of telehealth consults and the effective use of telehealth consulting as an educational tool:

> *I have a referral, go and ask the telehealth person, give it to them they'll sort it all out, and that has actually been great but there are just lots of little steps in that in terms of knowing who to book, how to book, how to set it all up, how to set up the tech on both sides and then set up the bookings...particularly in terms of this trial to make it a teaching experience.* [GP, site 2]

The support resulted in mutually beneficial outcomes with unanticipated benefits from the practice staff and students working together:

> *When it comes to the appropriateness of having students in with the telehealth consultation we find that it's well received on a couple of levels, one because we can provide the students with an opportunity to listen and take in the information and absorb. Two, they are there to support the clinicians and nurses in the treatment of the patient and the patients seem to enjoy it because it involves them more...it creates that relationship that's required to really get patients to open up.* [practice manager, site 1]

Practice-wide support was viewed as a facilitator for clinical and educational benefits, with principals referring to members of staff and their roles, and to "we" being interested in setting it up, with the decision being supported by all those working in the practice

> *The nurses are very good at supporting telehealth consults now, realistically the nurses…are doing a lot of the tech support for the telehealth and they have been the ones who have been setting up the telehealth consults with the specialist and a little bit the health worker have been supporting but it's basically been [practice manager] and [practice nurse] who have been doing the set up for the telehealth consults with the specialists for the patients.* [GP Site 1]

> *I guess we were interested in the perspective of setting it up for ourselves clinically but also that we have the Phase 3 students and using it for both students and registrars as a way of teaching.* [GP, site 3]

The Patient's Role in Medical Education and the Educational Opportunities for Family and Others

Through a wide range of cases, including psychiatry, rheumatology, and pediatrics, the patients enjoyed having what they perceived to be a valuable role in the medical education of the student and other learners:

> *The patient was very happy for everybody to be involved and in fact he was quite open and seemed to almost enjoy having this to be part of a teaching experience.* [GP site 2]

> *The direct observation of consultations, we find patients really enjoy that; having the students and knowing they are being part of educating the future generation of health professionals.* [practice manager, site 1]

Evolving a New Form of Parallel Consulting Through Engagement of a Specialist in Patient and Learner Education

The participants in telehealth consulting were varied. The majority of the consultations, which all were between the patient and a distal specialist, were with the GP and student or

doctor-in-training, and sometimes with the practice nurse with the learner. Although the learning opportunity was primarily for the medical student, the GPs also reported other benefits for those who became involved in the consultation, through being able to be a part of a parallel consulting experience involving the GP and patient, the specialist and patient, and the GP and specialist:

> *Having that access to a consultant is great...Often you might have seen that same patient with the GP. So to see the difference in how they approach the same condition from the GP to the consultant, that was nice to see as well.*" [student 2, site 1]

One GP saw a possible dual role for the doctor-in-training involving a different aspect of parallel consulting with the specialist, a role that the student might not have been suited to:

> *When the student is there they really are obviously there for a teaching experience and the experience they've had with patients so far they're very happy with that. From a practical point of view the registrar can actually add some clinical value just in terms of their seniority of experience...because the registrar had actually done it, they were able to finish the consultation, organize the script, book the next appointment in and do a hand over to me and bill to Medicare, whereas a student obviously couldn't have done any of those things without me being there so that's probably a practical role.* [GP, site 2]

Doubts concerning telehealth consultations were alleviated for some with the development of new forms of learner participation resulting:

> *I was just surprised with how well it flowed and the Internet line was great, it was very easy to communicate, there were no interruptions into the Skype. I think as well I was surprised how well the patient was able to interact with the clinician...it ran exactly how we had prepped for them in the phase 3 intro. [Clinical skills training at University of Wollongong] So he introduced himself and then got the patient to introduce himself and said, look, who else in the room? So I introduced myself and the clinician actually involved me throughout...The rapport throughout the consult was very, very good.* [student, site 1]

New forms of learner participation extended to the GPs' involvement in the telehealth consultations as well:

> *Well I think it offers a few things. We almost never get the opportunity to sit in when your patient goes to see the specialist so it's a unique situation of being able to do that. One of, I think, our greatest educational tools as a GP and particularly in the past, was specialist letters but better still, to actually be there and be able to say "No I don't...so what's that bit" and those sorts of things so I think that's a fabulous part of it.* [GP, site 9]

Educational Opportunities Specific to Mental Health Consulting

The majority of telehealth consultations in the participating practices were with psychiatrists. Many psychiatric consultations were considered by the referring GP to be inappropriate for learners to be a part of. However, those that did involve a learner were well received by patient, GP, specialists, and learners alike. They facilitated a breadth of learning opportunities and insights into the unique aspects of psychiatric consultations to which the learners and GPs felt they had not previously had access:

> *My perception of the trial at the start was that it was really for the students, and that it was mainly pragmatic education about how do you tele-psychiatry because in your lifetime you are going end up doing more of it and with [National Broadband Network] NBN rollout in regional areas it's just going to be a more of a fact of life. But I think the unexpected side effect for us anyway that it was an educational experience in a clinical context so it ended up learning how to do tele-Consulting but also ended up being a psychiatry modeling training experience for multi levels of learner.* [GP, site 2]

> *It's great with mental health patients which is one of the things I was skeptical about...I haven't had any patients that have been negative about it. I know that they discuss pretty much anything and everything the way they would on a one-on-one basis in person.* [nurse manager, site 1]

> *So, the opportunity to be in consultations which are usually quite guarded and where patients usually don't like for a third party to be present and especially the history taking skills and how to build rapport with patients with mental illnesses...It's really opened my eyes on how history taking can be done differently to glean more information...I have to say prior to this learning experience I probably treated mental health consultation very similarly to any other health consultation.* [Prevocational General Practice Placement Program [PGPPP] doctor-in-training, site 2]

> *Mutually beneficial [to patient and student] too because I learnt a lot...Also it was private practice mental health, which we haven't been exposed to before in our psych rotation since inpatient and it's a completely different patient population to private practice...So that was great actually. It gave psych a different light.* [student, site 1]

> *...to see somebody [the specialist] who was able to establish rapport and provide a lot of emotional support, some diagnostic input and then a whole lot of safety netting and then arrange the follow-up consultation, such that the patient said that it was probably the best psychiatric experience he had ever had in terms of support.* [GP, site 2]

Enhancement of Job Readiness

The majority of the research was in rural general practices. General practice trial participants indicated that learners demonstrated improved job readiness by being exposed to consultations with specialists and the use of telehealth consulting as an integral aspect of patient care:

> *It's really useful and as a registrar, it's a good learning tool for me. I'd love to, you know, continue doing the telehealth if I have a chance. I've never done it on my own but if I have a patient who will benefit from the telehealth I would definitely do that.* [doctor-in-training, site 9]

Job readiness enhancement was also seen in multidisciplinary team work exposure as a result of telehealth consulting:

> *It [telehealth consulting] gives a unique insight for training...getting a comprehensive understanding of what a real and true multidisciplinary care model is for a patient. You get some real insight what other Allied Health professions and disciplines are doing with patients...seeing the sort of questions that are being asked and the types of topics that are being focused on* [practice manager, site 1]

Augmenting skills through working with experienced health care workers in Aboriginal health and enhancement of cultural awareness linked with being involved in the telehealth consultations were other work readiness advantages:

> *The improved quality with the terminology and linguistic barriers and all that sort of area I think having a medical student observing that will improve their way—given when they become a GP or an Allied Health Service provider of how to communicate with the Aboriginal, Torres Strait Island community because they will observe the challenging questions that the practice nurses had to bring down to the grass roots level in terminology exchange and they will take that on board with them and that will make them become culturally safe practitioners.* [practice manager, site 3]

Related to work readiness was the perception that role of telehealth consulting in reducing rural isolation for health care staff in a rural situation:

> *I think one of the reasons—and this is a recruitment issue—one of the reasons that people are nervous about going into rural general practice is that they feel that they will be professionally isolated...this may also serve a purpose where the registrar thinks "Well, actually I have got this support. I can do this and I can learn from this now and forever by being part of these consultations and that I will have this to offer for my patients." So, yes, I think there's also another benefit that maybe we hadn't thought about with this.* [GP, site 9]

The Reported Clinical Benefits of Using Telehealth Consulting

Continuity of Care

Improvements in continuity of care with enhanced shared care for patients afforded better opportunity for triangulated communications between the patient, the GP or nurse, and the specialist, and patient feeling supported in the consultation. This was recognized as important in the learning opportunity for students and doctors-in-training when they had an established relationship with the patient and were then allowed by that patient to be involved in the 3-way consultations between a specialist and the patient and doctor or nurse:

> *You get to see the GP and you get to see what the specialist does further to that so you kind of get to see a bit more continuity of care and what happens at both levels and that's pretty valuable learning opportunity* [student, site 4]

The telehealth consultations gave a unique continuity of care with patients having the consultation in the primary care setting with which they are familiar with someone they know in the room. This aspect of continuity of care appears to give the patients more confidence. This was an often-mentioned theme and was felt to assist patients to "open up" in the consultation if they had an ongoing care-based relationship with the primary care team:

> *The patients themselves are being heard...that they can come back to the clinic here...they've got that one-on-one contact with the doctor visually...I just think that for the patient in particular, it's giving them confidence in the service that we're providing here in the clinic.* [practice nurse, site 1]

The continuity of patient care also enhanced the opportunity for stronger interactions between all those involved in a telehealth consultation. This can additionally lead to the patient feeing supported within the consultation:

> *They see what the GP is doing with this patient, they can then see the continuity of care with the specialist, they can then see that again when the patient goes back to review that consultation with the doctor on the same day, they've got that full flow through and understanding and comprehension of exactly what the total process is with the patient.* [practice manager, site 1]

> *I suppose having someone known to them from this practice sit in with them probably they feel more comfortable. Sometimes the nurses do need to interpret a bit about what the specialist is saying...Sometimes they are quite anxious about teleconferencing initially but having the nurse sitting with them helps a lot.* [practice nurse, site 1]

Timely Access to Specialists, Quicker Referrals and Follow-Ups, and Access to a Wider Range of Specialists Than Face-to-Face

Telehealth consultations were seen to have the potential to enhance clinical care of patients through allowing access to a range of specialists not limited by geographical proximity:

> *We can offer patients comprehensive service that's good for patient care and because we're rural and we're away from the city and we don't have resident specialists in town.* [GP, site 4]

> *The patients were actually very impressed at how the telehealth consults went...it's really massively improved in terms of access to specialists. We probably haven't used it as much as a rural place...but we had access to specialists that we seriously wouldn't have had access to otherwise.* [GP, site 3]

Timeliness was also viewed as an important clinical benefit:

> *Traditionally with specialists appointments there are waiting lists and there are also the geographical boundaries and the financial restraints...We find with telehealth there is a higher frequency for cancelations to pop up...which allows us to work with the patients availability.* [practice manager, site 1]

Normalization of Telehealth Consulting in Clinical Practice

The normalization of telehealth consultations into medical practice systems was facilitated by the perceived benefits and the support provided by the project's training and team:

> *Initially I was very skeptical. I couldn't really see how specialists could get a good perspective on a patient's health by seeing them over Skype and I actually thought the patients would find it difficult...But I've had a complete turnaround...the patients seem to have adjusted to it really well.* [nursing manager, site 1]

> *It's facilitated a process with us thinking about and putting things in place and encouraging the use of the technology to do consults...we've got the technology switched on things are in place.* [GP, site 4]

Discussion

Our data provide evidence of substantial capacity and potential for telehealth in a range of learning settings and a range of learners, with advantages for both the learners involved and the patient.

It is not always possible to separate completely the educational and clinical benefits of telehealth consultations—they are intricately linked. They afford the opportunity for the student or doctor-in-training to be involved in a unique parallel consulting situation with the patient, the specialist, and the GP or practice nurse. It appears that the benefits are for the patient, the primary care team, and the medical learner, and they coexist and are synergistic.

The success of this form of medical education was apparent in practices that were established in using telehealth as well as practices that have just started using telehealth. A common theme across both types of practices is that they all developed new practices, protocols, and methodologies to enable efficient use of this alternative to face-to-face consultation. Therefore, the process of change was different across the participating practices (and indeed 2 of the participating practices did not make the change to using telehealth consultations for medical education within the time frame of the project).

However, in all those practices where patients consented to "sharing" their telehealth consultation with at least one potential "learner" (either a doctor-in-training or a medical student), the experience proved to be a successful learning experience, provided the consultation was of sufficient length. Additionally, the experience for the patient was deemed to be successful from the clinical perspective. It also allowed the patient to identify their unique role within the learning experience of students or registrars in the general practice linking with specialists, with whom the learner would be unlikely to connect in other circumstances.

Mental Health: A Unique Opportunity

The unique opportunities enabled by patients with mental health issues who engaged with the learning process are of significant note. Although this is described here as a unique entity, it should be noted that this has the potential to also enhance job readiness in the learner and to have potential impact on future clinical practice. Management of mental health in rural general practice is a key area in which innovation has been sought [14] and telehealth consultations appear to be an ideal solution.

This was a short-term study; practices have changed or modified their use of telehealth consultations to incorporate into it the opportunity for medical education and learning. There has been a positive attitude to change, which has been demonstrated to enhance its efficacy [15]. Some practices were new to telehealth consulting, others experienced, but all those who used telehealth consultations within their practice for medical education report positive outcomes for both patient care and medical education. These positive outcomes were at all levels: patient, learner, practice managers, nurses, and GPs. It appears that having made the change to incorporating telehealth consultations into core business, the process undergoes normalization. Following staff training, practice-specific guidelines, and role allocation, the process is valued and becomes an inherent aspect of patient care.

The benefits of telehealth consulting are patient-centered, allowing a patient to have a consultation with their specialist and GP concurrently, in a new iteration of parallel consulting. However, the benefits do not solely come to the patient. The support in case management is enhanced, the rural practitioner is more connected with peers in a distant location, and there are opportunities for learning at all levels. It enabled conferring with medical colleagues directly and development of joint management plans involving participation of the patient. It also allowed for any misconceptions or lack of understanding to be rectified immediately. This study has demonstrated that there are perceived benefits specifically related to mental health

consultations because of the shared experience of being in a consultation with an experienced psychiatrist.

Utilizing telehealth for medical education did require all participating practices to review their policies, practices, and protocols, and in some cases develop these. It is clear that although the principles are the same in each case and all had a designated staff member to organize and facilitate, practices have individual methods of enabling telehealth consultations. There were differences in the equipment used and the room set up with some practices choosing to have facilities in all consulting rooms and others having dedicated rooms. There were also differences with the roles and involvement of practice nurses in the consultation procedure. Another important aspect was that all practices recognized the importance of a "plan B" should there be technical difficulties to enable a simple telephone link up with the specialist.

Strengths and Limitations

The strengths of this research are in the adherence to the published research protocol, which gave clear direction and scope [6]. Additionally, the research rigor was ensured by adhering as closely as possible to the criteria within the consolidated criteria for reporting qualitative research (COREQ) recommendations.

Factors limiting the study include the short study timeframe and that during the study period there was a change in the financial incentive payments through Medicare.

Conclusion

The benefits of involving learners in appropriate telehealth consultations can be recognized in terms of clinical benefits for the patient and educational benefits for the learner. Nevertheless, these 2 benefits are not separate entities, but are fused and their relationship is synergistic. Telehealth consulting can also enhance the total care of the patient through the development of professional relationships and shared care between the patients' GP and a wide range of specialist services.

Conflicts of Interest

None declared.

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Abbreviations

COREQ: Criteria for reporting qualitative research
GP: general practitioners
PGPPP: Prevocational General Practice Placement Program
RRMA: Rural, Remote and Metropolitan Areas

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Original Paper

Fair Balance and Adequate Provision in Direct-to-Consumer Prescription Drug Online Banner Advertisements: A Content Analysis

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Abstract

Background: The current direct-to-consumer advertising (DTCA) guidelines were developed with print, television, and radio media in mind, and there are no specific guidelines for online banner advertisements.

Objective: This study evaluates how well Internet banner ads comply with existing Food and Drug Administration (FDA) guidelines for DTCA in other media.

Methods: A content analysis was performed of 68 banner advertisements. A coding sheet was developed based on (1) FDA guidance documents for consumer-directed prescription drug advertisements and (2) previous DTCA content analyses. Specifically, the presence of a brief summary detailing the drug's risks and side effects or of a "major statement" identifying the drug's major risks, and the number and type of provisions made available to consumers for comprehensive information about the drug were coded. In addition, the criterion of "fair balance," the FDA's requirement that prescription drug ads balance information relating to the drug's risks with information relating to its benefits, was measured by numbering the benefit and risk facts identified in the ads and by examining the presentation of risk and benefit information.

Results: Every ad in the sample included a brief summary of risk information and at least one form of adequate provision as required by the FDA for broadcast ads that do not give audiences a brief summary of a drug's risks. No ads included a major statement. There were approximately 7.18 risk facts for every benefit fact. Most of the risks (98.85%, 1292/1307) were presented in the scroll portion of the ad, whereas most of the benefits (66.5%, 121/182) were presented in the main part of the ad. Out of 1307 risk facts, 1292 were qualitative and 15 were quantitative. Out of 182 benefit facts, 181 were qualitative and 1 was quantitative. The majority of ads showed neutral images during the disclosure of benefit and risk facts. Only 9% (6/68) of the ads displayed positive images and none displayed negative images when presenting risks facts. When benefit facts were being presented, 7% (5/68) showed only positive images. No ads showed negative images when the benefit facts were being presented.

Conclusions: In the face of ambiguous regulatory guidelines for online banner promotion, drug companies appear to make an attempt to adapt to regulatory guidelines designed for traditional media. However, banner ads use various techniques of presentation to present the advertised drug in the best possible light. The FDA should formalize requirements that drug companies provide a brief summary and include multiple forms of adequate provision in banner ads.

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KEYWORDS

direct-to-consumer advertising; prescription drugs; Internet; pharmaceutical policy; United States Food and Drug Administration

Introduction

Background

Direct-to-consumer advertising (DTCA) of prescription drugs has skyrocketed since the late 1990s. From 1996 to 2005, DTCA expenditures grew from US $985 million to more than US $4.2 billion, a 330% rise [1]. This rise was due to regulatory changes made by the Food and Drug Administration (FDA) in the late 1990s that clarified and relaxed the existing DTCA guidelines. Prior to 1997, all consumer-directed prescription drug ads broadcasted were required to provide a brief summary of a drug's risks and side effects to consumers. Brief summaries were often lengthy, and although it was straightforward to disclose the content of a brief summary in print media, this was more difficult in a broadcast advertisement. In 1999, the FDA released a final guidance [2] allowing drug manufacturers advertising on television and radio to include a "major statement" identifying the drug's major risks in lieu of the brief summary. This statement, which must be spoken, is relevant only to broadcast ads. The FDA also requires broadcast advertisers to provide "adequate provision," which the FDA defines as "an alternative way for drug companies to provide risk information about a drug in a broadcast ad" [3] in lieu of the brief summaries.

The new regulations detail appropriate ways drug companies can provide adequate provision. These include providing consumers with (1) a toll-free telephone number they can call to listen to a reading of the brief summary, (2) a webpage address where they can access product information, (3) a statement that encourages consumers to consult a health care professional for more information about a drug, or (4) an alternative mechanism, such as a print resource, to access the brief summary relating to the drug product. The FDA also reiterated certain existing regulations that stipulated all promotion must present a "fair balance" between information relating to the drug's risks and information relating to its benefits. With these changes, drug companies could broadcast product claim ads or ads that make benefit and risk claims for a prescription drug without listing numerous medical definitions and studies as stipulated by the previous regulations.

Although total DTCA expenditures from 2005 to 2010 declined slightly, the subcategory of online promotion experienced a significant increase in expenditures [4,5]. It is unclear whether the current DTCA guidelines for print, radio, and television media or the recent guidelines for select forms of Internet advertising apply to online banner advertising. Many scholars are concerned that policymakers are not doing enough to regulate the online prescription drug advertising environment [6-8]. A lack of detailed policies that target the various forms of online advertising may lead drug companies to fail to disclose adequate information about the risks and benefits of prescription drugs to consumers. This study investigates the degree to which one common form of Internet advertising, banner ads, comply with existing regulations for print and television ads, and the adequate provision and fair balance requirements, in particular.

Prior Work

Previous research has analyzed the risk and benefit content of prescription drug ads. In particular, studies have documented DTCA deficiencies, including (1) the use of false or misleading claims [9,10], (2) not giving adequate attention to risk factors or causes of a condition [11], and (3) describing benefits in vague and ambiguous terms without citing scientific studies [11,12]. However, studies have shown that, in general, pharmaceutical drug ads tend to comply with the adequate provision and major statement requirements [13-16].

Regarding fair balance in television and print ads, most research has found ads to be deficient. Many DTCA studies have found that ads play up benefits and give short shrift to risks [11,13,15,17-22]. For example, one study revealed that, on average, audiences were given a third less time to absorb the risks compared to the benefits; moreover, 83% of ads included in the study presented risks in a single continuous segment rather than at various points throughout the ad [13]. One exception is a study of television ads that concluded that fair balance was reached given that prescription drug ads had similar numbers of benefit and risk statements per 30 seconds of ad time [16]. This study's discrepant findings can be explained by the manner in which it measured fair balance. Studies that compare counts of references to side effects, contraindications, and effectiveness are more likely to conclude fair balance is achieved than studies that measure the way information is presented, such as a study examining whether information was presented in a continuous segment as well as the types of images shown during risk and benefit information presentation [13]. The authors of these studies are more likely to conclude that although the sample of ads contain more information about risks than benefits, the ads present information in such a way as to downplay those risks relative to the benefits. The FDA does not offer detailed guidelines on how to achieve fair balance, but it does advise that information about side effects and effectiveness should be of comparable "prominence and readability" [2], which suggests that advertisers should pay attention to the form and context in which information is being presented.

Online advertising comes in different forms, including banner ads, whole websites, social media, coupons, and email promotions, among others. Conducting research on banner advertising is important because although research shows that online ads are ignored by website viewers, this does not mean Internet promotion does not have an effect on consumers [23,24]. Research has found that banner ads can have an effect on consumers through unconscious cognitive processes [25,26]. One manipulated experiment found that both a group of participants who were directed to look at banner ads on websites and a group whose attention was not directed to banner ads developed more favorable attitudes toward the advertised brand compared to a control group [26].

Although traditional media remains the most common form of DTCA promotion, Internet promotion has accounted for an increasing proportion of all DTCA since the early 2000s [4]. There are now many studies that focus on online prescription drug advertising. However, these studies have mostly focused on investigating topics such as the prevalence and nature of

prescription drug advertising via social media [7,27-29], the stock market reaction to noncompliance [30], and commentaries about the political, ethical, and/or legal problems associated with various forms of online prescription drug promotion [6,31-35]. One recent review of the FDA Warning Letters and Notice of Violation Letters sent to pharmaceutical companies for online prescription drug ads in violation found that the majority of violations concerned a lack of risk information and/or misrepresentation of the drug's efficacy [36]. However, this study did not directly investigate the risk and benefit content of online advertising promotion, and there are very few such studies. Moreover, the few studies that do examine fair balance and adequate provision in online DTCA are dated and inconsistent as to whether drug manufacturers present risks and benefits in a fair and balanced way. For example, a study of 90 pharmaceutical company drug websites found that most websites meet fair balance and adequate provision guidelines and concluded that websites were superior to print advertisements because they offered consumers a greater degree of medical and drug information [14,37]. However, other studies of pharmaceutical company websites found that although the websites contain risk and benefit information, drug companies present this information so as to highlight benefits and downplay risks, thus not meeting the FDA guidelines [38,39].

Study Aims

The purpose of this study is to investigate the degree to which one form of online prescription drug promotion, Internet banner ads, comply with adequate provision and fair balance FDA guidelines (see Figure 1 and Multimedia Appendices 1A-E for examples of DTCA banner ads). Banner ads are visuals that are placed on a hosting website containing promotional information and often include hyperlinks to the sponsoring website that contains more detailed information about a product. Banner ads were chosen for analysis over other forms of Internet promotion for 2 reasons. First, banner ads continue to be a popular form of online advertising. In 2014, banner ad revenues were US $8 billion, a 16% share of online ad dollars [40]. Second, there has not been a DTCA content analysis of banner ads to date despite a need for research on this media. The focus of this study is on the adequate provision and fair balance guidelines because these are the central requirements for DTCA, although it is unclear whether the adequate provision guideline applies to banner ads. Given that these ads are typically small, it may be infeasible to display a lengthy brief summary. Therefore, this research investigates whether ads disclose the brief summary or not and, if not, whether they make adequate provision for the prescribing information. The ad's hyperlinked page, which almost always directs the user to the drug company website, was not chosen for analysis because the FDA does not uphold the "one-click rule," which states that an online prescription drug ad can mention the brand name and the benefits without including all or any of the major side effects as long as fair balance is just one click away.

The research questions of this study are as follows:

1. Do banner ads include brief summaries, major statements, or otherwise make adequate provision for prescribing information?
2. Do banner ads achieve fair balance as measured by the ratio of risk facts to benefit facts?
3. Do banner ads achieve fair balance as measured by the presentation of risk and benefit information in banner ads?

Figure 1. Actos banner advertisement.

Methods

Data Collection

Product-specific ads were selected over a 1-month period during April 2011. Because this project was concerned with ads that reach a broad audience rather than an information-seeking audience specifically, the sampling frame for online ads included websites geared to a broad audience. During preliminary testing, however, it was discovered that random browsing on popular websites made it difficult to locate prescription drug ads. This is likely due to drug companies' efforts to reach their target audiences by advertising heavily on websites related to health. Therefore, to increase the likelihood of locating drug ads, health-related websites were selected for monitoring.

Google's "List of the Most Visited Webpages" [41] for 2011 was used to identify the websites with high traffic volume. This list is based on unique visitors (users), as measured by Ad Planner, and includes information about the site category, the number of unique visitors, whether the site does or does not accept advertising, and the region(s) of the world where the website is popular. The top 10 Web portals and news websites found on this list were chosen. Web portals were chosen because they are highly trafficked general interest sites that serve as gateways to other areas of the Internet. Because there were a limited number of Web portals on Google's list, news websites were also included in the sampling frame.

Also, eBizMBA's "Top 15 Most Popular Health Websites" [42] for 2011 was used to select the health websites. eBizMBA compiled this list based on the average of each website's Alexa Global Traffic Rank, and US traffic rankings from both Compete and Quantcast. From this list, the top 10 websites that accept advertising funding from drug companies were monitored daily. Table 1 provides a summary of the monitored websites. A total of 68 unique banner ads were gathered. This is a sample size similar to those of other studies of online prescription drug promotion [17,37,39].

Table 1. Summary of monitored websites (N=20).

Website	Website type	US rank[a]	Unique visitors per month[a]
Health-related			
Yahoo! Health	Health	209	21,500,000
WebMD	Health	247	19,500,000
MedicineNet.com	Health	563	10,500,000
Drugs.com	Health	871	6,000,000
Everyday Health	Health	969	5,700,000
WrongDiagnosis.com	Health	1203	4,700,000
MedHelp	Health	1243	4,600,000
RightHealth	Health	1590	4,150,000
Wellsphere	Health	1726	3,900,000
RxList	Health	2601	2,400,000
Non–health-related			
Yahoo!	Web portal	2	110,000,000
MSN	Web portal	5	450,000,000
The Walt Disney Company	Web portal	13	81,000,000
AOL	Web portal	16	72,000,000
CNN	News	20	50,000,000
The New York Times	News	34	12,000,000
Fox News	News	50	8,200,000
The Huffington Post	News	51	7,500,000
The Washington Post	News	72	5,600,000
The Wall Street Journal	News	80	5,600,000

[a] Based on Google's "List of the Most Visited Webpages" for 2011 [41].

A preliminary examination of the websites revealed that almost all banner ads were animated at some point in the ad's duration and included a scroll feature containing a brief summary of indications and side effects (see Figure 1 and Multimedia Appendices 1,A, B, and E for examples of the scroll feature). In order to record a real-time account of animated ads, TechSmith's Camtasia Studio 7.0, a screen video recorder, was used to provide a timed account of every action that took place on the screen during ad play. For all monitored websites, 3 screen recordings—one in the morning, one in the early afternoon, and one in the evening—of each website were taken daily for a 1-month period. Screen recordings were taken at 3 different times of day to attempt to capture any variation in the types of ads that were displayed at different times of the day. The browser's cache was cleaned after recording each advertisement so as not to bias the sample based on previous browsing history. Ads that did not include an automatic scroll required the user to manually scroll within the ad to view additional information, such as risk and benefit information. The data were stored and managed in NVivo 10. A document composed of unitized statements, defined as complete assertions made or images displayed, was created for each ad. These documents were imported into NVivo along with an internal link to view the ad.

Coding Scheme

A coding sheet (see Multimedia Appendix 2) was developed based on (1) the FDA's guidance documents for consumer-directed prescription drug promotion on television and 2) previous DTCA content analyses [13,16,21]. The following descriptive information was gathered from all ads: the drug's brand name, the condition(s) the drug was promoted to treat, whether the ad described the condition the drug was promoted to treat, and any mention of the causes of or risk factors for the condition(s). The presence of a scroll and whether the scroll was automatic or manual (requiring the viewer to move the scroll button) was also documented. Also, all links were clicked on to determine whether they were active.

The brief summary was operationalized according to FDA brief summary guidelines, which require manufacturers to provide "all the risks listed in the drug's 'prescribing information' and at least one FDA-approved use of the drug" [3]. Although it was considered unlikely for major statements to be included in banner ads because major statements must be verbal and banner ads usually do not include audio, the presence of a major statement was documented. Adequate provision was measured by documenting the ad's reference to one of the 4 forms of adequate provision accepted by the FDA [13,16].

Fair balance was measured both in terms of the number of benefit and risk facts present in the ads and in terms of the presentation of the risk and benefit information. The number of benefit facts and risks facts were counted and a ratio of benefit to risk facts was calculated. Following the FDA [3] and previous research [16], a *benefit fact* was defined as any purported positive outcome from taking a drug and a *risk fact* was defined as any possible negative outcome from taking a drug. Neutral facts not related to risks or benefits (eg, identifying the generic name of a brand name drug or directives for how to use the drug) were not coded because the study was interested in analyzing the benefit and risk content of banner ads, which is how the FDA defines fair balance. The author referred to the FDA product label to determine the risks and indications of the promoted drug.

The presentation of risk and benefit information was analyzed because of research showing that contextual elements matter for how audiences absorb factual information in ads [13,16,38,39]. This study concentrated on 3 aspects of presentation identified in previous research [13]. First, the study documented whether qualitative or quantitative terms were used to describe benefits and risks. Qualitative terms included such words as “low,” “high,” and “reduce,” whereas quantitative terms used numbers to describe risks and benefits. Each benefit and risk fact was categorized as qualitative or quantitative. Second, the visual images shown during the presentation of risk and benefit facts were assessed. Images were grouped into 2 broad categories: positive and negative. Images were considered positive (see Multimedia Appendices 1A and B for examples) or negative if the visual scenes or actors evoked positive or negative feelings or were positive or negative portrayals. Finally, whether the benefits and risks were presented in the main part of the ad versus in the scroll box was assessed, and the percentage of risks and benefits presented in the scroll and main portions of the ad were calculated. The risk-to-benefit ratio for facts presented in the scroll and main portions of the ad was also calculated.

At the beginning of the coding process, an independent researcher was recruited to code 5 ads in order to pilot-test the coding scheme. The codebook was modified to resolve any discrepancies that came to light during the pilot test. For time and cost reasons, the author then completed the rest of the coding independently. At the end of the coding process, the researcher involved in the pilot test of the coding scheme coded a random sample of 17 ads (one-quarter of the sample) to test for intercoder reliability. Kappa coefficients were computed for the following variables related to the research questions: brief summary, major statement, adequate provision, risk and benefit facts, qualitative and quantitative language, positive and negative images, and the presence of risks and benefits in the main part of the ad versus in the scroll box. Intercoder agreement for the presence and absence of the brief summaries, major statements, and the different forms of adequate provision was perfect at $\kappa=1$. The kappa coefficients for the remaining variables ranged from .55 to .61, which can be regarded as moderate to substantial agreement [43]. See Table 2 for the kappa coefficients for each category.

Table 2. Kappa coefficients for intercoder reliability.

Variable	Kappa
Brief summaries	1
Major statements	1
Adequate provision	
Doctor reference	1
Print ad reference	1
Website address	1
Toll-free number	1
Prescribing information	1
Medication guide	1
Benefit and risk information	
All benefit facts	.61
Qualitative benefit facts	.55
Quantitative benefit facts	.58
Benefit facts in main portion of ad	.60
Benefit facts in scroll portion of ad	.61
Positive images display (benefits)	.61
Negative images display (benefits)	.59
All risk facts	.59
Qualitative risk facts	.56
Quantitative risk facts	.59
Risk facts in main portion of ad	.61
Risk facts in scroll portion of ad	.59
Positive images display (risks)	.60
Negative images display (risks)	.59

Results

Descriptive Statistics

A total of 212 (including repeat) ads and 68 unique banner ads were gathered; 43 brand names were represented in the sample (see Figure 2). Of these, the most common were Humira with 5 unique ads and Cymbalta and Vyvanse with 3 unique ads each. Figure 3 shows the frequency of health conditions targeted in the sample. In all, 26 conditions were represented in the sample, the most common being asthma, plaque psoriasis, attention-deficit/hyperactivity disorder (ADHD), and depression. Table 3 provides a summary of the condition-related descriptive statistics and the scroll type used to display the brief summary. Most ads did not go to great lengths to describe a condition. Approximately 29% (20/68) of all ads described the condition the drug was designed to treat. A little over 7% (5/68) of ads mentioned the causes of a condition and no ads (0%, 0/68) mentioned the risk factors for a condition. All banner ads (100%, 68/68) had a scroll box within the ad that contained the brief summary (see the “Important Safety Information” portions of Figure 1 and Multimedia Appendices 1A, B, D, and E for examples of brief summaries). Close to 46% (31/68) of ads had an automatic scroll and 54% (37/68) required the user to scroll. All links in all ads were active. Every banner included a hyperlink on the main part of the ad directing the user to the drug company webpage for the pharmaceutical drug in question (see the “Learn more” hyperlink in Multimedia Appendix 1C for an example). Occasionally, the main ad also included separate links to coupons (eg, the free trial offer shown in Multimedia Appendix 1D) or condition information. These webpages were always hosted on the drug company website.

Figure 2. Number of brands represented in sample.

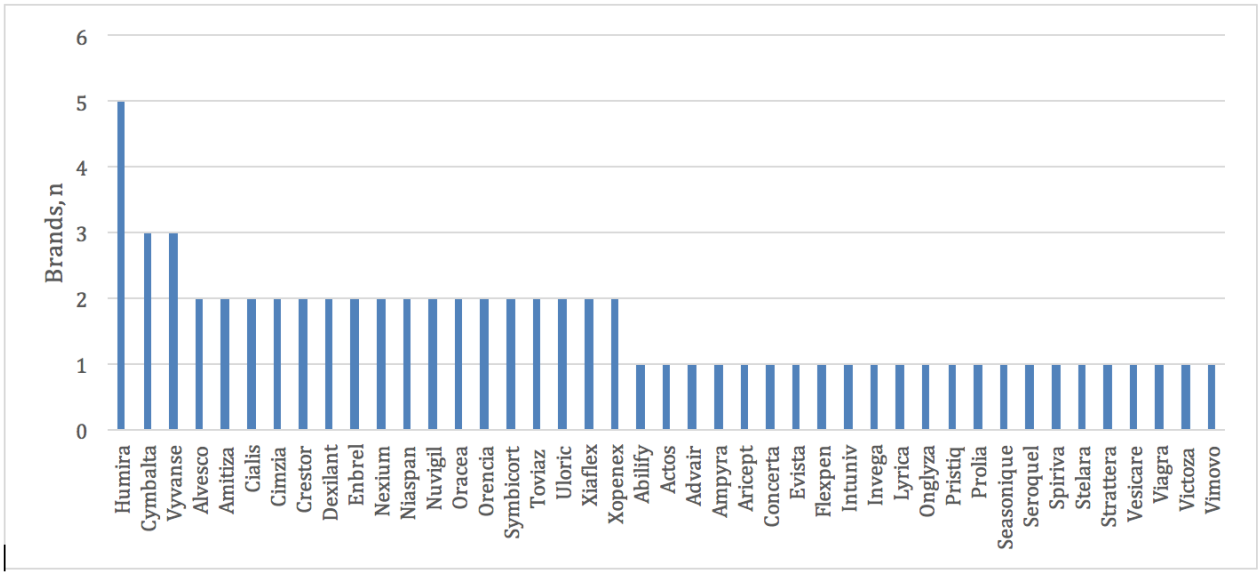
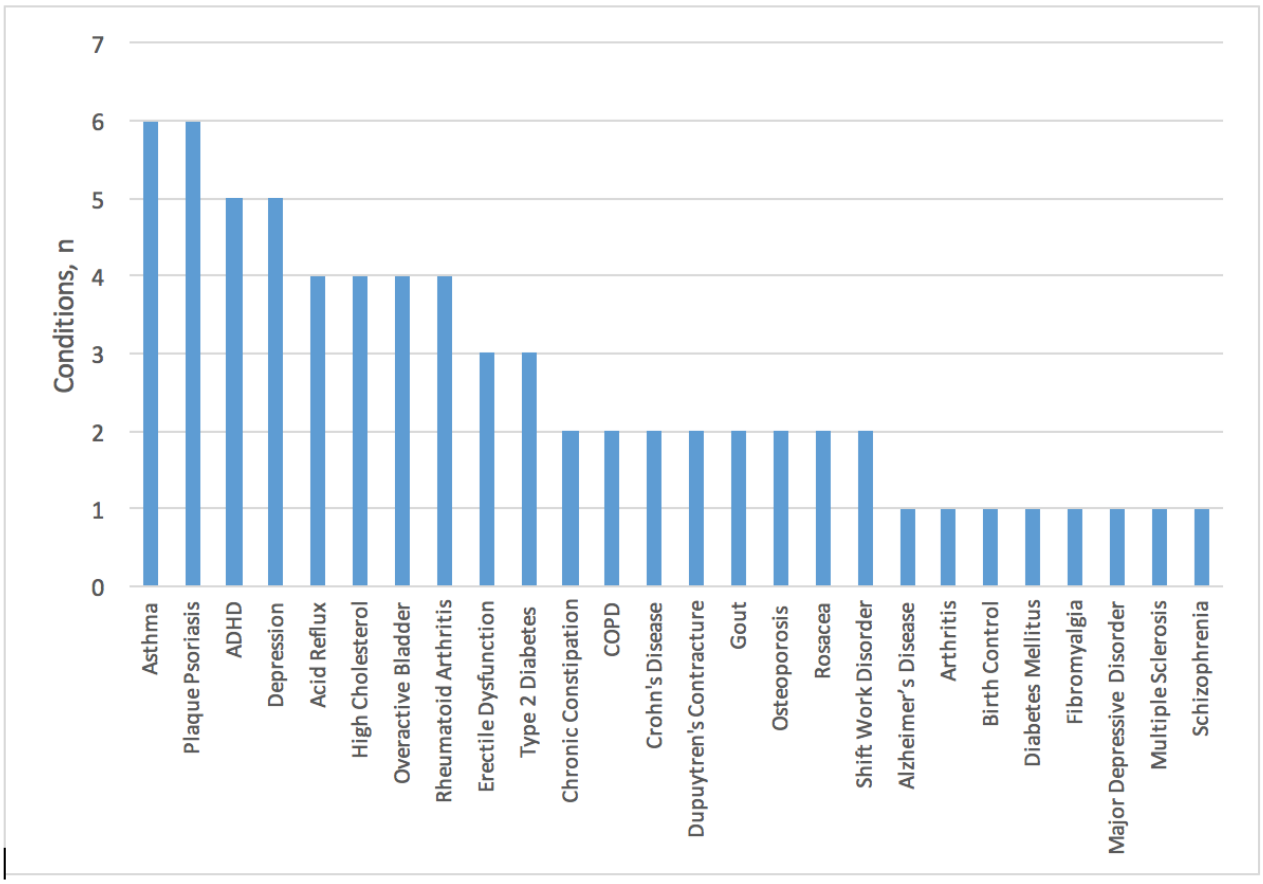


Figure 3. Number of conditions represented in sample.



Brief Summary, Major Statement, and Adequate Provision

All banner ads included the brief summary in the scroll box. No ads included a major statement. Because all ads included a brief summary, a major statement was not required under DTCA broadcast regulations. In addition to the brief summary, all ads except one included links to the drug's prescribing information (see Table 3; see the hyperlink in Multimedia Appendix 1B entitled "Prescribing Information" for an example). These links provided information about a drug's indications, contraindications, and risks. Many ads (53%, 36/68) also included links to the drug's medication guide (see the hyperlink in Multimedia Appendix 1B entitled "Medication Guide" for an example), which the FDA requires for certain prescription drugs and drug classes with particularly serious adverse effects, in addition to prescribing information. It should be noted that 46% (31/68) of banner ads were for drugs with black box

warnings. Some common drugs in the sample with black box warnings were indicated to treat Crohn's disease, ADHD, and depression. Although some drugs with black box warnings required medication guides and some did not, all the ads in the sample for drugs with medication guides disclosed links to these guides.

Table 3. Number of ads containing prescribing information and medication guides and different forms of adequate provision (N=68).

Variable	Total, n (%)
Type of guide	
Prescribing information only	31 (46)
Medication guide only	0 (0)
Both prescribing information and medication guide	36 (53)
Neither prescribing information nor medication guide	1 (1)
Type of adequate provision	
Doctor reference	68 (100)
Print ad reference	0 (0)
Website address	68 (100)
Toll-free number	0 (0)

If FDA broadcast ad regulations apply to banner ads, the inclusion of a brief summary in an ad would obviate the need to include adequate provision for the brief summary. However, all ads included some form of provision with additional information about the drug (see Table 3). All banner ads included both a doctor reference and a URL for full access to product information. No ads included a phone number or a reference to a print ad. In addition to the usual forms of adequate provision, 63% (43/68) of banner ads provided the audience with the contact information for MedWatch, the FDA's voluntary adverse event reporting program. According to the FDA Amendments Act of 2007, print (but not broadcast) ads must include a statement referring the audience to the MedWatch program (see the "Important Safety Information" section of Multimedia Appendix 1E for an example of a reference to MedWatch).

Fair Balance

Table 4 presents information on the number of risk and benefits facts and the risk/benefit ratios. There were 1307 risk facts in the total sample, with a mean 19.22 (SD 9.91) risk facts per total number of advertisements compared to 182 benefit facts in the total sample, with mean 2.68 (SD 1.32) per total number of advertisements. There were approximately 7.18 risk facts for every benefit fact. Most of the risks (98.85%, 1292/1307) were presented in the scroll portion of the ad, whereas most of the benefits (66.5%, 121/182) were presented in the main portion of the ad. The risk/benefit ratio was 21.18 for facts presented in the scroll portion of the ad and 0.12 for those presented in the main portion of the ad.

Table 4. Risk and benefit facts in ads.

Variable	n	Facts, mean (SD)[a]	Ratio of risk facts to benefit facts
Risk facts	1307	19.22 (9.91)	7.18
Main portion of ad	15	0.22 (1.08)	0.12
Scroll portion of ad	1292	19.00 (9.85)	21.18
Benefit facts	182	2.68 (1.32)	
Main portion of ad	121	1.78 (1.12)	
Scroll portion of ad	61	0.90 (1.25)	

[a] Per total number of advertisements.

Table 5 provides information on the presentation of risks and benefits in ads. Of the 1307 risk facts, 1292 were qualitative and 15 were quantitative. All ads (100%, 68/68) contained qualitative risk facts and 6% (4/68) contained quantitative risk facts. When presenting risks facts, 9% (6/68) displayed positive images and no ads displayed negative images. Thus, 91% (62/68) relied only on neutral image content when presenting risk facts.

Table 5. Presentation of benefit and risk information.

Variable	Ads, n (%)	Facts, n	Facts, mean (SD)[a]
Qualitative or quantitative presentation			
Risk			
Qualitative	68 (100)	1292	19.00 (9.97)
Quantitative	4 (6)	15	0.22 (1.05)
Benefit			
Qualitative	68 (100)	181	2.66 (1.30)
Quantitative	1 (1)	1	0.01 (0.12)
Image presentation			
Risk			
Positive	6 (9)	n/a[b]	
Negative	0 (0)	n/a[b]	
Neutral	62 (91)	n/a[b]	
Benefit			
Positive	5 (7)	n/a[b]	
Negative	0 (0)	n/a[b]	
Neutral	63 (93)	n/a[b]	

[a] Per total number of advertisements.

[b] The presence/absence of images rather than the number of images was coded.

Of the 182 benefit facts, 181 were qualitative and only one was quantitative. All ads contained qualitative benefit facts and only one ad contained a quantitative benefit fact. The majority of ads (93%, 63/68) displayed neutral images when presenting benefit facts; 7% (5/68) of ads showed only positive images and no ad (0%, 0/68) displayed negative images when the benefit facts were being presented.

Discussion

Principal Findings

This study supports prior content analyses of prescription drug ads that find that ads largely comply with the adequate provision and major statement broadcast requirements [13-16]. Although ads did not use a toll-free phone number and print ads as provision, they disclosed other forms of provision that may be helpful to patients. The banner ads abide by the print ad regulation requiring the inclusion of the MedWatch statement, which may be helpful to the public by informing them of this reporting mechanism. Banner ads did not achieve fair balance in terms of the ratio of risk to benefit facts in the main portion of the ad. Regarding presentation, the findings support prior research that concludes that ads highlight information about benefits more than information about risks [11,13,15,17-22].

In the face of ambiguous regulatory guidelines for online banner promotion, drug companies appear to make an attempt to adapt to regulatory guidelines designed for traditional media. However, banner ads use various techniques of presentation to present the advertised drug in the best possible light. First, ads display risks in a small box embedded in the ad. Because most ads either require the user to manually scroll or have a rapid automatic scroll, user engagement is often required to access risk information. Second, ads are more likely to show positive than negative images when presenting either risk or benefit information. Third, ads use qualitative as opposed to quantitative terms to describe risks and benefits. It is debatable whether the reliance on qualitative descriptions is good or bad for audiences. The FDA has recently acknowledged that the use of lay terms is preferable over an overreliance on medical terminology because consumers can more easily retain information communicated in consumer-friendly terms [44].

Policy Significance of Study

A review of the FDA Warning Letters that were sent to pharmaceutical companies in violation of FDA guidelines revealed that the FDA has sent pharmaceutical companies only 3 letters for banner advertisements in violation of FDA protocol. The FDA first sent an enforcement letter to a firm for a banner ad in violation in 1998. This letter informed GD Searle & Co that their website banner for Daypro failed to achieve fair balance by not providing any information related to side effects or contraindications [45]. The FDA sent a different letter to Novartis in 2008 for the same fair balance violation, claiming that 8 online banner ads for the drug Diovan presented only efficacy claims and omitted all risk information [46]. A third letter sent in 2009 to GlaxoSmithKline for 5 banner ads for Treximet reveals more about the FDA's regulatory approach toward banner ads [47]. According to this letter, the Treximet ads minimized serious risks by devoting most ad space to text and visual presentations of the drug's effectiveness while

underrepresenting risks by placing this information in an automatic scroll in a small slice of the banner ad. The letter stated: "Unlike the efficacy claims in the banners, the risk is presented without any signals or other attention-grabbing devices to alert readers that this is important information about the drug" (pg. 3) [47]. As revealed by this study's findings, the troublesome design elements of the Treximet ads are still common, showing that marketers have not altered their design of banner ads to address the concerns about fair balance communicated in the 2009 Treximet enforcement letter.

The FDA has responded to critics repeatedly calling for the FDA to directly address Internet advertising of medical products [48-51]. The FDA facilitated a public hearing in November 2009 to discuss the topic. At this meeting, many pharmaceutical industry representatives supported the "one-click rule." However, the enforcement letters sent by the FDA to companies displaying sponsored links on Google where audiences could access full product information in just one click indicate it does not support the one-click rule.

Subsequent to the November 2009 meeting, the FDA released a series of guidelines that are relevant to Internet promotion and social media. The first came in 2011 [52] and provided guidance to pharmaceutical companies on how to respond to unsolicited requests for off-label information about prescription drugs and medical devices. Many firms receive such requests through firm-controlled product websites, discussion boards, chat rooms, and other electronic forums. The guidance says that the pharmaceutical company's public response to unsolicited requests for off-label information should be limited to delivering the contact information of the medical or scientific personnel or department, should ensure that responses are not promotional in nature, and should not include any details regarding off-label information. The firm can only provide individuals with a detailed response about off-label uses privately, not publically.

A few years later, in June 2014, the FDA released 2 additional draft guidelines specifically devoted to the Internet and social media. The first document informs drug and device manufacturers how to correct misinformation on third-party websites about their products [53]. This guidance only applies to firms that are not responsible for the product communication that contains misinformation and, thus, does not apply to DTCA banner ads. The second targeted social media promotion with character space limitations, such as Twitter or sponsored links on search engines [54]. This guidance requires promotion via character-limited media to accurately present risk information along with benefit information. This is not possible in extremely limited message space, thus barring promotional activities in these media. The second guidance does not apply to online Web banners because the FDA deemed that this type of social media platform does not impose the same character space limitations as other forms of social media, such as online paid search ads and Twitter.

The new guidelines do not support the existence of a one-click rule. On May 20, 2015, Representative Billy Long of Missouri introduced Bill HR 2479 [55] to the House of Representatives that would make the one-click rule law. The bill would enable firms to engage in promotional activities in character-limited applications by regarding hyperlinked information in such media "as if the information appeared in introductory information" (ie, the original character-limited text). If signed into law, this bill would require the FDA to review and revise all guidance within 6 months and publish final regulations related to matters described in HR 2479 within 18 months. The future of this bill remains to be seen.

Limitations

This study has several limitations. The data are cross-sectional and, thus, represent only a snapshot in time. The Internet is a constantly changing medium and marketers will devise new innovations to utilize its functionalities in ways that can either benefit or hinder the public's understanding of the uses and risks of prescription drugs. The data were gathered in 2011; thus, this is not an up-to-date representation of the state of prescription drug banner advertising. However, a nonsystematic review of banner ads using Moat, an advertising search engine, revealed that banner ads do not differ much now in format or content compared to 2011 (see Multimedia Appendix 3 which displays screenshots of ads in the sample and newer ads [as found in Moat] for select drugs). Additionally, it is important to document how banner ads have changed over time. Future studies of banner DTCA can compare the quality and presentation of risk and benefit information to this study's findings. The sample size may be seen by some as small; however, it is similar to other DTCA content analyses [17,37,39]. Also, although an outside researcher was involved in testing the coding scheme and determining intercoder reliability, this was done for only a sample of the ads and not the full sample. In addition, some researchers express concern with reliabilities that range in the area of .5 to .6. [56,57]. Another limitation concerns the distinction between quantitative/qualitative language and positive/negative images, which are broad dichotomies and do not represent the full spectrum of how language and image content can be communicated. Finally, the search strategy was constrained by the fact that website tracking determines the advertisements that websites display to consumers. This makes it difficult to gather a truly representative sample of prescription drug banner ads.

Conclusions and Future Research

Although helpful in regulating many problems that drug companies confront in the Internet social media climate, the new guidance that pertains to electronic media does not provide much direction to firms seeking to generate banner ads in compliance with regulations. Given the constantly changing nature of the Internet, it is difficult to create guidelines for each specific medium. However, the FDA should nonetheless continually construct new guidance and revise past guidance so as to provide direction to the industry and identify instances of malfeasance. The United States is only one of two developed countries in the world to allow DTCA (the other is New Zealand). If it is to continue to permit DTCA, it is the FDA's responsibility to strictly monitor and enforce existing regulatory principles for the protection of patients and this involves keeping up with the changing media climate. Given the ubiquity of the

Internet, the quality of information in the United States could impact patients outside the United States as well.

For banner ads in particular, the FDA should resolve the apparent inconsistency with its statements in the GlaxoSmithKline Treximet letter and its subsequent lack of action on banner ads with the very same features as the Treximet ads. It should consider formalizing a requirement that drug companies disclose the brief summary in banner ads or, if not, identify the appropriate forms of adequate provision. If the FDA were to make the one-click rule law, studies of banner ads would need to review the hyperlinks on banner ads to determine fair balance.

This is the first content analysis of banner ads. Future research on banner ads should investigate (1) how audiences receive information in the typical design format of DTCA banner ads and (2) how banner ads can be altered—if at all—so as to achieve optimal audience understanding of the risks and benefits of medical products. Research on other types of Internet promotion, such as email advertising and online forums on drug company websites, is also necessary to advise the FDA on how best to deliver accurate information about prescription drugs to consumers. Evidence-based research can provide insight as to how the Internet's functionalities can be utilized to better communicate risk and benefit information to consumers. The interactive nature of the Internet allows for features not possible with traditional media, such as pop-up windows, links to more information, and embedded videos. Thus, viewers learning about a prescription drug for the first time on the Internet can quickly access additional information. Future studies should also assess the strategies the industry uses to target certain patient groups and demographic populations via online marketing.

Conflicts of Interest

None declared.

Multimedia Appendix 1

(A) Cialis banner advertisement. (B) Evista banner advertisement. (C) Niaspan banner advertisement. (D) Abilify banner advertisement. (E) Niaspan banner advertisement.

[PDF File (Adobe PDF File), 359KB - jmir_v18i2e33_app1.pdf]

Multimedia Appendix 2

Coding scheme.

[PDF File (Adobe PDF File), 27KB - jmir_v18i2e33_app2.pdf]

Multimedia Appendix 3

Screenshots of original ads in sample and newer ads for select drugs.

[PDF File (Adobe PDF File), 955KB - jmir_v18i2e33_app3.pdf]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
DTCA: direct-to-consumer advertising
FDA: Food and Drug Administration

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Original Paper

Patients Know Best: Qualitative Study on How Families Use Patient-Controlled Personal Health Records

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Abstract

Background: Self-management technologies, such as patient-controlled electronic health records (PCEHRs), have the potential to help people manage and cope with disease.

Objective: This study set out to investigate patient families' lived experiences of working with a PCEHR.

Methods: We conducted a semistructured qualitative field study with patient families and clinicians at a children's hospital in the UK that uses a PCEHR (Patients Know Best). All families were managing the health of a child with a serious chronic condition, who was typically under the care of multiple clinicians. As data gathering and analysis progressed, it became clear that while much of the literature assumes that patients are willing and waiting to take more responsibility for and control over their health management (eg, with PCEHRs), only a minority of participants in our study responded in this way. Their experiences with the PCEHR were diverse and strongly shaped by their coping styles. Theory on coping identifies a continuum of coping styles, from approach to avoidance oriented, and proposes that patients' information needs depend on their style.

Results: We identified 3 groups of patient families and an outlier, distinguished by their coping style and their PCEHR use. We refer to the outlier as controlling (approach oriented, highly motivated to use PCEHR), and the 3 groups as collaborating (approach oriented, motivated to use PCEHR), cooperating (avoidance oriented, less motivated to use PCEHR), and avoiding (very avoidance oriented, not motivated to use PCEHR).

Conclusions: The PCEHR met the needs of controller and collaborators better than the needs of cooperators and avoiders. We draw on the Self-Determination Theory to propose ways in which a PCEHR design might better meet the needs of avoidance-oriented users. Further, we highlight the need for families to also relinquish control at times, and propose ways in which PCEHR design might support a better distribution of control, based on effective training, ease of use, comprehensibility of data security mechanisms, timely information provision (recognizing people's different needs), personalization of use, and easy engagement with clinicians through the PCEHR.

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KEYWORDS

electronic health record; patient empowerment; self-determination theory

Introduction

Overview

Patients and parents of patients with complex chronic diseases face social, psychological, and organizational challenges. Many of them need to see 5 or 10 specialty departments of a hospital on a regular basis. They typically need to take medication daily, adhere to a special diet, and perform complex procedures at home such as injections or blood tests. Without prior medical knowledge, it is hard for patients and their families to understand the meaning of diagnoses, test results, and proposed treatments. Hence, they have traditionally had to surrender significant control to their doctors, who are responsible for their care, and to comply with recommendations. Anderson and Funnell [1] refer to this traditional approach to health care as the "acute-care paradigm."

However, two decades ago a new paradigm set out to change the balance of power: patient empowerment. Its goal is that patients set their own health goals that, then, both clinicians and patients work toward [1,2]. The process of patient empowerment requires patients to learn about their disease, to understand possible treatment options, and to participate in decision making. A popular way to educate patients and to provide them with information and choice is through technology such as Web-based self-management tools [3]. It is hoped that the feeling of control that patients gain through these tools will help them to better cope with and manage their illness [4]. Numerous studies have attempted to measure the effect that health management tools have on patient empowerment. For example, a meta-analysis by Samoocha et al [5] compared 14 randomized control trials that measured the effect of Web-based interventions on patient empowerment and found only small positive effects overall. The 14 studies measured patient empowerment with self-efficacy scales such as the Diabetes Empowerment Scale, assuming that the output of patient empowerment is increased self-efficacy and control. However, other researchers [6,7] have questioned this assumption. Another deficit of many studies on patient empowerment, such as those reviewed by Samoocha et al [5], is that they reveal little about the lived experiences of patients who use a Web-based self-management tool.

This study set out to close this gap: to better understand patients' lived experience with a patient-controlled electronic health record (PCEHR) and how the use of such a technology may lead to patient empowerment. The study took place in a specialist children's hospital, so most patients are cared for by a parent, and it was the parent who engaged with the PCEHR. For simplicity, we use the term "patient" to refer to the user of the PCEHR acting on behalf of the patient, and only make a distinction between patient and parent where that distinction is important to the account of their experience.

Background

As noted in the previous section, the study reported here started with the intention to better understand patient families' experiences with a PCEHR, based on the assumption that better experience would result in better engagement, and hence greater empowerment. Early data gathering and analysis led us to challenge our own assumptions, to draw on literatures related to coping, self-efficacy, and self-determination, and to shape subsequent data gathering and analysis focusing more directly on the relationship between individual coping styles and experiences of PCEHR use. In this section, we introduce previous work on personal health records (PHRs) and PCEHRs as well as literature related to coping styles.

Previous Work on Personal Health Records and PCEHRs

A common definition of a PHR is "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." [8]. In this work, we use the term "PCEHR" to refer to a record that gives all rights to the user who can then decide to share (parts of) the record with various health care providers. Researchers have proposed a variety of potential benefits of PHRs and PCEHRs, such as improved patient experience, support for patients with chronic conditions, improved transparency, increased referral rates, and better continuity of care beyond the hospital walls [9]. The main focus of this work is PHRs as a means to foster patient empowerment.

Previous studies of PHR user needs and design recommendations [8-13] have identified unresolved design questions.

Should Patients Be Given Immediate Access to Test Results?

While many patients seem to be interested in viewing their PHR [10], it is unclear whether new test results should be displayed immediately or after consultations [9]. While Byczkowski et al [14] found that participants were well prepared and appreciated immediate access, others [11,15] concluded that abnormal results should be discussed with the health care professional first.

Should Patients Be Able to Edit the Health Record?

It is unclear whether patients want to edit or add data in their health record, thus exercising control over their PHR [9]. Munir and Boaden [10] found that even though a majority of patients wanted to view their record, most of them did not want to control it. They concluded that patients' desire to be empowered (in terms of exercising control) varies and depends mainly on age and technical literacy. By contrast, Winkelman et al [11] found that patients welcomed the opportunity to edit and add data.

What Are Patients' Information Needs?

Providing the right amount of information and presenting it in a comprehensible fashion to patients seems to be challenging: Gysels et al [16] found that only some patients felt better informed thanks to a PHR, and Earnest et al [15] and Byczkowski et al [14] found that patients need more explanatory information about relevant disease markers and better presentation of the information. In contrast, Pai et al [17] reported that patient's felt better informed thanks to the PHR. Recognizing that patients' information needs depend not only on their condition but also on the context of use, Attfield et al [18] investigated how patients' information needs vary over time, specifically before and after consultations. Although it is now clear that both the condition and the context of use

influence patients' information needs, other factors still need to be investigated, such as patients' personal priorities and motivations.

Users of PCEHRs: People With Different Coping Styles

Users of a PCEHR include people with a chronic disease, their caregivers, and health care professionals. An important source of variability among our participants that influenced their relationship to the PCEHR was found to be their coping styles.

Although many researchers have attempted to conceptualize coping strategies and styles, the effects of coping on psychological, physiological, and behavioral outcomes are poorly understood [19]. However, much of the coping literature distinguishes between approach- and avoidance-oriented coping [19-23]. *Approach-oriented coping* typically involves information seeking, problem solving, seeking social support, actively attempting to identify benefits in one's experience, or creating outlets for emotional expression. *Avoidance-oriented coping* typically involves cognitive strategies such as denial and suppression and behavioral strategies such as disengagement.

Many researchers [20] have argued that approach-oriented coping is more effective than avoidance-oriented coping. However, pushing people to take more responsibility and control can be counterproductive. Giving patients control, responsibility, or information when they do not want it can, for example, increase distress [7]. There is an alternative viewpoint that coping strategies are not inherently good or bad; rather, coping styles can be more or less appropriate and effective in certain contexts, depending on, for example, the controllability of a situation [24,25]. Folkman and Moskowitz [19] argue that the focus should be on coping-environment fit and on assessing people's coping flexibility, defined as their ability to modify their coping according to the situational demands.

Our study prompted us to question whether and how a PCEHR can meet the needs of patients with different coping styles.

Facilitating Approach-Oriented Coping With Self-Determination Theory

As noted earlier, people's coping styles are associated with their motivations. Self-Determination Theory (SDT) [26] offers an account of the circumstances under which people develop intrinsic motivation, that is, their natural tendency to seek out novelty and challenges, to learn, and to extend and exercise their capabilities. According to SDT, motivation can range from amotivation (ie, total lack of motivation) through various degrees of extrinsic motivation to intrinsic motivation. While intrinsic motivation is completely internalized, extrinsic motivation can be more or less shaped by internal factors, and internal motivators are typically stronger than external ones. According to this theory, intrinsic motivation will flourish if basic needs for competence, autonomy, and relatedness are fulfilled [26].

C*ompetence* refers to a feeling of confidence and effectiveness in the domain of behavior in focus. Feelings of competence can, for example, be enhanced when people around the actor provide meaningful positive feedback [27].

Autonomy refers to an internal perceived locus of control or regulation by the self. An autonomous individual experiences his or her behavior as self-organized [26].

Relatedness refers to a sense of connection with others and belonging. This implies a feeling of being cared for and included within the domain of action [26].

Greater internal motivation is associated with more interest, engagement, and positive coping with failure and—in the realm of health care—with greater adherence to medications and better long-term health outcomes [26]. Motivation is likely to become more self-determined when the needs for competence, relatedness, and autonomy are fulfilled. The notion of need fulfilment leading to internalization of motivation was a guiding theme in our analysis.

Taking and Relinquishing Control: An Alternative View on Patient Empowerment

It is widely assumed that self-efficacy, mastery, and control are outcomes of patient empowerment [5] and that a patient's being or feeling in control of a disease is beneficial for treatment [28-31]. This view of patient empowerment focuses on "activating" patients who, as a result of "rejecting the passivity of sick role behavior and assuming responsibility for their care (...), are more knowledgeable about, satisfied with, and committed to their treatment regimens" [32]. Indeed, Salmon and Hall [7] argue that "The validity of the view that patients should be empowered to take control and make choices is...widely assumed to be unassailable."

Aujoulat et al [6] have questioned this common model of self-efficacy and bodily control. They argue that this view ignores the patient's need for security, self-determination, and a continuous sense of self. They present a concept of patient empowerment characterized by two processes: first, patients need to separate their illness from their selves by taking control and, second, they need to accept their illness and illness-driven boundaries by relinquishing control. *Taking control* involves learning to control the disease, developing cognitive coping strategies, controlling social roles, and separating the disease from one's own identity. Psychological research [33-35] confirms that this process helps chronically ill people to regard themselves as fundamentally sound and healthy. *Relinquishing control* involves asking for help, accepting that not everything can be controlled, and developing a sense of coherence, as well as awareness and acknowledgement of personal boundaries. In the study by Aujoulat et al [6], participants explored the origin or cause of their illness, for example, genetic predisposition and precipitating factors, as part of the process of relinquishing control. Based on this work, we discuss to what extent it is reasonable to push patients to take more responsibility and control with PCEHRs.

Methods

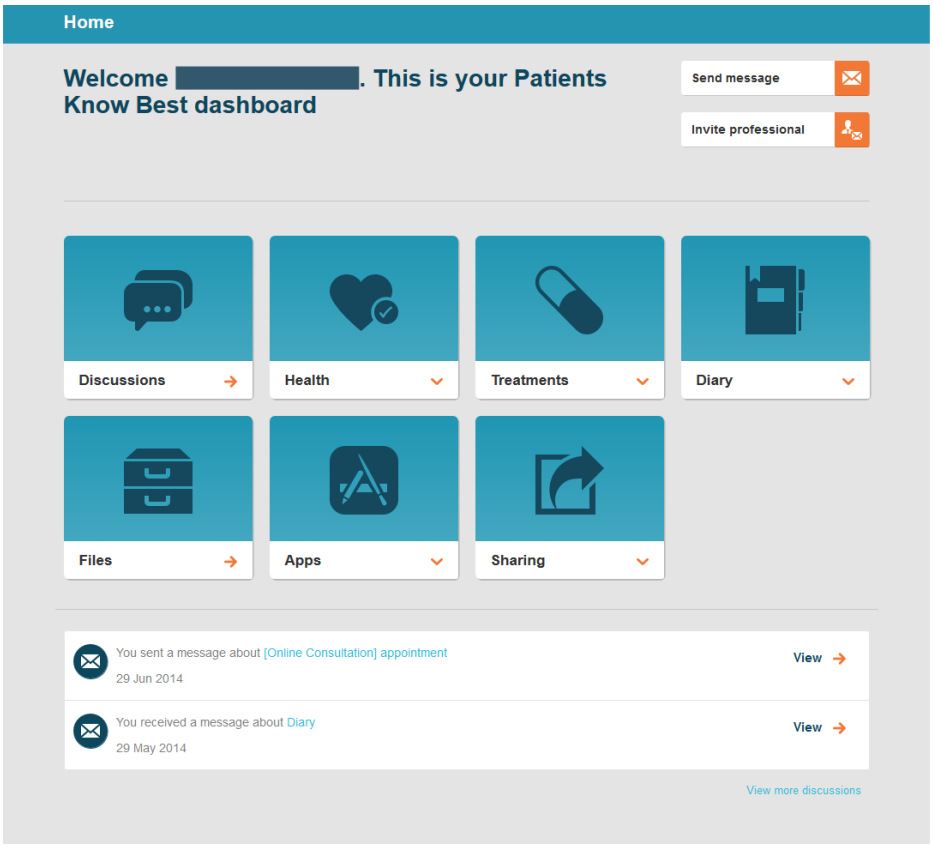
As noted earlier, our initial aim was to better understand the lived experiences of families using a PCEHR. The focus evolved toward how the PCEHR supported or obstructed people's sense of being in control (as described in more detail in the following section) as the study progressed. A qualitative methodology

suited the research questions being addressed, as it focuses on patients' experiences and practices [36]. Before the study commenced, ethical clearance was obtained from a UK National Health Service Research Ethics Committee (reference number 14/NS/0045).

The System

The PCEHR used in this study was Patients Know Best [37] (Figure 1). It allows patients and clinicians alike to upload, enter, view, and edit various health data (eg, symptoms, medications, diagnoses, test results, and body measurements). Changes are tracked and previous versions can be retrieved to ensure that both clinicians and patients can use the record at their convenience. In addition, it provides features that are traditionally not part of a health record, such as electronic messaging, video conferencing, and file management. Although the PCEHR can be tethered to the EHR of a hospital, this was not the case in our study setting. Therefore, the PCEHR contained information and documents that members of the clinical team, patients, or other doctors involved in the patient's care uploaded.

Figure 1. Screenshot of the patient interface of Patients Know Best.



Context and Participants

Data gathering took place in 2 departments within 1 hospital; Department A specializes in intestinal failure and Department B in inflammatory bowel disease.

Department A cared for around 20-30 highly complex outpatients between the ages of 1 and 25. These patients were dependent on parenteral/intravenous nutrition (PN) that was managed at home by their parents. Their parent/s had undergone formal training that taught them how to safely administer PN. This requires the patients to take a lot of responsibility and control as soon as they became outpatients. The PCEHR had been introduced about 2 years prior to the start of this study, and many families had been attending Department A for years before that. Because of their medical complexity, many patients were in the care of multiple medical teams. To coordinate care with the medical teams near patients' homes, and to provide the patient families with the necessary support in between 3- or 6-month consultations, the hospital team had frequent contact with them via telephone calls and via the PCEHR.

Department B cared for 60-80 children and teenagers under the age of 18. The treatment of Department B's patients usually consisted of taking prescribed medication, depending on the severity of symptoms, and patients were often required to adhere to a special diet. In Department B, nurses and a few patient families had been using the PCEHR for about half a year when the study commenced. Because of the large number of patients, consultants did not use the PCEHR. According to one of the clinicians interviewed, due to the slow consent and sign-up process and a low take-up rate, only about 10% of patient families in Department B were using the PCEHR when the study was conducted. Consequently, it was only possible to recruit 2 participants from Department B.

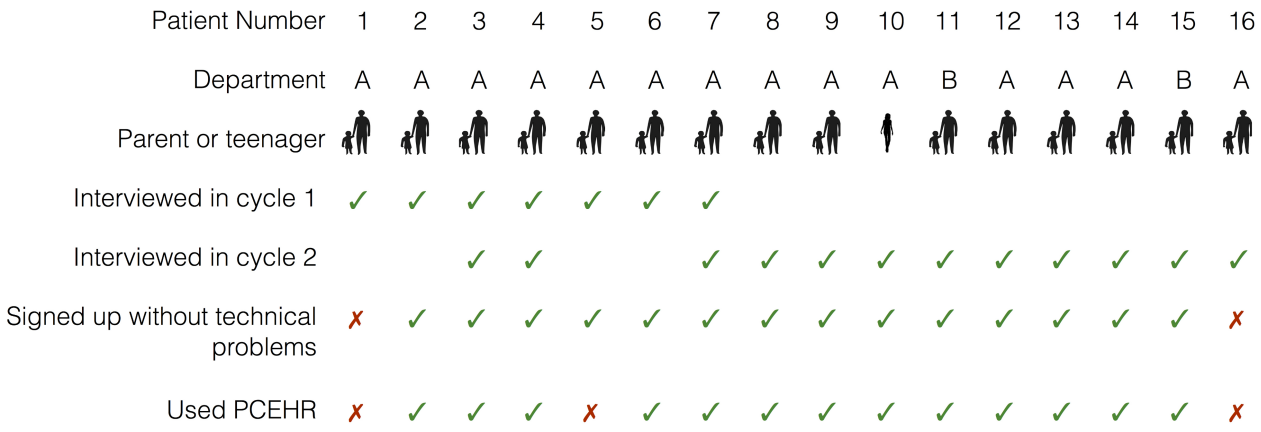
We interviewed all patient families of Department A who signed up for the PCEHR and agreed to participate in our study (in total 14 patient families) and 2 patient families of Department B to get insights into whether our results generalize across

departments. We also interviewed 7 clinicians from Department A and 4 from Department B to gather their complementary perspectives on families' experiences.

Figure 2 summarizes participant profiles of patient families, from both departments. In the following, we refer to patient families as P1 to P16 and to clinicians as C1 to C11. Participant numbers were assigned sequentially with P1 being the first and P16 being the last patient family participating. In 15 of the patient families, a parent of the patient was the principal participant; P10 was a teenage patient who participated directly.

Members of the clinical team were invited to take part by the researcher; patient families suitable for the study were identified, invited to take part, and consented by hospital staff.

Figure 2. Overview of interviewed patient families.



Data Gathering

The data gathering comprised a total of 23 hours of observations and approximately 9 hours of interviews. Interviews took between 7 and 45 minutes (with an average of 23 minutes). Our interviews aimed at understanding participants' use and nonuse of certain features of the PCEHR and their underlying motives.

Our study was structured in 2 cycles of exploratory data gathering and data analysis. Some participants were interviewed in both cycles (Figure 2). In Cycle 1, study participants were recruited with the goal to get as broad a representation of users of the PCEHR as possible (including patients who use the PCEHR themselves, carers who use it on behalf of a patient, and various people involved in a patient's care, eg, nurses, consultants, clinical assistants, dieticians, and pharmacists). Following a critical incident technique [38], in this cycle of data gathering and analysis, we asked about specific events involving the PCEHR rather than for general opinions, which tend to be less accurate. The interview script included questions such as the following:

- When was the last time you used the PCEHR?
- Do you remember a time when using the PCEHR helped you a lot/frustrated you?
- Can you walk me through how you used it?
- What was your goal?
- Do you use the PCEHR for other purposes as well?

We also included open questions that prompted participants to reflect on any changes caused by the PCEHR, such as the following:

- Do you feel the PCEHR has changed the relationship between you and your clinicians?
- Do you feel the PCEHR helps you to make better decisions in your/your child's care?

In the second cycle of data gathering and analysis, having identified important dimensions of variability in our data (such as motivation to use PCEHR and to take responsibility and control in the treatment), we adopted a theoretical sampling approach: we recruited new participants who we anticipated might show new or extreme manifestations of our identified dimensions, such as very intense PCEHR use. In this cycle of data gathering and analysis, we specifically asked questions referring to the identified dimensions of variability in the data. For example, we asked participants what features of the PCEHR they used or would use, to classify their motivation to use PCEHR.

Most interviews were conducted during 9 hospital visits; 3 took place by telephone. In practice, several factors constrained data gathering with patient families. First, only outpatients had been invited to use the PCEHR, and they visited the hospital infrequently; where possible, we scheduled interviews with PCEHR users to coincide with visits. However, later in the process, we conducted phone interviews as well. Second, patients' families live extremely stressful lives, and had limited time to spare after their appointments. Many families came with several small children, had to visit several departments in the hospital, and had many tasks to juggle during their visits. As a consequence, some interviews were rushed. A total of 2 interviews took place while walking with a family from one part of the hospital to another, making audio recordings impracticable. In these cases, handwritten notes were taken. This practice is less than ideal, but it was a necessary adaptation to the constraints of the hospital setting [39,40], and meant that participants were not excluded simply because they did not have time to participate in a more formal interview.

Observations focused on how the clinical team made use of the PCEHR and other tools during consultations as well as on patient-clinician interactions in general. Interviews and

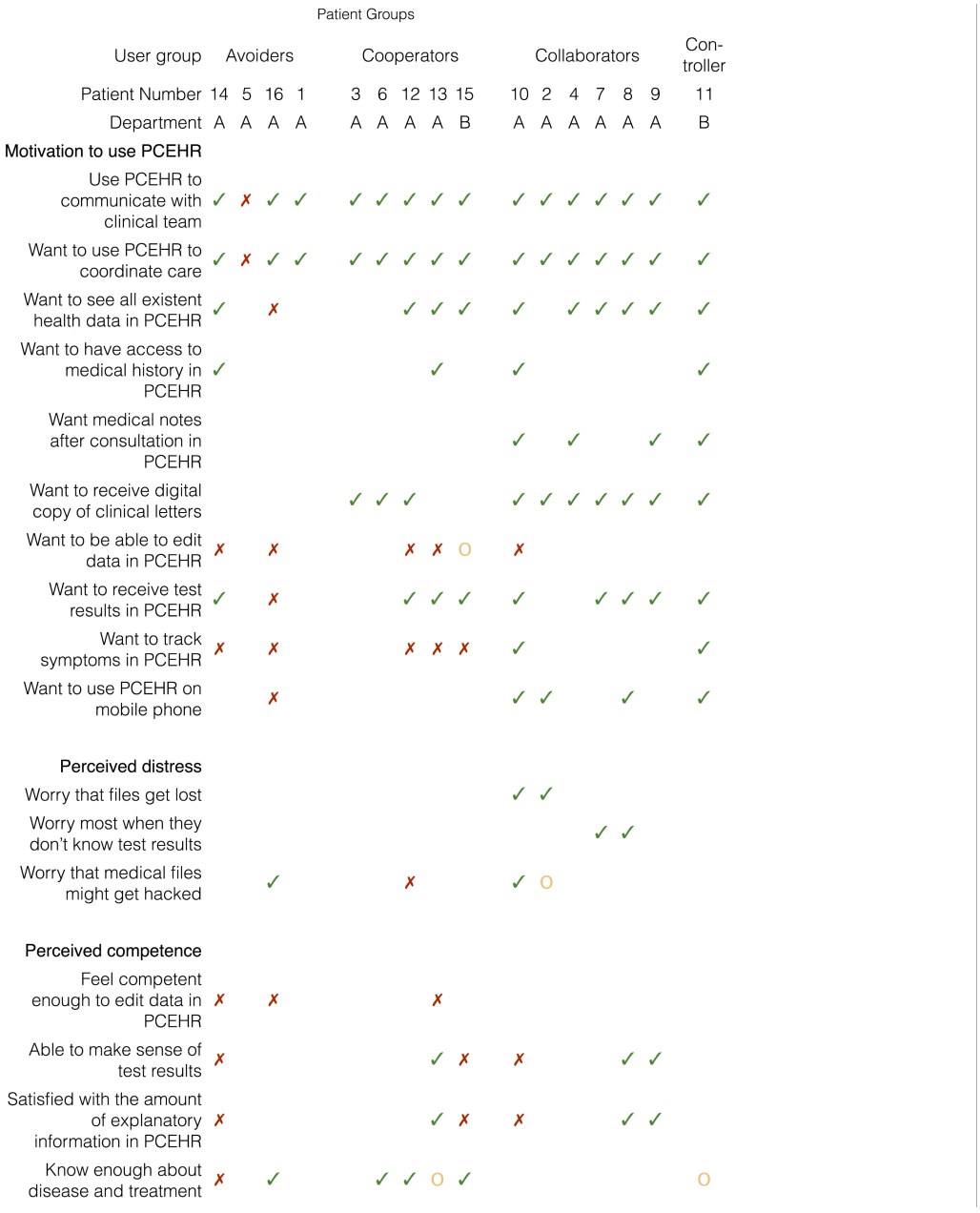
observations with clinicians proved more straightforward to plan and conduct than those with patients and their families.

Data Analysis

Within both cycles of data gathering and analysis, we adopted a Grounded Theory approach, as defined by Strauss and Corbin [41]. The first stage, "open coding," involved deconstructing transcript data and field notes into short phrases capturing key components of the participants' perceived reality. The second stage, "axial coding," involved comparing these text fragments within and across participants' datasets, resulting in loose concepts and ideas. The third stage, "selective coding," aimed at identifying the relationships between these ideas, resulting in a structured framework of higher-level themes. In the final step, "theoretic coding," these themes were compared with existing theories in the literature, an integral part of Grounded Theory [42].

Earlier transcripts were recoded, and early participants were asked to participate in follow-up interviews until newly gathered data ceased to generate new codes, a stage termed "conceptual saturation" [43]. The codes identified from participants' stated attitudes and needs are summarized in Figure 3. In this figure, participants are ordered according to subsequent stages of analysis as presented in the following section.

Figure 3. Grouping of participants and reported needs and practices.



For every participant and code, we assigned one of the 4 variables: "need felt" (indicated by a green tick in 5), "partly/unsure" (yellow circle), "need not felt" (red cross), or "no statement" (indicated by the absence of any mark). To assign these values, we read through all participant transcripts again and identified statements that revealed the participant's attitude toward a code.

We assigned the value "need felt," when the participant mentioned a need either spontaneously or (especially in later

interviews) when asked by the researcher—for example, "Do you use the function to track symptoms in the PCEHR? Why (not)?".

We assigned "no statement" when the interview did not reveal a participant's attitude toward a need at all. Both the openness of participants and the time frame and context of the interviews (described earlier) influenced whether the participant made a statement about a need or not. In later interviews, we asked more theoretically guided questions, resulting in more statements on identified needs.

We assigned the value "unsure" when a participant was asked about a specific need and was not sure about the answer, for example,

> *Would you like to be able to edit data?* [Interviewer]
>
> *I don't know.* [P15]

or when the participant's answer was ambiguous, for example,

> *Are you interested in participating more in medical decisions?* [Interviewer]
>
> *Well, I noticed, that I have faith that these people know more than me, that they are educated. There would always be the case when I trust the decisions that they make. If I wasn't happy or if it wasn't the best for my child, ultimately the decision is still down to me. But I have to trust them, I have to.* [P14]

Based on the codes in Figure 3, which were shaped by both the data analysis and the theoretical perspectives presented earlier, we identified 8 dimensions of variability, as outlined in the following section. These dimensions of variability are not mutually exclusive. The dimension "motivation to use the PCEHR" is conceptually different from the other 7 dimensions (it is what we set out to examine), while the other dimensions emerged from our data and seemed to correlate with PCEHR use. While previous work suggested that computer, reading, or health literacy influence the adoption or nonadoption of a PHR [44], in our data the patient's adjustment toward the disease more clearly correlated with motivation to use the PCEHR.

Motivation to Use the PCEHR

Motivation to use the PCEHR guided the grouping of our participants into a controller, collaborators, cooperators, and avoiders. This dimension was directly inferred from our data by statements on how often and how many features of the PCEHR participants used or wanted to use (eg, some participants used the PCEHR to track symptoms, medications, and other treatment-related markers, whereas others did not). Moreover, some participants' feature requests indicated that they would use the PCEHR even more if possible (eg, to see all existing health data, have access to the medical history, receive medical notes after a consultation, receive digital copies of clinical letters, edit data, receive test results, and use all features of the PCEHR on a mobile phone).

Continuum From Avoidance- To Approach-Oriented Coping

Motivation to use the PCEHR correlated with participants' coping styles. As detailed earlier, coping styles vary from approach oriented to avoidance oriented. Statements that indicated an approach-oriented coping style included the following: "Investigating the data is a way of coping for me," "I use the PCEHR to prepare for clinical appointments," "I want to understand medical decisions," and "I want to take part in medical decisions." Statements that indicated an avoidance-oriented coping style included "I try to avoid thinking about the disease," but avoidance was typically characterized by the absence of more approach-oriented statements.

Continuum From Amotivation to Internal Motivation

4 dimensions of variability were derived from the SDT [26]: perceived competence, perceived autonomy, perceived relatedness, and (hence) internalization of motivation. During analysis, the first 3 were inferred from our data, whereas the last was inferred from the other 3.

Statements that indicated perceived competence included "I feel competent enough to edit medical record," "I feel I'm able to make sense of the test results," "I'm satisfied with the amount of explanatory information in PCEHR," and "I feel I know enough about the disease and the treatment."

Statements that indicated perceived autonomy included "I double-check all medication prescriptions," and "I want to be able to edit data in the PCEHR."

Statements that indicated perceived relatedness to health care professionals included "I completely trust my doctors."

Statements that indicated intrinsic motivation included "I want to understand medical decisions," "Investigating the data is a way of coping for me," "I double-check all medication prescriptions," and "I use the PCEHR to prepare for clinical appointments."

Control Taken and Relinquished

The last 2 dimensions were derived from the work of Aujoulat et al [6], namely, the amount of control taken and control relinquished. The amount of control taken and control relinquished were both directly inferred from our data. The use of features such as feature tracking, the investigation of test result, and the double-checking of medication prescriptions indicated a high amount of control taken, whereas statements such as "I trust the decisions of my doctors" and "I rather spend quality time with my child than to think about the condition" indicated a high amount of control relinquished.

We clustered participants into groups, based on the codes in Figure 3. We refer to the outlier as controlling, and the groups as collaborating, cooperating, and avoiding.

To validate our classification, we conducted a 2-step cluster analysis in SPSS using 4 clusters and all codes. The results of the cluster analysis matched the clustering based on the researchers' judgment for 12 of the 16 participants. We resolved the discrepancy of the 4 exceptions [P14, P3, P6, and P10] based on their location on the identified dimensions.

We assigned P10 to the collaborating group, even though the cluster analysis assigned P10 as a controller. Unlike P10, P11 was preoccupied with tracking symptoms, medications, food

intake, and other disease markers. The *low relatedness* that characterized P11's behavior was not observable in P10 either.

We assigned P3 and P6 to the cooperating group, whereas the 2-step cluster analysis assigned them to the collaborating group. As these interviews took place in Cycle 1, data were thinner than the data we had about other participants. The key reason for our assignment decision was that P3 and P6 said they wanted to spend as little time as possible with the treatment or the PCEHR, either because they were stressed [P6] or because they prioritized spending quality time with their children [P3]. They shared this characteristic with other patient families in the collaborating group who used the PCEHR mainly to communicate with the clinical team and to coordinate care efficiently.

Finally, we assigned P14 to the avoiding group, whereas the cluster analysis assigned this patient family to the cooperating group. Patient families in the cooperating group seemed to have accepted the illness and consciously relinquished control, whereas P14 leaned toward denial. As a result, this patient's family spent as little time with the PCEHR as possible. What differentiated P14 from other participants in the avoiding group was that this family had used the PCEHR, whereas other participants in the avoiding group had not.

Results

Some PCEHR user needs were common to all participants in our study: the need for quick and easy communication with the clinical team; to coordinate care efficiently across multiple medical teams; to conceptually understand the PCEHR and receive adequate training; and to access the PCEHR on mobile devices. However, we also found differences between the PCEHR needs of patient families based on their motivation to take responsibility and control of their health management. As described earlier, 3 groups of users and an outlier were identified. The following sections elaborate on the behaviors, attitudes, and needs of these groups, starting with the outlier with the most intense PCEHR use and moving to the group with least use.

The Controller

One patient family (P11) used the PCEHR much more than all other participants. We present this patient family as a singleton because we believe that this observation might be of interest for researchers who observe similar behavior and because they have important properties when it comes to designing and deploying a PCEHR. We cannot be sure how common such behavior is, and therefore, these results should be interpreted with caution.

This patient family (P11) reported negative experiences with health care providers, and thus, learned to take an unusual degree of control of their child's treatment, in an attempt to ensure and improve the quality of care. As a result, P11 used the PCEHR extensively as a personal tool for health management, exemplifying their approach-oriented coping style,

> *We signed up for it and also invited a number of consultants who are connected with [my child's] health. I used the symptoms charts; I put lots of notes on there; I've put medicines on there; I put everything on there. It's more of a record for me as a parent so I can go back to this. But I thought in the beginning I would be able to use it as a tool when I speak to clinicians, to have it on my phone as an app to get the information, but I found that of all the clinicians I invited, only this hospital and the local podiatrist signed up for it, no one else has done it, I've chased it a number of times, [my child] sees about 12 different people.* [P11]

The aforementioned statement illustrates that the *perceived relatedness* of this family was low. When the family received blood test results during consultations or as PDF attachment to a message, they wished to store this information in the intended section of the PCEHR. However, P11 felt insecure about entering these data themselves, indicating low *perceived competence*:

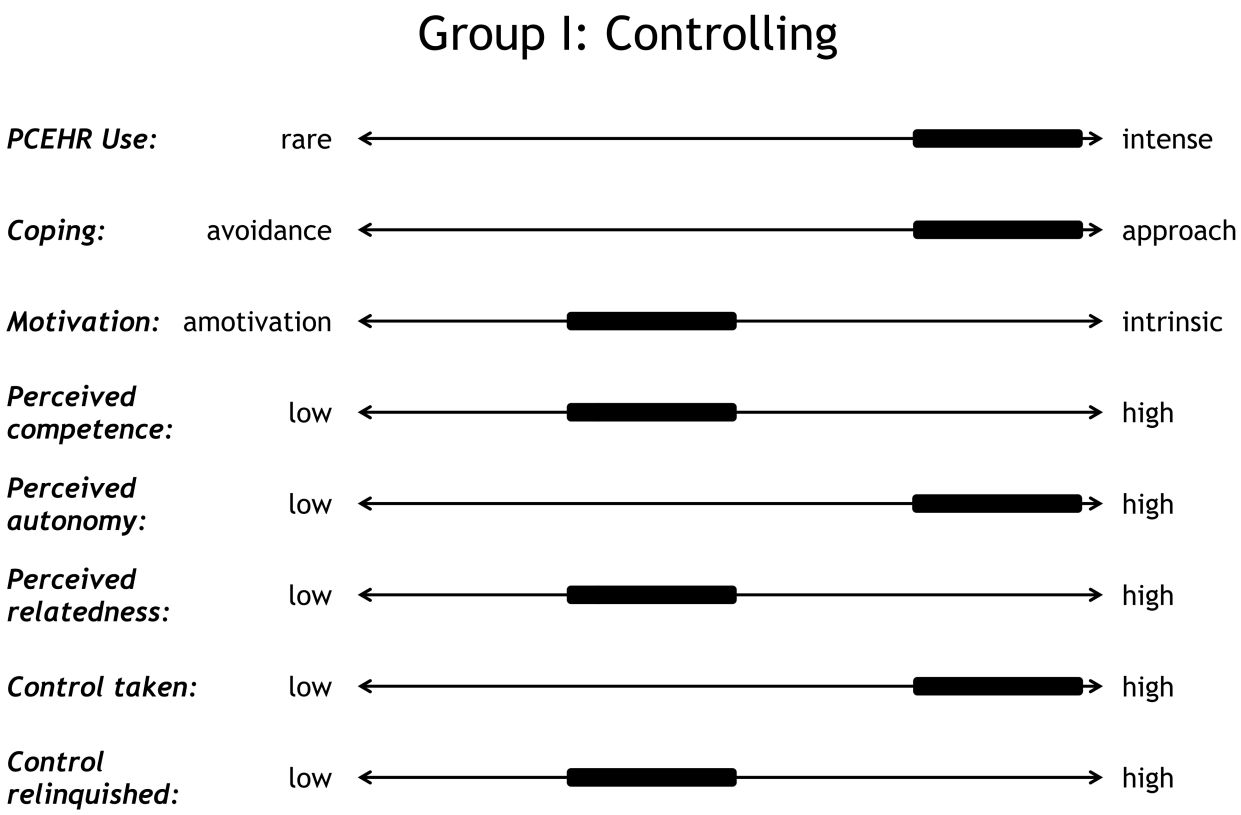
> *Initially, I wasn't sure I was doing it right. I've actually uploaded blood test results myself, even though I don't feel comfortable doing it, because there are lots of [differences] between the labs that are doing [measurements], but I uploaded some.* [P11]

According to SDT, low *perceived competence* and *relatedness* impede the development of *intrinsic motivation*. Indeed, P11's motivation to take control and responsibility seemed to be at least partly driven by fear and mistrust. Although approach-oriented coping is consistently associated with indicators of positive adjustment to chronic disease [20], this patient's family experienced *high distress:* The family members were worried about whether they were using the PCEHR correctly (see above) and whether the care received from the medical teams was good:

> *The communication [with the local surgery] is really poor. If for example my medication has changed here, by the time it gets to the surgery, it takes them about a week, 4-5 days, to actually process the fax that has come through to them to get into the system. And I had a case where they've duplicated the medication; they've done it wrong, so every time I've got to check and double-check what they are issuing.* [P11]

This patient's family demonstrated that *intense PCEHR use* does not necessarily correlate with successful coping. Therefore, P11 exemplified that taking a *high amount of control* does not necessarily indicate patient empowerment (as stated by Aujoulat et al [6]): the complementary process of relinquishing control was not reflected in P11's statements. These features are summarized in Figure 4.

Figure 4. Profile of the controller.



The Collaborators

The collaborating group (P2, P7, P8, P9, P4, and P10) shares one characteristic with the controller: proactivity. However, what differentiates the collaborators from the controllers is that they perceived high levels of *competence*, *autonomy*, and *relatedness*. Thus, their proactivity is grounded in *intrinsic motivation* (Figure 5). In contrast to the controller, the collaborators experienced *low levels of distress* although both of them adopted an *approach-oriented coping style*. Moreover, the collaborators perceived high treatment-related *competence*, as illustrated by the following statements:

> *My GP knows that I'm much more of an expert than he is and he believes me with all I say about my child's care.* [P9]

Their *autonomy*, or internal locus of control, was accompanied by an awareness of the limitations of their clinical team:

> *There are a lot of times when parents by going back over the results find something and then ask the consultant. Because they've got soooo many patients, they won't have the time to do what you are doing. When you are stressing about your child, you know what I mean.* [P8]

However, this awareness did not negatively impact on the families' confidence in the clinical team. Instead, they developed motivation to ensure that nothing was missed in the care of their child. They, therefore, collaborated with the clinical team, indicating their *perceived relatedness*. P9, for example, described how they discussed doubts, suggestions, and decisions together.

> *Recently I requested to see [a specific test] result before clinic. This week it was really important because looking at the result on Monday I saw something unexpected and asked my consultant through [the PCEHR]. She then decided to do a [specific] X-ray when we came in on Tuesday...The results of that one could now mean that my child needs to have a surgery. So it made quite a significant difference that I asked for the test results before clinic. I also pointed out that there was an X-ray in December and I reminded them that this ought to be compared to the new one that was made.* [P9]

P9's clinician reported the same incident and was happy about P9's involvement:

> *Recently actually, I had a little lad, it was part of his annual review, there were several investigations and that involved a chest X-Ray. And the little lad had some [symptoms]. So the mother questioned that and I hadn't actually seen the film myself yet. And as it turned out he needed [a specialist] X-ray and is now most likely going to end up with surgery. So that was very helpful the mother chased it up herself. He was very well when he came into clinic so there wouldn't have been any immediate concern about this. So it is helpful in that respect. I think it gives parents a little bit of responsibility as well which I think is the whole idea of the new NHS that patients are actually responsible for their own health, to an extent.* [C6]

Given the *competence*, *autonomy*, and *relatedness* these families experienced, their *high intrinsic motivation* to use the PCEHR and to take control and responsibility in their care is consistent

with SDT. In a partnership with their clinicians, patient families were able to both take and relinquish control, and experienced *less distress* than the controllers (P8 and P9 worried most when waiting for test results, see the following conversation between the interviewer and P8). We, therefore, perceived the collaborators as empowered, according to the definition of Aujoulat et al [6]. Indeed, participants themselves reported that the PCEHR helped them to cope with their situation by giving them the means to investigate the medical data themselves. P8, for example, reported that seeing if they could find something the doctors were missing helped them to cope with the situation:

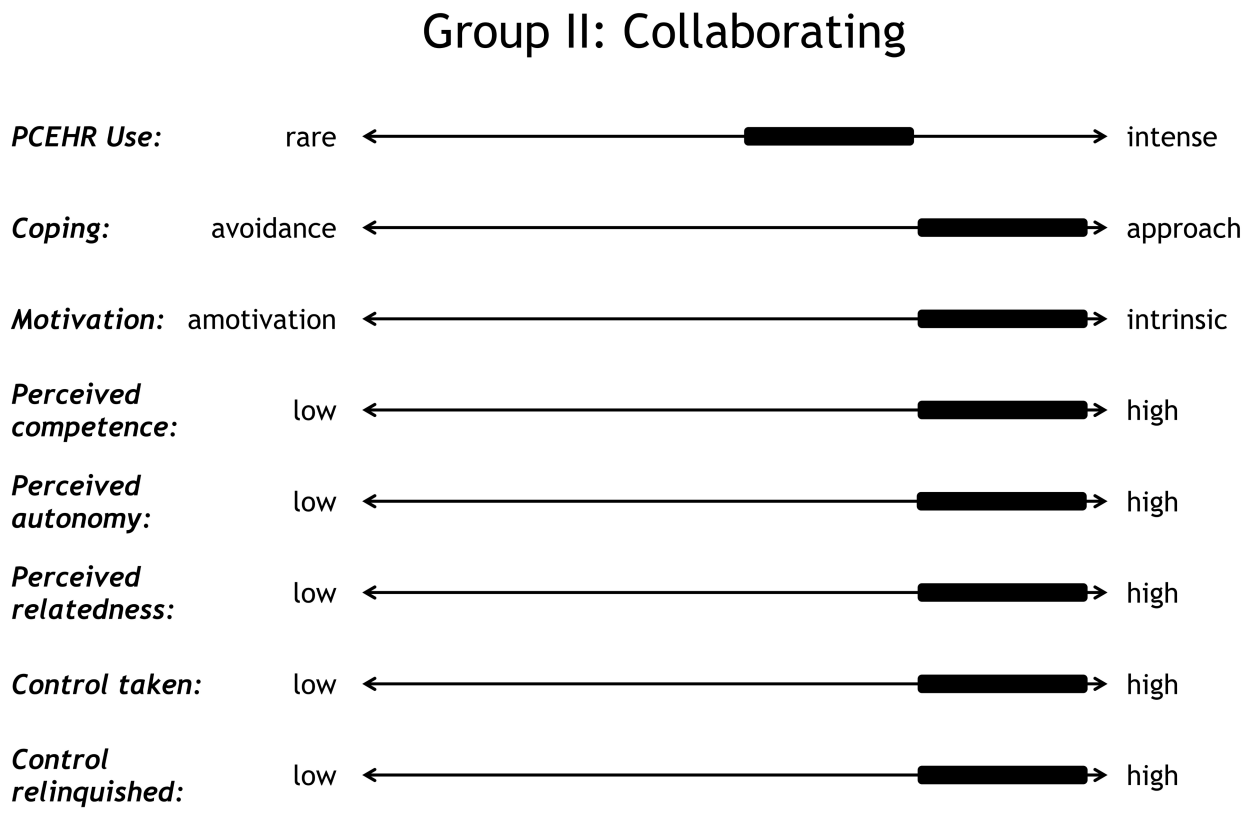
> *What does that mean to you to get the results immediately?* [Interviewer]
>
> *Less worry because every parent sits there and wonders and I know a lot of friends who use [the PCEHR]. And you sit and you worry about what the result is and so to get them quicker puts you out of your misery, if you know what I mean, you got to relax much, much easier. [...] I think that's the way I cope with it. I have to see if I can find something out that they are missing.* [P8]

Clinicians confirmed that the way these patient families used the PCEHR was helpful and desirable,

> *The families use it very appropriately. Sometimes excellent actually, [...] when they actually upload a picture then you say "ah yeah it's this or that", then you can say "this is ok, I'm not worried" or "this is not ok you should see your local hospital" or "we actually want to see you here". I think that is quite useful.* [C6]

As the way the collaborators used the PCEHR helped both patients and clinicians, we infer that the current design of the technology addresses their needs well. However, it is less suited for cooperators and avoiders.

Figure 5. Profile of collaborators.



The Cooperators

The 5 patient families in the cooperating group (P3, P6, P12, P13, and P15) displayed *competence*; for example, P6, P12, and P15 said they felt like they knew enough about the disease and the treatment and P13 was confident in interpreting test results. They also displayed *relatedness* (eg, P6, P12, P13, and P5 said they felt well supported by the clinical team and trusted their doctors' decisions), like the collaborators. However, the cooperators did not want to use the PCEHR as much as the collaborators. They were equally interested in having access to health data, receiving blood test results immediately, and receiving a digital copy of clinical letters via the PCEHR, but mainly to make managing the condition more efficient and to reduce the time and effort they needed to spend on it. In contrast to the collaborators, the cooperators were not interested in additional features of the PCEHR, such as symptom tracking and journaling, and they *used the PCEHR less intensely* (Figure 6):

> *Do you think tracking symptoms might be useful for you?* [Interviewer]
>
> *No, I don't think so... I don't know if it could be too much. You'd sit there thinking, which symptoms and worry. Like when you Google things you get a*

> *headache, don't you? "Oh god, oh god, it's this." It would be like that.* [P13]

When being asked about the reason for this, many of them replied that they did not want to think about the condition when not really necessary and they would rather spend quality time with their children. While "seeing if I can find something the doctors might have missed" [P8] was a coping strategy for the collaborators, the cooperators tried to think as little about the condition as possible (Figure 6).

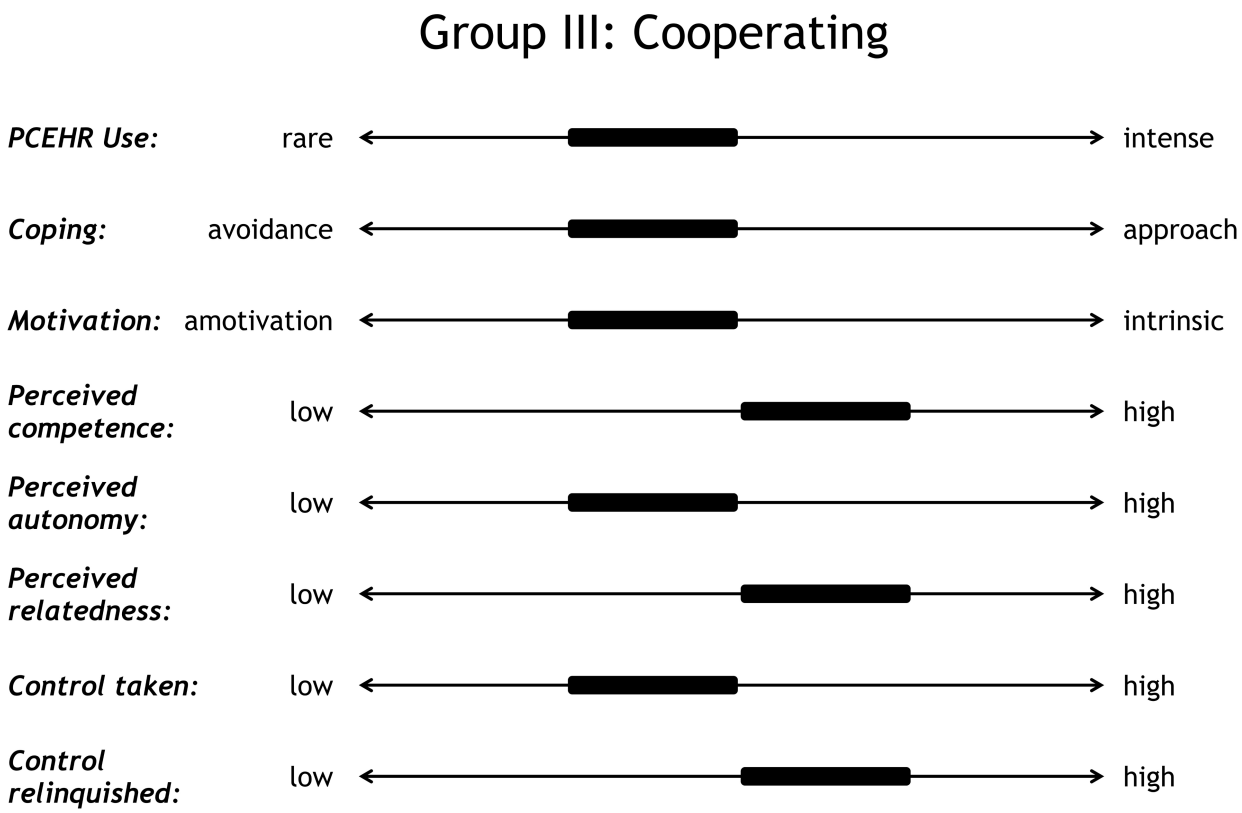
As cooperators perceived a similar level of *competence* and *relatedness* to the collaborators, *autonomy* is the only factor that could have impeded the development of intrinsic motivation according to SDT [45]. When being asked if they do or do not want to take part in medical decisions, P12 replied yes, P13 was not sure, and P15 did not want to take part:

> *Would you like to participate in medical decisions?* [Interviewer]
>
> *No, up to the doctor…* [P15]
>
> *Would you like to participate more in the care of your child?* [Interviewer]
>
> *No I rather want to live life without thinking about it too much. I know the doctors are very busy and I am also very busy with these two children.* [P15]

We also noted that the cooperators did not display the same awareness of their doctors' limitations as the collaborators.

On the continuum from *approach to avoidance*, the cooperators adopted a slightly more avoidant coping strategy. They consciously decided to relinquish a certain amount of control and were often articulate about their reasons, for example, that they preferred not to think about the illness (see statement above). As, according to Aujoulat et al [6], relinquishing control is equally important for patient empowerment as taking control, the cooperators can also be regarded as empowered. As the cooperators did not show any sign of anxiety or distress, there is no obvious reason to encourage them to use more PCEHR features unless health care providers expect clear benefits in terms of treatment outcome. A PCEHR that reflects this insight would not nudge patients to make use of all features but allow them to spend just the necessary amount of time to keep track of key data.

Figure 6. Profile of cooperators.



The Avoiders

The avoiding group [P1, P5, P14, and P16] is characterized by engaging neither with the PCEHR nor with the disease and by a tendency toward denial (Figure 7). In this study, there were no participants who were identified as engaging well with clinicians and treatment while actively avoiding using the PCEHR. It is possible that in a larger study such people might have been identified, but we speculate that the benefits that the PCEHR provided for families would mean that those who were actively engaged in managing their child's health would be motivated to learn the basic features of the PCEHR.

Like cooperators, P14 and P5's priority was to minimize the impact of the illness on their lives. However, the cooperators seemed to have accepted the illness and decided to live lives that were as fulfilled as possible. Avoiders by contrast leaned toward denial. As a result, P14, for example, spent as little time with the PCEHR as possible:

> *I try to normalize life. I escape the treatment, that's what I do 12 hours a day. On the day when [my child] doesn't have to be on the machine, I pack all things away and just ignore it. Maybe that's why I don't spend so much time on the PCEHR. I don't know if it helps to deal this way with it but when you can't deal with it I don't like to wallow in it.* [P14]

P5 had never used the PCEHR because this family was overloaded with work and the care of their chronically ill child:

> *I have a work. So at the time I come home from work I get TPN [total parental nutrition] out of the fridge so that it is at the temperature to put [my child] up. Then I go and collect my children from the childcare, then I get home and I make two different types of dinner due to [my child's] special requirements and then I put my [child] on the TPN, then I put [my other child] to bed, then there is time to clear up and sit down. Yeah, there is no time. I get the bags ready for the next day for school for [my children] and me to go to work...I'm exhausted; I'm so sleepy.* [P5]

The remaining 2 patient families [P1 and P16] in the avoiding group had never used the PCEHR because they had experienced technical problems when initially signing up, and had not pursued gaining access.

Avoiders did not feel that they understood medical data and decisions, unlike patient families in the other groups. While P16 preferred to wait for the next clinic appointment in 3 or 6 months, so that blood results would be explained properly, P14 was interested in receiving them but needed more explanatory information to make sense of the data:

> *Well, I don't know what [the blood results] mean anyway, so I always presume that they're normal, and if they weren't I imagine that someone would tell me. I don't really know what I'm reading; I don't really know what any of it means.* [P14]
>
> *Would you like to get more information with it to help you understand what they mean?* [Interviewer]
>
> *Yes. You just get the figures at the end, which means nothing to me.* [P14]

P14 and P16 were not confident in their own *disease-related competence* and, consequently, did not prefer to annotate their medical record:

> *Would you like to be able to comment on medical notes? Maybe there would be something that doesn't appear in the medical record but you think it might be important.* [Interviewer]
>
> *No because sometimes, I don't know what is important and what isn't when doctors talk to me. So, it's the same kind of thing like with the blood test results. I always kind of presume that if it is important than it would be written down. And if it is something that is just mentioned and it's not in the notes I would imagine that it doesn't need to be. You know it's just impossible for them to put down absolutely everything.* [P14]

Although P14 expressed trust in the competence of their doctors, they did not always feel well supported by the health care system:

> *When we came here four months ago, it took me a while to figure out how things worked at my local, and here that was very confusing and frustrating for the first few months [...]. And the trouble really was, there is nothing worse than a consultant standing in front of you and saying that he doesn't really know how to look after [your child] and then getting another one saying it. You know, all these doctors are saying that they have no experience at all with children like mine; they just haven't got the knowledge. And I'm also acutely aware that we cannot come back to this hospital where the experience is.* [P14]

This lack of *relatedness* and the lack *of perceived competence* could have inhibited the development of intrinsic motivation to use the PCEHR and to take more control and responsibility in the treatment, according to SDT [26]. As a result, the patient families neither took nor consciously decided to relinquish control in the way necessary for patient empowerment. Therefore, the avoiding group was not empowered, according to Aujoulat et al [6].

In contrast to the cooperators, the avoiders experienced anxiety and distress: P14, for example, was distressed because they did not feel that they understood diagnosis and test results enough to comprehend the doctors' conclusions:

> *[...] I'm not sure now that after the surgery these results still stand. And when they are talking about opening my child's diet I'm kind of concerned that opening the diet...that these test results don't still stand because things have changed since then. I would like to be able to educate myself because that would help me to make day to day decisions with confidence rather than guessing. So I think having access [to all the data] would be very helpful. If I would have more information I would feel like I can make informed decisions.* [P14]

While access to more health data and information would have helped P14, other patient families experienced more distress when confronted with such data. P8, for example, mentioned that a friend does not want to see test results in the PCEHR, because it is too upsetting:

> *A lot of people worry, I have a friend who doesn't want to see it because it is too upsetting, so would rather not look through the results. But for me, I need to know what's happening. I'd rather be above it before something is happening and not know.* [P8]

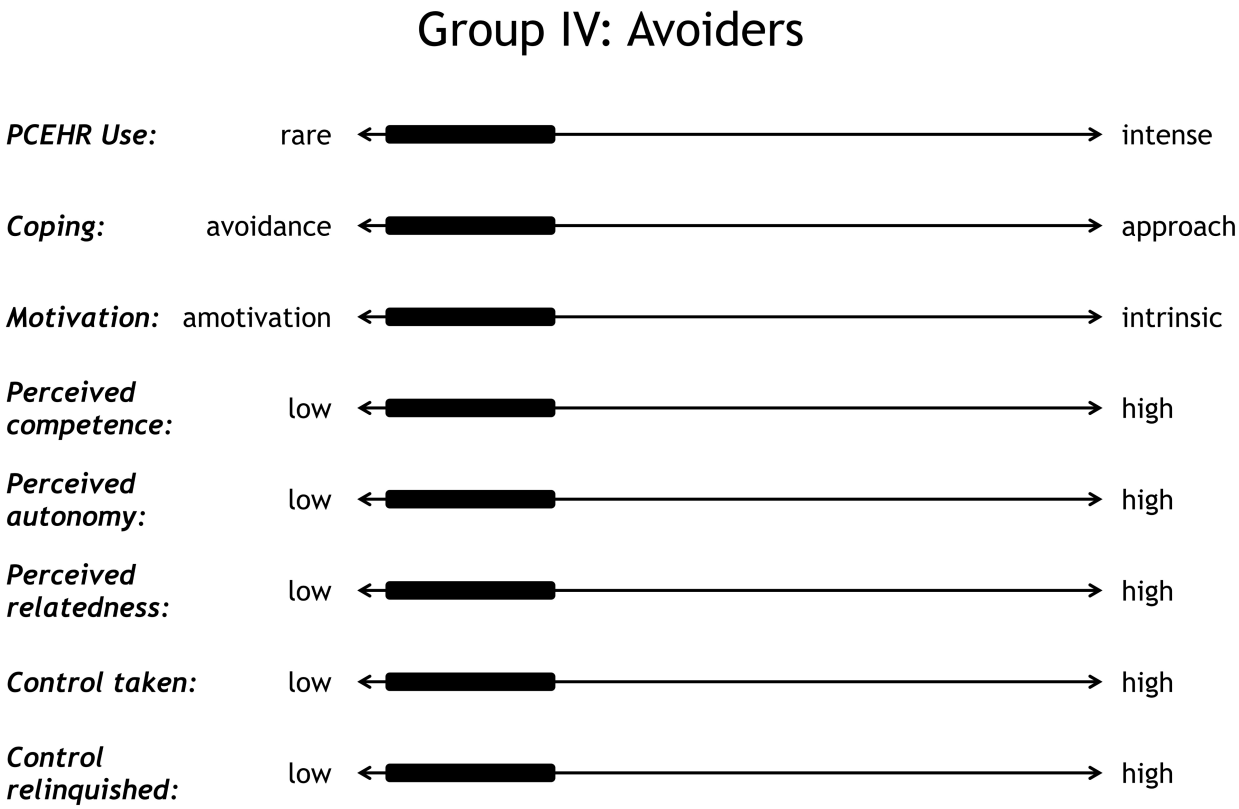
Similarly, a clinician (C2) mentioned that some patient families want to see data, in this case children's growth charts, only when the child has recently developed well:

> *I always offer them to see the [growth] chart, sometimes they are very interested, and sometimes they are not. Depends, I guess, on whether they've done well or if their child is losing weight. Sometimes*

> *they feel a little bit like, no, we don't want to see it today, but when they've done really well they want to see the child, you know this is where we're going.* [C2]

Providing patients who have an avoidance coping strategy with test results and medical information can both decrease and increase the level of distress they experience. The timing and mode of information provision should be adapted to the patient and designed carefully. While clinicians might be able to judge people's ability to take in such information, a PCEHR design has to consider scenarios in which patients are overwhelmed by information upfront.

Figure 7. Profile of avoiders.



Discussion

As discussed earlier, most of the literature on technology for patient empowerment implicitly assumes that patients are willing and waiting to take power and responsibility for their health. Our study has shown that this willingness depends heavily on the patient's coping style and perceived competence, autonomy, and relatedness. These findings match with existing theory on coping styles, on self-determination (SDT), and with the work by Aujoulat et al [6] on patient empowerment. In this section, we propose ways of applying these theories to the design of future technology for patient empowerment that will meet patients' needs better.

Theory on Coping Styles

In our study, the way patient families coped with the chronic condition of their child strongly influenced their PCEHR use: The controller made extensive use of the PCEHR but the clinical team neither noticed nor benefitted from their engagement; according to their clinicians, collaborators made excellent use of the PCEHR and cooperated with clinicians in a very helpful way; the cooperators felt comfortable using the PCEHR but generally chose to use it less than the collaborators; and the avoiders barely used the PCEHR at all. Based on this analysis, we conclude that patient families with different coping styles have different user needs that need to be considered when designing PCEHRs, and these differences extend far beyond simple information needs.

By employing theory on coping styles for the design of patient empowerment technology, we can both help to ensure that a specific coping style is supported by the technology and help patients to cope more effectively. While the technology should respect the needs of patients with different coping styles, there are potential benefits in helping patient families to develop an approach-oriented coping style, as this style has been found to be more effective in limiting psychological distress [46].

SDT [26] provides a promising approach to the development of intrinsic motivation which, in turn, is a driver for approach-oriented coping. In the following section, we identify possibilities to incorporate the principles of SDT in PCEHR design.

Theory on Self-Determination and Intrinsic Motivation

We are not the first to use SDT [26] to design interventions within health promotion and health care contexts or understand their effectiveness. Ng et al [47] conducted a meta-review of 184 studies that applied SDT to the health care context. Their review confirmed the expected relations among the SDT variables and positive relations of psychological need

satisfaction and autonomous motivation to beneficial health outcomes. Furthermore, they found a positive association between a supportive health care climate, better mental health, self-regulated behavior, quality of life, and satisfaction of all 3 psychological needs (competence, autonomy, and relatedness). Consistently, controlling health care climates results in people feeling undermined, with low motivation and sense of well-being.

Competence

By conducting a path analysis with the reviewed studies, Ng et al [47] found that competence explained the largest proportion of the variance in health outcomes. According to them, this result highlights that feeling competent is imperative for making the right behavior changes.

Looking at health management technology and PCEHRs in particular, patients are faced with 2 types of competence to acquire, namely, technological competence and disease-related competence.

Not feeling competent and comfortable using the technology can be a barrier even for patients who are in general comfortable using technology. Contributing to or editing a PCEHR may seem frightening, as patients may believe that any mistake can cause severe consequences for their health and treatment. In our study, the controlling patient family, P11, for example, was afraid of entering data incorrectly. The PCEHR stored the author of every data item, so that clinicians can check that the information is reliable. However, this feature was not obvious for this patient family. This highlights a need for the user interface to *make data security mechanisms very clear to users*, so that they feel comfortable to explore and to learn about the technology. Furthermore, *adequate introduction* and training are essential, and *ease of use* is of paramount importance.

PCEHRs can foster disease-related competence by providing general and personal medical information easily, securely, and efficiently. Patient families in our sample did not express a need for more information. However, 5 patient families mentioned that they had needed more information immediately after diagnosis. When technology is used to inform and educate patients, the information provided has to be relevant for the patients and fit their current level of knowledge and competence. Some researchers have investigated the variance of patients' information needs. Attfield et al [18] investigated how patients' information needs vary over time, specifically before and after consultations, and Al-Busaidi et al [12] presented an approach to providing patients with personalized and comprehensible information about their condition. They designed a patient portal that linked data from a patient's medical record with relevant information on the Web and presented that information in patient-adequate language. These investigations provide first insights into ways to tailor to different information needs. Future work could investigate how such systems could also take patients' previous knowledge and perceived competence into account.

Autonomy

The second basic need that SDT identifies is autonomy. Providing patients with access to their health record was found to increase their sense of autonomy [48]. One explanation for this effect is that giving patients access to their data allows them to reflect on it, to draw their own conclusions, and to make their own decisions [49].

On the contrary, nudging patients to use a PCEHR could decrease their perceived autonomy, causing anxiety and distress [47]. Indeed, Ng et al [47] found that positive results obtained with pressure to use a PCEHR are often short term. Concluding, the use of a PCEHR and all its features has to be voluntarily (as it was in this study). However, the effects of autonomy on nonadherence (eg, when a patient chooses not to adhere to a recommendation) would benefit from future research [47].

Relatedness

The third basic need of SDT is relatedness. Ng et al [47] confirmed that all 3 basic psychological needs predicted indicators of patient welfare. Relatedness correlated with an autonomy-supportive health care climate. In our study, the controlling patient family (P11) had had negative experiences with their health care providers. One way to prevent this family from experiencing distress or taking too much control might be to validate their negative experiences and to work with them to reframe it in a way that promotes relatedness.

A PCEHR could contribute to a positive health care climate if it allows patients to communicate their needs, values, and personal illness narratives to clinicians involved in their care. Furthermore, a PCEHR can connect all people involved in the patient's care as well as patients in a similar situation who are looking for exchange and support. The potential and benefits of digital support networks have been demonstrated by others [50]. In our study, participants did not explicitly mention the need to connect to people other than their health care providers through the PCEHR, but the potential benefits of facilitating social support through PCEHRs should be investigated in future research.

Theory on Taking and Relinquishing Control

Aujoulat et al [6] argue that the process of relinquishing control is as necessary as gaining control for patient empowerment. A strong sense of mastery and a feeling of control can sometimes even indicate that a patient is avoiding awareness of the impact illness has on his/her life [6]. Technologies for patient empowerment are usually designed to foster the feeling of mastery and control. However, in line with the findings of Aujoulat et al [6], our study shows that these technologies have to support the process of relinquishing control as well. We have identified 2 ways in which PCEHRs might help patients to relinquish control.

First, as noted by Aujoulat et al [6], understanding and accepting the cause of the illness can help with relinquishing control. Therefore, one approach is to provide patients with enough information to comprehend the rationale behind diagnosis and treatment, and to understand that they are not to blame for the diagnosis and that their control over the disease is limited.

Second, technology for patient empowerment might enable patients to articulate their needs for support: patients could communicate their needs and values in the PCEHR, share their

illness narrative with their health care providers, request support, and explicitly choose not to take control and responsibility for a part of the treatment. In some cases, this may mean that patients elect not to receive information (eg, test results) before their next clinic appointment: for some patients, information can increase anxiety, when the patient is not prepared to take responsibility for interpreting that information independently of their clinical team. If self-awareness and choice are central themes in patient empowerment, the conscious decision not to take control of some aspects of an illness can itself be empowering.

Study Limitations

For reasons outlined earlier, the number of participants in some groups (particularly the outlier) was small; however, in terms of theoretical constructs, the study maps closely onto constructs that have previously been identified by others (while highlighting their significance in a new study context), giving confidence that the findings are likely to generalize beyond this particular study population.

The study was conducted across 2 departments of one children's hospital. Apart from participant 10, who was a patient under the care of the hospital, all participants were families; in most cases, the mother was the principal participant. Because the findings resonate with those of earlier studies on patient empowerment [6] and on patients' coping styles, it is likely that these findings would generalize to patients as well as families, but this should be verified through a complementary study in an adult hospital, with individuals who are managing their own health. Another area for future research is the transition period (ie, when parents relinquish control to the patient), and how the PCEHR can support that transition.

The controlling patient family (P11) had had negative experiences with health care providers. Future research is needed that investigates whether patients with a different coping style, for example, collaborators or cooperators, would adopt similar behavior if they experienced a significant negative health event like a clinical error.

Participants were all families in which a child was suffering from a chronic and complex condition, under the care of a specialist children's hospital. Many of the children involved were under the care of multiple clinicians across several sites (eg, General Practitioner/Primary Care practitioner, local hospital, specialist hospital), so their needs for care, and for coordination of care, are at an extreme of complexity. Consequently, participants might be expected to have strong motivations to engage with a PCEHR that helps with managing that complexity; also, most of them were highly experienced at coping with their child's condition. The distribution of coping strategies and ways of engaging with a PCEHR might be different in a user population with less complex conditions, or conditions of shorter duration. Nevertheless, we have no reason to believe that the relationship between coping style and engagement with the PCEHR would differ substantively from that found in this study.

Patient families' coping, and consequently their user needs, are likely to vary over the course of a disease. A patient who was recently diagnosed might, for example, have a greater need for explanatory information than a patient who has lived with a disease for many years. As our study was conducted in 3 months, we were not able to gather data about changing user needs; this is an area for future work.

While previous work suggested that computer, reading, or health literacy influence the adoption or nonadoption of a PHR [44], in our data the patient's adjustment toward the disease correlated with motivation to use the PCEHR. Our data do not support the level of analysis necessary to discard or confirm the influence of participants' literacy; again, this is an area for future work.

Conclusion

In summary, in this study, we found that not all patient families are willing to take more control and responsibility in their health management, or motivated to use technology that is meant to empower them.

An important source of differences in patient families' needs and wants was found to be their coping styles. Approach-oriented people were found to use the PCEHR heavily to track symptoms, medication, and food intake and to investigate test results. By contrast, avoidance-oriented people used the PCEHR only when necessary to coordinate care or to communicate with the clinical team, or did not use it at all.

Importantly, extensive use of a PCEHR did not necessarily indicate that a patient family felt empowered. As noted by Aujoulat et al [6], true patient empowerment necessitates both taking and relinquishing control. However, motivation to take control is only empowering if it is intrinsic: that is, if basic needs for competence, autonomy, and relatedness are fulfilled.

The focus of this study has been on PCEHRs, which can increase motivation to take responsibility in health management, potentially allowing people to better understand causal relations between treatments, other actions, and outcomes, and to identify opportunities for improvement. Timely access to health information also gives people, who are experts in managing their own (or their child's) care, the opportunity to see if they can find something the doctors are missing.

Looking to the future, patient empowerment interventions should be systematically designed to meet people's needs in managing care. In the study reported here, coping style was identified as an important attribute that needs to be taken into account in designing and deploying interventions. It is not sufficient to "activate" patients as if all patients respond in the same way to being given access to information and responsibility for managing care. The challenge is to tailor future systems to meet patients' (and families') needs, including their needs for autonomy, competence, and relatedness. We have outlined possible approaches to addressing these needs, while also highlighting areas for future study.

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Conflicts of Interest

None declared.

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Abbreviations

PCEHR: patient-controlled electronic health record
PHR: personal health record
PN: parenteral nutrition
SDT: Self-Determination Theory

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Original Paper

Effectiveness of a Web-Based Simulation in Improving Nurses' Workplace Practice With Deteriorating Ward Patients: A Pre- and Postintervention Study

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Abstract

Background: Nurses play an important role in detecting patients with clinical deterioration. However, the problem of nurses failing to trigger deteriorating ward patients still persists despite the implementation of a patient safety initiative, the Rapid Response System. A Web-based simulation was developed to enhance nurses' role in recognizing and responding to deteriorating patients. While studies have evaluated the effectiveness of the Web-based simulation on nurses' clinical performance in a simulated environment, no study has examined its impact on nurses' actual practice in the clinical setting.

Objective: The objective of this study was to evaluate the impact of Web-based simulation on nurses' recognition of and response to deteriorating patients in clinical settings. The outcomes were measured across all levels of Kirkpatrick's 4-level evaluation model with clinical outcome on triggering rates of deteriorating patients as the primary outcome measure.

Methods: A before-and-after study was conducted on two general wards at an acute care tertiary hospital over a 14-month period. All nurses from the two study wards who undertook the Web-based simulation as part of their continuing nursing education were invited to complete questionnaires at various time points to measure their motivational reaction, knowledge, and perceived transfer of learning. Clinical records on cases triggered by ward nurses from the two study wards were evaluated for frequency and types of triggers over a period of 6 months pre- and 6 months postintervention.

Results: The number of deteriorating patients triggered by ward nurses in a medical general ward increased significantly (P<.001) from pre- (84/937, 8.96%) to postintervention (91/624, 14.58%). The nurses reported positively on the transfer of learning (mean 3.89, SD 0.49) from the Web-based simulation to clinical practice. A significant increase (P<.001) on knowledge posttest score from pretest score was also reported. The nurses also perceived positively their motivation (mean 3.78, SD 0.56) to engage in the Web-based simulation.

Conclusions: This study provides evidence on the effectiveness of Web-based simulation in improving nursing practice when recognizing and responding to deteriorating patients. This educational tool could be implemented by nurse educators worldwide to address the educational needs of a large group of hospital nurses responsible for patients in clinical deterioration.

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KEYWORDS

Web-based simulation; clinical deterioration; nursing education; online learning; transfer of learning; nursing practice

Introduction

In contemporary acute health care settings, there have been increasing numbers of patients with complex health problems who are more likely to deteriorate during their hospital admission, leading to significant adverse events. This trend is expected to continue as a result of an increasing number of older and more acutely ill patients being cared for in general wards [1,2]. Adverse events are defined as unintended complications and injuries that lead to mortality, unplanned intensive care unit admissions, and cardiopulmonary arrests [3]. There is evidence suggesting that adverse events occurring in general wards are often related to suboptimal care provided by ward nurses [4]. Having the most frequent direct contact and responsibility for monitoring patient vital signs, ward nurses are in the best position to recognize warning signs, report these signs to appropriate health care staff, and initiate immediate actions before the arrival of appropriate help [5,6].

A patient safety initiative, the Rapid Response System (RRS), was widely implemented in acute care hospitals to improve the care of patients with unexpected clinical deterioration, with the aim of preventing serious adverse events [7]. This system consists of an afferent limb and an efferent limb. The afferent limb involves detecting patient deterioration and triggering a response, followed by the efferent limb where the response team treats and prevents further deterioration of the patient [8]. The problem of the afferent limb where ward nurses continue to fail in triggering patient deterioration still persists despite the implementation of track-and-trigger systems such as the Early Warning Score System (EWSS) [9,10].

Staff education is advocated for improving ward nurses' competencies in the care of deteriorating patients [5,11,12]. To date, simulation using mannequins has been widely implemented to provide opportunities for nurses to problem solve clinical situations of patient deterioration in a safe and controlled environment [13,14]. However, given the resource-intensive nature of this simulation, which requires simulation facilities, trained facilitators, and small group learning, it has constraints in providing a scalable and sustainable training [15]. With the advancement in multimedia technology, these constraints could be eased as it is now possible for situating simulations in Web-based learning, known as Web-based simulation [16].

Web-based simulation has been widely adopted for training health professionals [16,17]. A Web-based simulation using a virtual patient, known as e-RAPIDS (Rescuing a Patient in Deteriorating Situations), was developed at the National University of Singapore (NUS) by a multidisciplinary health care team from academic and clinical institutions for undergraduate nursing training to enhance student nurses' clinical performance in assessing and managing deteriorating patients. Using a randomized controlled trial (RCT) study, e-RAPIDS was shown to be at least as effective as, if not better than, the mannequin-based simulation in improving nursing performance [18]. The successful implementation of the Web-based simulation for undergraduate nurses has prompted us to further develop Web-based simulation for training of hospital nurses. As a large group of hospital ward nurses was to be trained, Web-based simulation appeared to be a more cost-effective training method compared to the mannequin-based simulation. To address the educational needs of hospital nurses, more learning content was added and delivered through a variety of instructional strategies (animation and multimedia instructional materials) in e-RAPIDS. The learning materials were validated by a hospital nurse educator and medical clinician [19]. The effectiveness of e-RAPIDS in improving hospital nurses' competencies at assessing and managing clinical deterioration was demonstrated in a simulated environment through an RCT [20].

Although previous studies have used rigorous research methodologies like RCTs to evaluate the outcomes of e-RAPIDS [18,20], the quality of evidence was limited in the context of a simulated environment and at Level 2 (learning outcomes) of Kirkpartick's hierarchy of educational outcomes [21]. This study aimed to evaluate the impact of e-RAPIDS in clinical settings on improving nursing practice in recognizing and responding to deteriorating patients. The outcomes were measured across the levels of Kirpatrick's evaluation model adapted by Tochel et al [22] with changes in nursing practice on triggering rates of deteriorating patients (Level 4A) as the primary outcome measure. We hypothesized that the number of cases triggered by the nurses would increase after the e-RAPIDS training. Secondary outcome measures included motivation (Level 1), knowledge (Level 2b), and perceived training transfer (Level 3).

Methods

Study Designs, Setting, and Participants

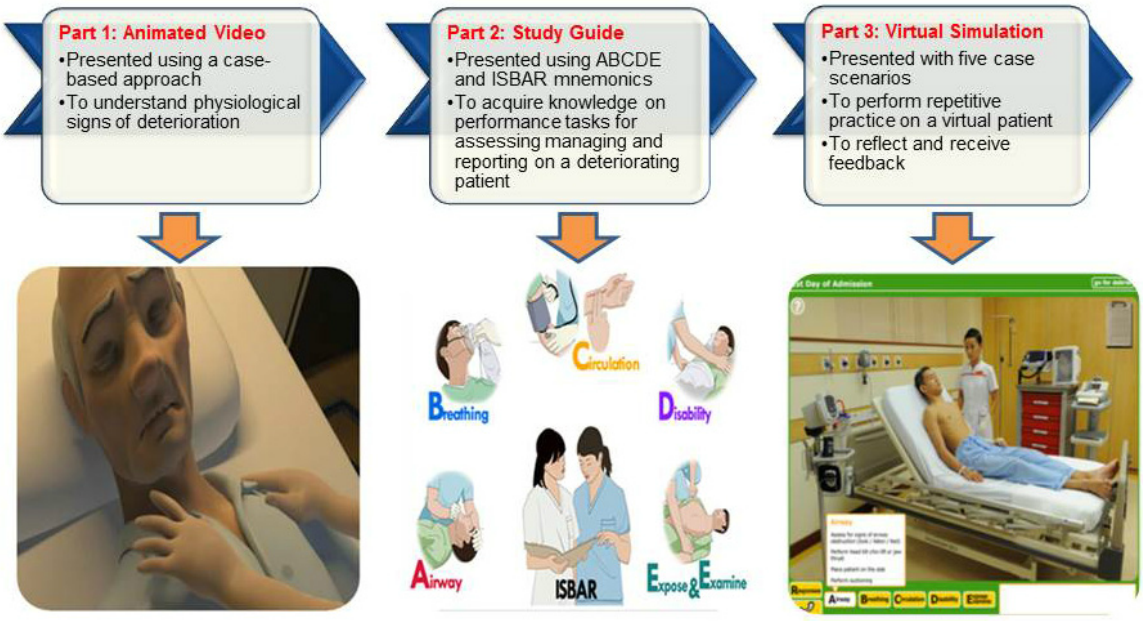
After receiving approval from an institutional review board, a pre- and postintervention study was conducted on one surgical ward and one medical general ward at an acute care tertiary hospital. The hospital is a 991-bed teaching hospital at a university in Singapore. These two study wards were chosen for their specialties and their high triggering rates based on previously recorded trigger forms. All registered nurses (RNs) and enrolled nurses (ENs) who were working in these two wards during the study period were scheduled to undertake the e-RAPIDS training, as part of their continuous nursing education, at the Centre for Healthcare Simulation from June 1-August 14, 2014.

Implementation of e-RAPIDS

The nurses were individually brought into a room equipped with a computer set-up. The RNs and ENs were assigned a different version of e-RAPIDS: the RN version for RNs and the EN version for ENs. They were all instructed to follow the learning path and complete three parts of the program (see Figure 1). The first part required the participants to watch an animated video that focuses on early detection of changes in vital signs. Using a case scenario of a deteriorating patient, the animated video presented the early underlying compensatory mechanisms that highlighted the importance of recognizing an increase in respiratory rate and heart rate as early signs of patient deterioration. The second part was a study guide, which was presented using multimedia instructional materials (eg, texts, illustration, and audio of lung sounds), on the list of performance

tasks to assess, manage, and report on a deteriorating patient. These tasks were organized using the ABCDE (Airway, Breathing, Circulation, Disability, and Expose/Examine) and ISBAR (Identity, Situation, Background, Assessment, and Recommendation) mnemonics. The lists of tasks included in the RN version and EN version were based on the scope of practice and roles as RNs or ENs. The final part of the program was a virtual simulation that was embedded with five simulation scenarios associated with a patient who has deteriorating conditions. The nurses were instructed to attempt all five scenarios. In each scenario, the nurses were taken through 4 steps: (1) select appropriate actions from the control menus (eg, ABCDE and ISBAR) to assess, manage, and report on the deteriorating patient, (2) reflect on the simulation experience using the debriefing questions, (3) review the evaluation checklist and receive feedback on the actions taken in the simulation scenario, and (4) to undertake a short multiple-choice questionnaire (MCQ) to evaluate their knowledge of the subject content. The entire e-RAPIDS lasted approximately 2.5-3 hours, and the website can be accessed by anyone [23].

Figure 1. Learning path in e-RAPIDS.



Evaluation of e-RAPIDS

The Kirpatrick's evaluation model, adapted by Tochel et al for classifying the outcomes of educational intervention, was applied in this study to guide the evaluation of e-RAPIDS. These levels include Level 1 (participation), Level 2a (modification of attitudes), Level 2b (modification of knowledge or skills), Level 3 (behavioral change), Level 4a (change in organizational practice), and Level 4b (benefit to patients/clients) [22].

Participation: Motivational Reaction (Level 1)

All participants were invited to complete the Instructional Material Motivation Survey (IMMS), which used a 5-point Likert scale, immediately after completing the e-RAPIDS. The survey assessed their motivational reactions to the program using the four characteristics (Attention, Relevance, Confidence, and Satisfaction) from Keller's model of motivational design [24]. Cronbach alpha reported for this study was .79 for scores from all IMMS dimensions.

Modification of Knowledge (Level 2b)

The participants' knowledge on clinical deterioration was assessed through the 30-item MCQ that was administered immediately before and after e-RAPIDS. Two sets of questionnaires, RN-MCQ for RNs and EN-MCQ for ENs, were developed that aligned with the program's learning objectives. The content validity of the questionnaires was established by a panel of medical and surgical care experts.

Behavioral Changes: Training Transfer at Workplace (Level 3)

This level was evaluated through a self-reported questionnaire that was conducted 3-4 months after the e-RAPIDS took place. All nurses who had undertaken the learning were invited to complete a questionnaire, which used a 5-point Likert response scale, on their perceived training transfer at workplace. The questionnaire was adapted and modified from a previous study [25] to fit our study's situation. While a previous study reported a Cronbach alpha of <.80 [25], our study obtained a high internal consistency of Cronbach alpha=.94.

Change in Organizational Practice: Trigger Cases (Level 4a)

Clinical records on cases triggered by ward nurses from the two study wards were checked by an investigator for frequency and types of triggers over a period of 6 months pre- (December 2013 to May 2014) and 6 months postintervention (August 2014 to February 2015). The types of trigger included respiratory rate, oxygen saturation, pulse rate, blood pressure, acute change in mental status, and serious concern. The patient characteristics of the two wards, including the number of admitted patients,

number of occupied beds, length of stays, and age were also measured from the hospital admission.

Data Analysis

Descriptive statistics of the study population and ward characteristics are presented using means, standard deviations, counts, and percentages. Means and standard deviation were calculated to examine the participants' motivational reaction and perceived transfer of learning. Paired *t* test was used to examine any significant changes between the baseline and posttest knowledge scores. Independent sample *t* test was used to determine any significant differences between the RN and EN groups. Chi-square test or Fisher's exact test was performed for comparisons of binomial proportions between the pre-and postintervention periods.

Results

Demographics

A total of 99 nurses (85% participation rate) from the surgical ward (53/99, 54%) and medical ward (46/99, 46%) participated in the e-RAPIDS training, with a total of 64 RNs and 35 ENs. Most of them were female (95/99, 96%) with an average age of 27.63 years (SD 5.54). About half had a bachelor's degree (49/99, 50%) and less than 3 years of work experience (48/99, 49%). All of them completed the IMMS and knowledge tests. Among those nurses who undertook the education, 84% (83/99) of them (25 ENs and 58 RNs) completed the questionnaire on their perceived training transfer at workplace.

Motivational Reaction

As shown in Table 1, the overall IMMS mean scores (mean 3.78, SD 0.56) of the nurses indicated that they were motivated to learn the e-RAPIDS. The subscale score of the IMMS indicated that the nurses perceived highly positively the practical relevance of the content and were highly satisfied with the program. The program was also perceived to be more stimulating in capturing attention (mean 4.06, SD 0.52 vs mean 3.00, SD 0.48, $P<.001$) as well as building a higher level of confidence (mean 3.83, SD 0.44 vs mean 2.73, SD 0.53, $P<.001$) among the RNs than the ENs. The overall scores of the RNs (mean 4.02, SD 0.43) were significantly higher ($P<.001$) than the ENs (mean 3.34, SD 0.51).

Table 1. Mean motivation scores (N=99).

	Mean (SD)	95% confidence interval
Overall	3.78 (0.56)	3.67-3.89
Subscales		
Attention	3.67 (0.73)	3.52-3.81
Relevance	4.11 (0.58)	3.99-4.22
Confidence	3.44 (0.71)	3.30-3.58
Satisfaction	4.01 (0.71)	3.87-4.15

Knowledge

After the educational intervention, the RN group demonstrated a significant increase ($P<.001$) on knowledge posttest scores (mean 22.47, SD 2.99) from pretest score (mean 18.80, SD 3.05). Similarly, the EN group also showed a significant improvement ($P<.001$) on the knowledge posttest scores (mean 19.57, SD 3.97) from the pretest score (mean 16.57, SD 3.99).

Training Transfer at Workplace

As shown in Table 2, the participants demonstrated positive attitudes (mean 3.89, SD 0.49) toward the transfer of learning to clinical practice with mean scores on each item that ranged from 3.39-4.13. No significant difference was found between the RNs (mean 3.82, SD 0.52) and ENs (mean 4.06, SD 0.39).

Table 2. Perceived attitudes towards training transfer among the nurses (N=83).

Items	Mean (SD)	95% confidence interval
I will make a plan to put into practice what I have learned after I get back to the workplace.	3.99 (0.57)	3.86-4.11
I will work as hard as possible to put into practice what I have learned for the patients' benefit.	4.05 (0.62)	3.91-4.18
My work is more organized after I have put into practice what I have learned from the training.	3.87 (0.60)	3.74-4.00
It will be disgraceful if I do not put into practice what I have learned from the training I attended.	3.72 (0.77)	3.55-3.89
I am sure that what I have learned from the training is put into practice for the patients' benefit.	4.13 (0.54)	4.02-4.25
I feel motivated toward my role in patient deterioration after having attended the training programs.	3.95 (0.71)	3.80-4.11
My commitment towards my role in patient deterioration has increased as a result of attending the training programs.	3.90 (0.76)	3.74-4.07
Supervisors or peers have told me that my performance has improved following the training programs.	3.39 (0.68)	3.24-3.53
I work with more confidence after putting into practice what I have learned from the training.	3.95 (0.64)	3.81-4.09
I have changed my behavior in order to be consistent with the material taught in the training programs.	3.87 (0.62)	3.73-4.00
I knew that I would benefit from the training.	4.07 (0.69)	3.92-4.22
My work performance improved after I attended the training.	3.88 (0.65)	3.74-4.02
My work will be rewarded if I put into practice what I have learned.	3.75 (0.66)	3.60-3.89
I am capable of putting into practice what I have learned from the training even though I am busy.	3.98 (0.54)	3.86-4.09

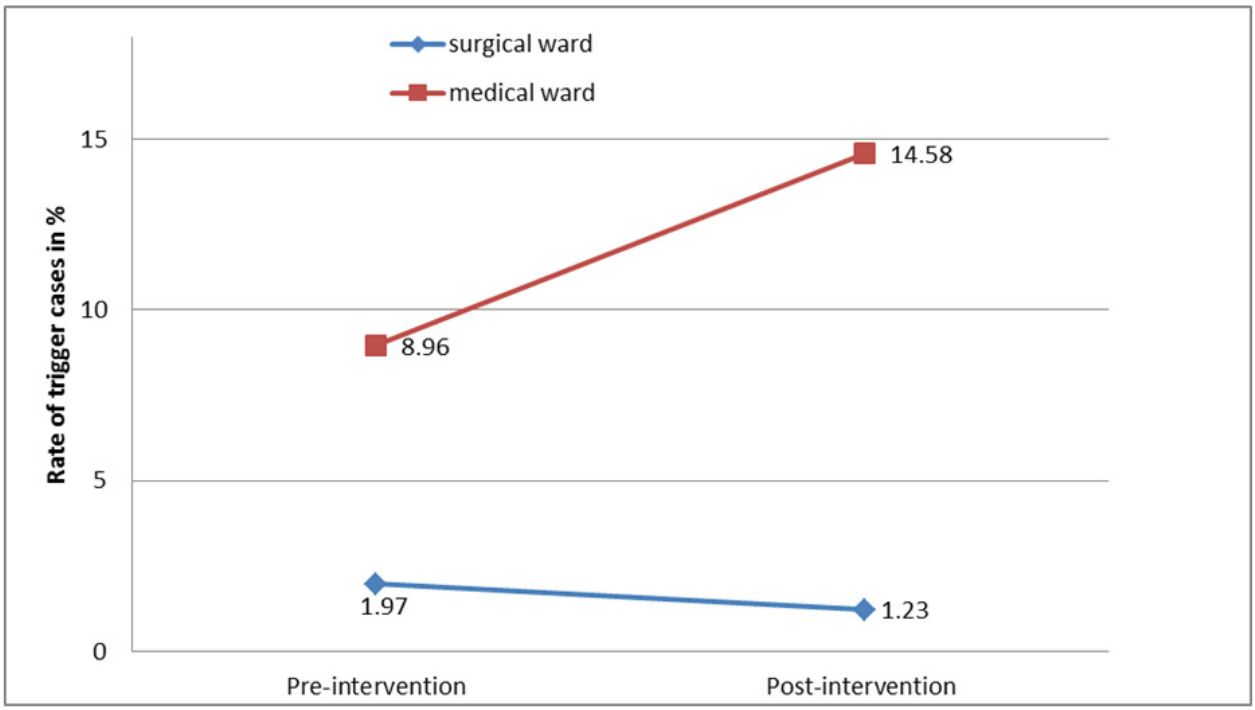
Trigger Cases

We studied 2155 patients during the pre-intervention period compared to 1841 patients during the postintervention period. The characteristics were similar between the two periods, but there was a significant increase (P<.05) in hospital length of stay in the surgical unit (see Table 3). As shown in Figure 2, the number of cases triggered by nurses in the medical ward increased significantly (P<.001) from 8.96% (84/937) in the pre-intervention period to 14.58% (91/624) in the postintervention period. However, no significant difference (P=.15) between the pre- (24/1218, 1.97%) and postintervention period (15/1217, 1.23%) was found in the surgical unit. The analysis of each type of trigger did not show any significant differences between the pre- and postintervention periods.

Table 3. Characteristics of the two wards during the study period.

	6 months, pre- (n=2155)	6 months, post (n=1841)	*P* value
Age of patients in years, mean (SD)			
Surgical unit	60.64 (17.78)	61.11 (18.01)	.21
Medical unit	68.30 (18.35)	69.73 (18.96)	.51
Length of stay in days, mean (SD)			
Surgical unit	5.68 (7.71)	6.01 (9.36)	.02
Medical unit	6.50 (7.54)	6.66 (8.27)	.06
Occupied beds per day, mean (SD)			
Surgical unit	42.29 (0.79)	41.79 (0.87)	.21
Medical unit	43.10 (0.63)	43.11 (0.32)	.84

Figure 2. Rate of trigger cases at 6 months pre-intervention and 6 months postintervention.



Discussion

Principal Findings

We measured the outcomes across the levels of an existing adaptation of Kirpatrick's model [22] during a 14-month period to evaluate the impact of e-RAPIDS. At Level 4a, change in organization practice, we found a significantly increased number of cases being triggered by nurses in the medical ward but no changes in the surgical ward. This could be due to the characteristics of patients admitted to the medical ward who were more likely to deteriorate from their underlying medical diagnosis and comorbidities than the surgical patients. Nevertheless, the improved outcome from the triggering data of the medical ward provided some evidence to support the effectiveness of e-RAPIDS in improving nursing practice on recognizing and responding to deteriorating ward patients. This evidence was further supported by the self-reported perceived training transfer (Level 3) that verified the change of nurses' behaviors in their workplace after the educational intervention. This improvement in nursing practice could ultimately lead to better patient outcomes. However, as the intervention focused only on the afferent limb of RRS, the evaluation of patient outcomes (Level 4b) that are also dependent on the effectiveness of the response team (efferent limb) is beyond the scope of this study.

As shown in our study, the knowledge gained from e-RAPIDS has resulted in the transfer of learning to the nurses' clinical practice. Consistent with a previous study [20], our findings reinforced the effectiveness of e-RAPIDS in improving the nurses' knowledge in recognizing and responding to deteriorating ward patients. This study therefore supports the acquisition of this relevant learning content in supporting the role of nurses in their care of deterioriating patients in clinical practice. However, given the relatively low level of confidence reported by the ENs, the level of difficulty of the learning content for the EN version may need further examination. Apart from the learning content, the knowledge gained observed could be uniquely attributed to the variety of instructional strategies incorporated into e-RAPIDS. The acquisition of factual knowledge using multimedia such as animation video, text, and audio was followed by the application of knowledge through repetition, practice, and feedback in the virtual patient scenarios [19]. The resemblance of the virtual patient scenarios to equivalent real-life scenarios provides an authentic learning context that reflects the way knowledge and skills will be applied in the actual workplace [18]. This authenticity was identified as a critical determinant of learning transfer [26].

Nurses' positive motivation to engage in e-RAPIDS was reported in this study, demonstrating the acceptability of this learning strategy as part of their continuing nursing education. Similar to the learning of cardiopulmonary resuscitation, the opportunity to engage in repetitive training is essential for the retention of knowledge and skills in assessing and managing deteriorating ward patients. A previous study demonstrated the effective use of either the virtual patient simulation or mannequin-based simulation, with no superiority over each other, as a refresher learning strategy for maintenance of clinical performances [18]. However, with the high resource intensity associated with the mannequin-based simulation, the feasibility of engaging in repetitive training to maintain the competency of a large group of hospital nurses is challenging [19]. In contrast, e-RAPIDS provides unlimited training opportunities, which makes it a viable option for training a large number of nurses to achieve long-term retention of learning. Apart from using it as a refresher training course, e-RAPIDS could serve as a promising self-directed learning strategy to prepare nurses for mannequin-based simulation experience [19]. Future training

could implement these learning strategies, forming part of a blended-learning strategy [27], to optimize the impact of RRS. While the e-RAPIDS could emphasize the nursing role in assessing and managing a deteriorating patient, the mannequin-based simulation could extend this to involve effective communication and teamwork through interprofessional training. Future studies could evaluate the effectiveness of this blended-learning strategy on the RRS by evaluating patient outcomes.

Limitations

An important limitation of this study is the lack of a control group that received no educational intervention. The vast difference in characteristics between the wards at the study hospital made it difficult to identify the control wards that are comparable to the intervention wards. Nevertheless, the before-and-after design, the follow-up at 2-3 months after training, and the triangulation of the results provided reassurance on the robustness of the study outcomes. Another limitation is the clinical outcome measure that we evaluated based on the documented triggers. Given the short timeline of this study, the triggering rates were measured for a relatively short period. Moreover, due to the logistic constraints of this study, we did not assess triggers that were missed from the vital signs documentation.

Conclusion

Using a before-and-after study design that was conducted over a 14-month period, this study provides evidence on the effectiveness of e-RAPIDS on improving nursing practice in recognizing and responding to deteriorating patients. This evidence was demonstrated by the significantly increased number of deteriorating patients triggered by ward nurses in the medical ward after the implementation of the educational intervention. The study also provides evidence on the knowledge gained from e-RAPIDS that resulted in the transfer of learning to the nurses' clinical practice. This Web-based simulation could be used by nurse educators worldwide to address the educational needs of nurses in clinical deterioration. Future effort is needed to optimize the use of e-RAPIDS with other educational strategies such as interprofessional simulation training and to evaluate the impact of this blended-learning strategy on patient outcomes.

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Conflicts of Interest

The first author is the owner and developer of e-RAPIDS.

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Abbreviations

ABDCDE: airway, breathing, circulation, disability, and expose/examine
ENs: enrolled nurses
EWSS: Early Warning Score System
IMMS: Instructional Material Motivation Survey
ISBAR: identity, situation, background, assessment, and recommendation
MCQ: multiple choice questionnaire
NUH: National University Hospital
NUS: National University of Singapore
RAPIDS: Rescuing A Patient In Deteriorating Situations
RCT: randomized controlled trial
RN: registered nurse
RRS: Rapid Response System

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Original Paper

Behavioral Outcome Effects of Serious Gaming as an Adjunct to Treatment for Children With Attention-Deficit/Hyperactivity Disorder: A Randomized Controlled Trial

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Abstract

Background: The need for accessible and motivating treatment approaches within mental health has led to the development of an Internet-based serious game intervention (called “Plan-It Commander”) as an adjunct to treatment as usual for children with attention-deficit/hyperactivity disorder (ADHD).

Objective: The aim was to determine the effects of Plan-It Commander on daily life skills of children with ADHD in a multisite randomized controlled crossover open-label trial.

Methods: Participants (N=170) in this 20-week trial had a diagnosis of ADHD and ranged in age from 8 to 12 years (male: 80.6%, 137/170; female: 19.4%, 33/170). They were randomized to a serious game intervention group (group 1; n=88) or a treatment-as-usual crossover group (group 2; n=82). Participants randomized to group 1 received a serious game intervention in addition to treatment as usual for the first 10 weeks and then received treatment as usual for the next 10 weeks. Participants randomized to group 2 received treatment as usual for the first 10 weeks and crossed over to the serious game intervention in addition to treatment as usual for the subsequent 10 weeks. Primary (parent report) and secondary (parent, teacher, and child self-report) outcome measures were administered at baseline, 10 weeks, and 10-week follow-up.

Results: After 10 weeks, participants in group 1 compared to group 2 achieved significantly greater improvements on the primary outcome of time management skills (parent-reported; *P*=.004) and on secondary outcomes of the social skill of responsibility (parent-reported; *P*=.04), and working memory (parent-reported; *P*=.02). Parents and teachers reported that total social skills improved over time within groups, whereas effects on total social skills and teacher-reported planning/organizing skills were nonsignificant between groups. Within group 1, positive effects were maintained or further improved in the last 10 weeks of the study. Participants in group 2, who played the serious game during the second period of the study (weeks 10 to 20), improved on comparable domains of daily life functioning over time.

Conclusions: Plan-It Commander offers an effective therapeutic approach as an adjunct intervention to traditional therapeutic ADHD approaches that improve functional outcomes in daily life.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 62056259; http://www.controlled-trials.com/ISRCTN62056259 (Archived by WebCite at http://www.webcitation.org/6eNsiTDJV).

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KEYWORDS

attention deficit-hyperactivity disorder; ADHD; serious game; Internet; children; treatment; randomized controlled trial

Introduction

Attention-deficit/hyperactivity disorder (ADHD) is the most common childhood neurodevelopmental disorder with young patients experiencing functional impairments in different areas of daily life [1-5]. Compared to children without the disorder, children with ADHD have more difficulties at school making schedules to finish assignments on time, executing complex planning tasks, organizing material needed for assignments, remembering task instructions, and setting priorities [6,7]. Thus, it is not surprising that children with ADHD are more likely to show academic underachievement, poor academic performance, and educational problems compared to their counterparts without the diagnosis [8]. Children with ADHD also show impairments in social functioning. They are rejected more often by their peers and have more conflicts with other children and adults compared to their counterparts who do not have ADHD [9]. Although understudied, impaired social functioning in children with ADHD has serious long-term consequences for the development of conduct disorder and even some substance use disorders [10]. Without proper interventions, functional impairments in the areas of time management, planning/organizing, and prosocial behavior skills often endure and escalate into adolescence and adulthood [6,7,11-14].

Although stimulant medication has been shown to reduce ADHD core symptoms among children with ADHD, effects are limited with regard to children's behavioral, social, and cognitive functioning in daily life [15]. Behavioral interventions developed to improve these children's functional outcomes, although effective [7,14,16], are often time-consuming, costly, and not easily accessible to all children who might benefit from them [17-19]. Moreover, it appears that 50% of patients with ADHD discontinue treatment regardless of its efficacy or symptom severity [20]. Because of their difficulties with sustaining attention and motivation, patients with ADHD experience low engagement during therapy [21]. Consequently, there is a need to explore more rich interactive experiences with visual effects in computer-based therapy approaches in addition to traditional pharmacological, school-based, and mental health approaches that positively impact the daily life functioning of children with ADHD. The use of Internet-based therapeutic approaches to support and improve health care is growing because of their potential to offer attractive, easily accessible, and efficient interventions outside the clinical setting [19,22,23]. This fits into the World Health Organization Mental Health Action Plan 2013-2020, which promotes accessible user-driven options emphasizing early intervention and autonomy of individuals, thereby promoting nonpharmacological therapies for young patients [22].

A growing number of computerized training programs for ADHD have been designed to improve working memory and executive functioning, thereby addressing specific neurocognitive deficits and ADHD core symptoms [24,25]. Commercial versions of the tasks used in these studies have become readily available (eg, Cogmed, Cognifit, and Memory Booster) [26]. Although these programs show some evidence for short-term effects on targeted working memory outcomes as measured by neurocognitive tests similar to the ones practiced in the games, they have not shown compelling evidence that these effects generalize beyond neurocognitive outcomes to important domains of functioning in the daily lives of children with ADHD (so-called "far-transfer effects") [27-29]. These findings are consistent with studies examining the effectiveness of "brain training" games within a "normal" population [30]. Moreover, few have game mechanics features with a narrative journey structure. It is worth exploring whether or not an Internet-based therapeutic approach with richer interactive experiences with visual effects could improve functional outcomes in children with ADHD.

Serious gaming (ie, [digital] games used for purposes other than purely entertainment) is a novel and promising approach to support the treatment of clinical symptoms and improvement of adaptive functioning among diverse patient groups [31-35]. Such games offer an environment in which attractive learning tasks are presented in a way that addresses the difficulties that children with ADHD often have in engaging with "boring" and repetitive training tasks [36-38]. These games are characterized by a high-intensity immediate reinforcement and this appears to improve task performance, especially within ADHD populations [39,40]. Serious games differ from existing computerized neurocognitive training programs in several ways. Firstly, they offer an overall game environment that allows for

exploration and a meaningful ongoing "journey narrative" instead of offering a "casual" gamelike interface [41]. Secondly, these games not only focus on repeating training tasks, but also offer behavioral strategies (eg, reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison) to increase daily life functioning, thereby potentially enhancing generalization effects. Serious games offer an attractive and accessible online learning environment in which children with ADHD stay motivated to train their skills and learn strategies to deal with impairments that affect functional outcomes in daily life. Although the scientific evaluation of serious games precludes making conclusive statements about their impact on "real-world" behaviors, several controlled trials of serious games have shown to affect these behaviors in diverse patient groups [42].

To our knowledge, a serious game designed to enhance behavior strategies for children with ADHD to improve their daily life functioning has not been scientifically evaluated in the literature. We developed a serious game intervention for children with ADHD to teach and reinforce daily life skills, such as time management, planning/organizing, and cooperation skills [43]. Previous exploratory research in a pilot study of a prototype of the game demonstrated improvement of time management (KCMB, unpublished data, 2016). This study examines the effects of this serious game (called "Plan-It Commander") as an additional Internet-based adjunct to the treatment of ADHD in children. We hypothesized that participants playing the serious game would improve on primary outcome measures of time management, planning/organizing, and cooperation skills compared to participants in the crossover control group. We hypothesized that participants would also improve on secondary outcome measures of working memory, social skills (ie, responsibility, assertiveness, and self-control) and self-efficacy because these skills were also trained within the overall game environment. We further hypothesized that treatment effects would be maintained at 10-week follow-up for the group that played the serious game for the first 10 weeks of the study.

Methods

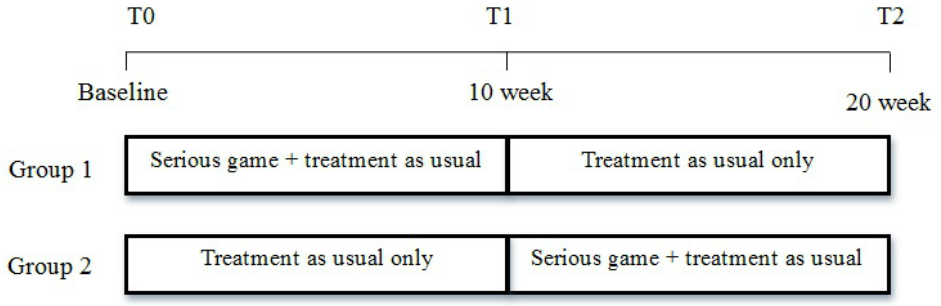
Participants

A total of 182 participants were recruited from January to March 2013 across 4 outpatient mental health care clinics and institutions in the Netherlands and Belgium. Eligible parents and children were informed by their clinician about this study. In other cases, the patient organization provided information about the study to their members; these parents directly applied for the study. Once the clinician identified eligible parents and children, they received detailed written and verbal information about the study from the researcher. After signing informed consent, they were invited for a screening visit (performed by trained research assistants with MA in psychology) to verify inclusion and exclusion criteria. This resulted in a sample of 170 participants. Inclusion criteria were (1) a *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (*DSM-IV-TR*) diagnosis of ADHD (confirmed by the Kiddie Schedule for Affective Disorders and Schizophrenia-Lifetime version [K-SADS] [44,45]), (2) aged between 8 and 12 years, (3) stable on pharmacological and/or psychological treatment for ADHD 8 weeks before baseline (determined by health care professionals on the basis of medication data and behavioral observation), (4) no initiation or change of pharmacological and/or psychological treatment for ADHD during the study period, (5) availability of a computer workstation at home with Internet and sound facilities, and (6) sufficient understanding of the Dutch language by the child and by at least one of the parents. ADHD severity was measured by the parent version of the Disruptive Behavior Disorder Rating Scale (DBDRS) [46,47] and children with common comorbid disorders of ADHD (eg, oppositional defiant disorder as measured by the DBDRS) could participate in the study. Exclusion criteria were (1) an estimated total Intelligent Quotient (IQ) lower than 80 (determined by vocabulary and block design subtests of the Wechsler Intelligence Scale for Children III [WISC-III] [36,48,49], (2) substance abuse problems (eg, drugs, alcohol), (3) conduct disorder, (4) autism spectrum disorder (both previously diagnosed by health care professionals), (5) comorbid acute psychiatric disorder (eg, depression, mania; confirmed by the K-SADS [44,45]), and (6) participation in a previous pilot study with a prototype of Plan-It Commander. Children with a severe physical disability (eg, blindness, deafness) or learning disability (eg, dyslexia) were also excluded on the basis of the child's medical file and a standardized interview administered by phone to parents. Written informed consent was obtained from parents and children aged 12 years. All study procedures were approved in advance by the Erasmus (Dutch; MEC-2012-539) and Leuven (Belgian) Medical Ethical Committees.

Design

This study used a 20-week multisite randomized controlled crossover open-label trial design (see Figure 1). The intervention was an online serious game called Plan-It Commander. Participants were randomized to a serious game intervention group (group 1) or a treatment-as-usual crossover group (group 2). Participants randomized to group 1 received a serious game intervention in addition to treatment as usual for the first 10 weeks and then received treatment as usual only for the next 10 weeks. Participants randomized to group 2 received treatment as usual for the first 10 weeks and crossed over to the serious game intervention in addition to treatment as usual for the subsequent 10 weeks. All participants in the study received treatment as usual and most participants (91.8%, 156/170) were on medication. Participants were instructed to play the serious game for a maximum of 65 minutes approximately 3 times per week. The game was programmed so that participants could not play more than 65 minutes in one 24-hour period to prevent excessive use of the game. The CONSORT EHEALTH checklist is presented as Multimedia Appendix 1

Figure 1. Study design with both groups.



Randomization and Blinding

Randomization was carried out on a 1:1 ratio and based on a prespecified computer-generated randomization list. Allocation was stratified by study site and gender and arranged in permutated blocks. Group assignment was performed online using the next available number on the randomization list corresponding to the site and gender of the participant. It was not possible to blind participants to their treatment allocation. After screening and baseline assessment, parents received an email with the notification to which group (group 1 vs group 2) their child was allocated. Although all efforts were made to keep the investigator blind during baseline assessments, full blinding of researchers and teachers at the other assessment points could not be guaranteed because participants could spontaneously talk about the game during the study.

Intervention

The serious game is an online adventure game (called Plan-It Commander) developed by health care professionals, researchers, and game experts in collaboration with parents and children with ADHD. In collaboration with a focus group of parents, the multidisciplinary game development team agreed on the game's learning goals and play frequency/time. After each prototype build, usability tests were iteratively performed to examine whether children liked the game and understood how to use it and navigate within the game. User data were evaluated and incorporated in the design process for the final game format, which was examined in this study. Plan-It Commander was designed to improve domains of daily life functioning with a primary focus on time management, planning/organizing, and cooperation skills in children with ADHD. Unifying their knowledge and expertise resulted in a unique online learning environment in which principles of behavior therapy and game-based learning were combined [43]. Players had their own password and ID to log on to the Internet-based serious game from their home where they could access 2 game components: (1) a mission-guided game environment with minigames related to the learning goals of time management, planning/organizing, and cooperation skills and (2) a closed social community. The game was linked to a database in which data about play frequency and duration were registered from each participant.

Plan-It Commander is a mission-guided game divided into 10 different missions and several side missions (Figure 2). Missions guide the player's behavior throughout the game as he or she follows the storyline and is asked to solve problems requiring specific skills. Central parts are the 3 minigames addressing time management, planning/organizing, and prosocial behavior that are embedded in the structure of the game. The first minigame is focused on teaching the player time estimation and time management skills. The second minigame is focused on enhancing planning skills; the player is taught to plan ahead and break down the total assignment into pieces. The third minigame focuses on enhancing prosocial behavior, teaching the player to help their team members and to cooperate with each other. In addition to the mission-guided game, players could access a closed social community (called "Space Club") to stimulate prosocial behavior (eg, helping other players, giving compliments) (Figure 3). Players can ask for help or help other players through predefined messages and reward them with a thank you message. The player's profile is presented within the community and shows an overview of his or her progression throughout the game. When a player completes certain "challenges" in the mission-guided game, an achievement is unlocked in the community. Every player has an overview of awarded achievements in the form of badges or medals in their profile within the community. By making progress in the game and reaching certain milestones, the player unlocks rewards in the community. Rewards can vary in form, such as papercraft models, desktop wallpapers, and music from the game. Players can see each other's profiles and this generates competition between players. Details of the development and content of Plan-It Commander are described elsewhere [43].

Figure 2. Screenshot of Plan-It Commander game world.

Figure 3. Screenshot of game social community (called “Space Club”).

Measures

Multi-informant (parent, teacher, and self-report) measures were administered at baseline (T0), at 10 weeks (T1), and at 10-week follow-up (T2). Parent and teacher reports were administered through online questionnaires. Questionnaires were administered to the children during face-to-face appointments at each assessment time point. At baseline, demographic information and children’s game experience were collected through parent reports. The parent reported on the game experience of their child as starter, amateur, experienced, or expert. For the primary outcomes, parents filled in the following questionnaires during the 3 assessment time points: (1) a time management questionnaire (Multimedia Appendix 2), (2) the subscale Plan/Organize of the Behavior Rating Inventory of Executive Function (BRIEF; parent version) [50,51], and (3) the subscale

Cooperation of the Social Skills Rating System (SSRS; parent version) [52,53]. The time management questionnaire gave a more detailed insight into children's behavior strategies used to improve their time management skills compared to other existing questionnaires (primarily focusing on time perception and/or coordination) and demonstrated good reliability (α=.85) in a pilot study (KCMB, unpublished data, 2016). Secondary outcomes consisted of parent, teacher, and self-reports. Parents filled in the subscale Working Memory of the BRIEF (parent version); the subscales Responsibility, Assertiveness, Self-Control, and Total of the SSRS (parent version); and the It's About Time Questionnaire (IATQ; parent version) [54]. In addition, teachers were asked to fill in the time management questionnaire, the subscales Plan/Organize and Working Memory of the BRIEF (teacher version), and the SSRS (teacher version) to provide an indication of how the participant functioned at school. Further, we asked participants to fill in a self-efficacy questionnaire (Multimedia Appendix 3) [55]. After receiving the serious game, both parents and participants filled in a satisfaction questionnaire indicating general satisfaction with the serious game on a 10-point Likert scale. Table 1 includes a description of each measure.

Table 1. Description of primary and secondary outcome measures.

Measures[a]	Respondent	Description	Cronbach alpha[b]
Primary outcomes			
Time management questionnaire	Parent and teacher report	This 11-item scale is a measure of children's time management behavior. Parents were asked to rate this behavior on a 10-point Likert scale (ranging from true to not true). The total score ranges from 11 to 110. Higher scores indicate better time management skills.	.83/.90
BRIEF (subscale Plan/Organize)	Parent and teacher report[c]	A measure of executive functioning in home situations in children aged 5-18 years. For this study, the subscale Plan/Organize, consisting of 12 items, was used to measure children's planning and organizing skills. The answers are scored on a 3-point Likert scale (never—sometimes—often). The total score ranges from 12 to 36. Higher scores indicate better planning skills.	.81/.80
SSRS (subscale Cooperation)	Parent and teacher report[d]	A measure of social functioning in children aged 8- 12 years. This questionnaire consists of 4 subscales (ie, Cooperation, Responsibility, Assertiveness, Self-Control) of 10 items each. The answers are scored on a 3-point Likert scale (never—sometimes—often). Two items load on 2 subscales; therefore, the total scale consists of 38 items and has a possible range from 0 to 80. Higher scores indicate better social skills.	.70/.84
Secondary outcomes			
IATQ	Parent report	A measure of children's skills in time perception and organization. It consists of 25 items scored on a 3-point Likert scale ranging from 0 "rarely" to 3 "almost always." The total score ranges from 0 to 75. Higher scores indicate better time-oriented behavior.	.74
Self-efficacy	Self-report	A measure of one's confidence in his/her ability to carry out specific behaviors related to time management, planning, and social functioning. This measure was constructed in accordance with the standard method for designing self-efficacy scales [55]. As such, it was designed specifically for this study to assess self-efficacy beliefs targeted in the game. Children were asked to rate 14 items on a scale from 0 to 10 how certain they are that they can master certain skills. The total score ranges from 0 to 140. Higher scores indicate more perceived self-efficacy.	.88
Satisfaction	Parent and self-report	Satisfaction was indicated on a 10-point Likert scale in which both children and parents were asked: "What grade would you give to this game?"	N/A

[a] BRIEF: Behavior Rating Inventory of Executive Functioning; SSRS: Social Skills Rating System; IATQ: It's About Time Questionnaire.

[b] Cronbach alpha is an indication of construct validity. Coefficients were calculated from baseline data in this sample.

[c] The subscale Working Memory (10 items) from the BRIEF was used as a secondary measure for parents (Cronbach alpha=.83) and teachers (Cronbach alpha=.85).

[d] The subscales Assertiveness, Responsibility, and Self-Control and the Total Score were used as secondary outcome measures for parents and teachers (except for the subscale Responsibility).

Statistical Power and Analyses

The sample size was determined in advance by power calculations on the basis of previous pilot study descriptive results (mean, SD) on primary outcome measures, which indicated that 78 participants per group would give 87% power to detect differences of a medium effect size (at least 0.5) between groups (α=.05; 2-sided). In the current study, differences in baseline characteristics were tested with an independent samples *t* test or a chi-square test. For primary and secondary outcome measures, changes from baseline to 10 weeks (reflected by its difference scores) were compared between group 1 and group 2 with ANCOVAs, with baseline score as a covariate and gender and site as factors. To assess

improvement during treatment within both groups, paired samples *t* tests were performed on primary and secondary outcome measures before and after playing the serious game. To assess whether effects were maintained after playing the game for 10 weeks within group 1, within-group comparisons of changes at 10 weeks versus 10-week follow-up were performed. Intention-to-treat analyses were used and included all randomized participants. Linear trend at point was used as an imputation method. All statistical analyses were performed using SPSS version 19.0 statistical software (IBM Corp, Armonk, NY, USA) and were 2-sided with a level of significance of α=.05. The significance level for primary outcome measures was adjusted on the basis of the Hochberg procedure [56]. Effect sizes were reported for all analyses using Cohen's *d* [57].

Results

Patient Flow

A total of 170 participants met the inclusion criteria and participated in the study. Mean scores for primary and secondary outcome measures and characteristics of groups 1 and 2 did not differ significantly at baseline (see Table 2). Most participants (91.8%, 156/170) received medication as their treatment as usual. Medication use did not differ between 4 outpatient mental health care clinics and institutions (χ^2_3=3.7, *P*=.29).

Table 2. Demographic information of the sample at baseline.

Baseline characteristics	Total (N=170)	Group 1 (n=88)	Group 2 (n=82)	Group comparison		
				t_{168}	χ^2 (*df*)	*P*
Sex, n (%)					0.1 (1)	.72
Male	137 (80.6)	70 (79.5)	67 (81.7)			
Female	33 (19.4)	18 (20.5)	15 (18.3)			
Age (years), mean (SD)	9.85 (1.26)	9.89 (1.28)	9.82 (1.24)	–0.36		.79
Total IQ,[a] mean (SD)	106.18 (14.79)	105.40 (14.46)	107.02 (15.18)	0.72		.55
ADHD subtypes, n (%)					3.2 (2)	.21
Combined	126 (74.1)	66 (75.0)	60 (73.2)			
Inattentive	38 (22.4)	17 (19.3)	21 (25.6)			
Hyperactive-Impulsive	6 (3.5)	5 (5.7)	1 (1.2)			
Attention deficit, [b] n (%)					1.6 (1)	.21
Normal	62 (36.5)	36 (40.9)	26 (31.7)			
(Sub)clinical	108 (63.5)	52 (59.1)	56 (68.3)			
Hyperactivity, [b] n (%)					1.9 (1)	.17
Normal	84 (49.4)	39 (44.3)	45 (54.9)			
(Sub)clinical	86 (50.6)	49 (55.7)	37 (45.1)			
Oppositional defiant disorder, [b] n (%)					2.1 (1)	.14
Normal	149 (87.6)	74 (84.1)	75 (91.5)			
(Sub)clinical	21 (12.4)	14 (15.9)	7 (8.5)			
Game experience, n (%)					4.3 (3)	.23
Starter	29 (17.1)	13 (14.7)	16 (19.5)			
Amateur	55 (32.4)	29 (33.0)	26 (31.7)			
Experienced	82 (48.2)	42 (47.7)	40 (48.8)			
Expert	4 (2.4)	4 (4.5)	0 (0)			
Special education? (yes), n (%)	25 (14.7)	14 (15.9)	11 (13.4)		0.2 (1)	.65
Medication use? (yes), n (%)	156 (91.8)	80 (90.9)	76 (92.7)		0.2 (1)	.67
Psychoeducation for parents? (yes), n (%)	9 (5.3)	5 (5.7)	4 (4.9)		0.1 (1)	.82

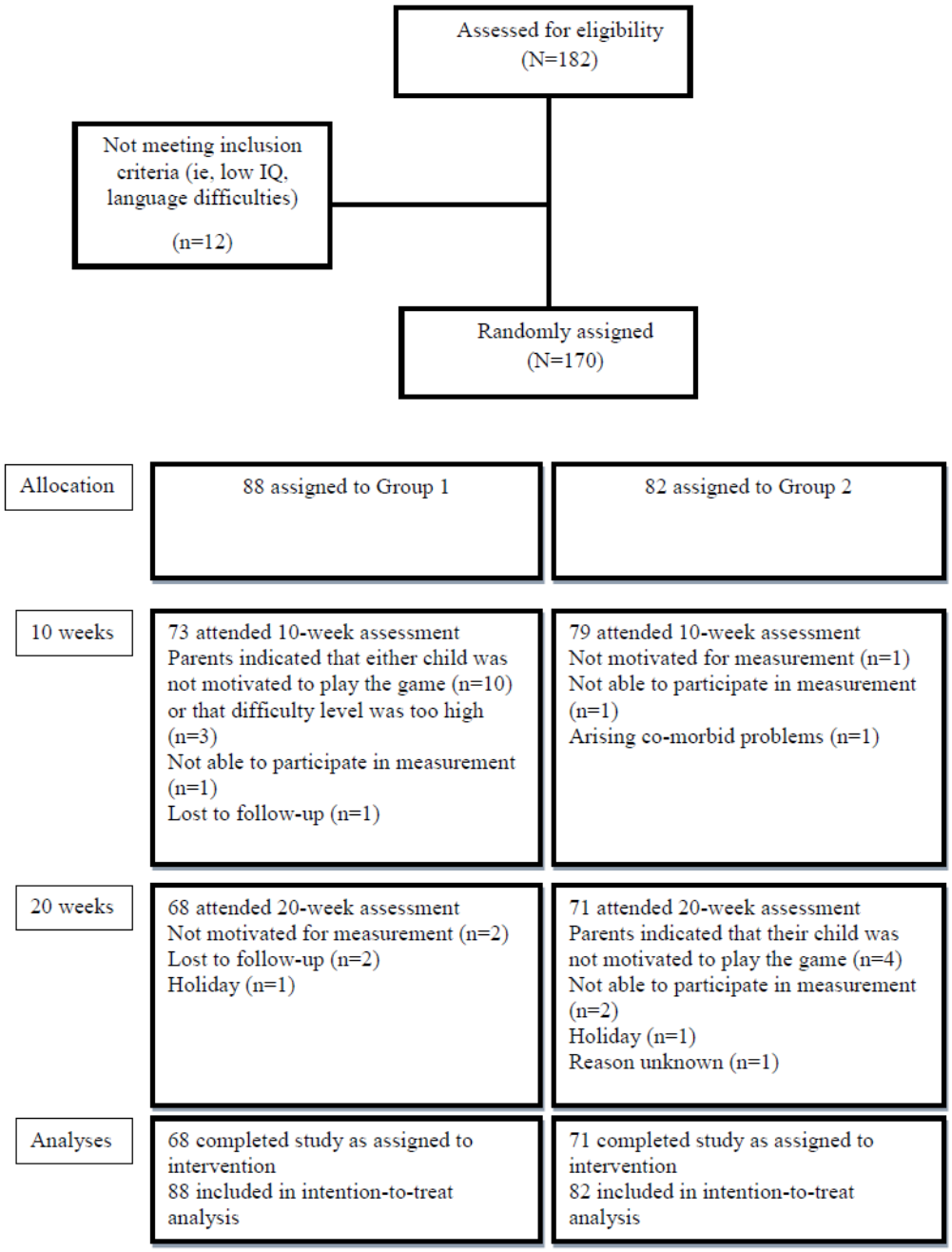
[a] IQ: Intelligence Quotient.

[b] ADHD and ODD severity are based on clinical and subclinical scores on the parent version of the DBDRS.

At 10 weeks (T1), 152 of 170 participants (89.4%) completed the study and 139 of 170 (81.8%) completed at the 10-week follow-up (T2). At 10 weeks (T1), the dropout rate was higher in group 1 compared to group 2 (χ^2_1=8.0, *P*=.01). The dropout rate did not differ between the 2 study groups at 10-week follow-up (χ^2_1=2.5, *P*=.12). Participants who dropped out during the study period did not differ according to age (t_{168}=–1.34, *P*=.18), gender (χ^2_1=2.2, *P*=.13), ADHD subtype (χ^2_2=2.5, *P*=.29), or intelligence (t_{168}=–1.66, *P*=.10) compared to participants who did not drop out (for flow diagram see Figure 4). However, children who dropped out during the study (mean 45.06, SD 15.79) had higher ADHD severity scores compared to children who completed the study (mean 39.07, SD 14.16; t_{168}=2.09, *P*=.04).

Participants played for a mean 19.04 (SD 9.61) days in the mission-guided game and a mean 11.20 (SD 8.55) days in the closed social community. Additionally, participants played the mission-guided game for a total duration of a mean12.56 (SD 6.57) hours and engaged with the closed social community for a mean 54.27 (SD 70.00) minutes. A difference was seen between group 1 (mean 13.53, SD 6.25) and group 2 (mean 11.53, SD 7.25) with regard to the amount of time playing the mission-guided game (t_{155}=1.81, *P*=.07) but it did not meet statistical significance. There was a significant difference between group 1 (mean 12.61, SD 8.60) and group 2 (mean 9.70, SD 8.28) with regard to the number of days they engaged with the closed social community (t_{157}=2.17, *P*=.03). With regard to the amount of time playing in the closed social community, there was a difference between group 1 (mean 1.04, SD 1.16) and group 2 (mean 0.44, SD 1.02; t_{156}=1.82, *P*=.07), although this was not statistically significant. There were no differences between the 2 groups with regard to the number of days playing the mission-guided game. Both parents (mean 6.96, SD 1.40) and participants (mean 7.33, SD 1.87) reported moderate to high satisfaction with receiving the serious game intervention.

Figure 4. Study flow diagram.



Between-Group Differences (Group 1 Versus Group 2)

To test the hypothesis that participants playing the serious game would improve on primary and secondary outcome measures, differences between group 1 and group 2 from baseline to 10 weeks (T1; posttest) were evaluated with ANCOVAs (see Table 3). On the primary outcome measures, group 1 showed significantly greater improvements in parent-rated time management skills compared to participants in group 2. Group 1 also showed more improvement in parent-reported planning/organizing skills compared to group 2, although this did not meet statistical significance (P=.07). There were no differences concerning participants' cooperation skills.

Table 3. Univariate analyses of covariance comparing group 1 and group 2 on primary and secondary outcome measures during first 10 weeks.

Measures[a]	Group 1 (n=88)		Group 2 (n=82)		ANCOVA		
	Least square mean (SE)	95% CI	Least square mean (SE)	95% CI	$F_{1,163}$ [b]	*P*	Cohen's *d*
Parent-reported							
Primary outcomes							
Time management	10.66 (1.64)	7.42, 13.89	4.68 (1.72)	1.29, 8.07	8.56	.004[c]	0.39
BRIEF (subscale Plan/Organize)	1.47 (0.36)	0.75, 2.18	0.64 (0.38)	–0.11, 1.39	3.32	.07[c]	0.35
SSRS (subscale Cooperation)	1.10 (0.34)	0.43, 1.78	0.46 (0.36)	–0.25, 1.16	2.32	.13[c]	0.16
Secondary outcomes							
It's about time	2.74 (0.73)	1.30, 4.17	1.18 (0.76)	–0.32, 2.68	2.98	.09	0.20
BRIEF (subscale Working Memory)	0.75 (0.32)	0.11, 1.38	–0.17 (0.33)	–0.83, 0.49	5.16	.02	0.51
SSRS (Total)	2.24 (0.81)	0.64, 3.83	0.58 (0.85)	–1.09, 2.26	2.68	.10	0.05
SSRS (subscale Assertiveness)	0.32 (0.27)	–0.22, 0.85	–0.06 (0.28)	–0.62, 0.49	1.28	.26	0.04
SSRS (subscale Responsibility)	0.75 (0.25)	0.27, 1.23	0.11 (0.26)	–0.39, 0.62	4.28	.04	0.04
SSRS (subscale Self-Control)	0.24 (0.29)	–0.34, 0.81	0.22 (0.31)	–0.38, 0.83	0	.97	0.07
Teacher-reported							
Time management	5.30 (1.32)	2.70, 7.90	–0.16 (1.38)	–2.88, 2.56	11.05	.001	0.41
BRIEF (subscale Plan/Organize)	0.78 (0.34)	0.11, 1.44	0.14 (0.35)	–0.55, 0.84	2.30	.13	0.18
BRIEF (subscale Working Memory)	1.32 (0.34)	0.65, 2.00	0.50 (0.36)	–0.20, 1.20	3.79	.05	0.22
SSRS (Total)	2.95 (0.67)	1.64, 4.27	2.36 (0.70)	0.98, 3.74	0.51	.48	0
Self-reported							
Self-efficacy	3.06 (2.42)	–0.73, 7.84	–2.13 (2.55)	–7.16, 2.90	2.95	.09	0.26

[a] BRIEF: Behavior Rating Inventory of Executive Function; SSRS: Social Skills Rating Scale.

[b] Pillai's Trace.

[c] Adjusted *P* values are .01, .14, and .13 for parent-reported time management, BRIEF (subscale Plan/Organize), and SSRS (subscale Cooperation), respectively.

Regarding the secondary outcome measures, group 1 also improved significantly more than the group 2 on measures of parent-reported working memory and responsibility skills. Participants in group 1 showed greater improvements in participants' time perception compared to group 2, although this did not meet statistical significance (*P*=.09). Teachers reported greater improvements in group 1 than group 2 on the measure of time management and working memory, although this latter effect did not meet statistical significance (*P*=.05). Finally, the same accounted for participants' self-efficacy in which participants in group 1 showed greater improvements as compared to group 2 (*P*=.09), but it did not meet statistical significance. No differences were found on parent-rated total social skills (with subscales assertiveness and self-control) and teacher-rated total social skills and planning/organizing skills.

Group 2 Within-Group Effects

Within-group differences for group 2 were evaluated (see Table 4). While receiving treatment as usual for the first 10 weeks, participants improved significantly on parent-reported time management and teacher-reported social skills. After crossing over to the serious game intervention in addition to treatment as usual for the subsequent 10 weeks, significant improvements in outcomes of parent-reported time management, time perception, planning/organizing, working memory, and social skills (primarily cooperation and assertiveness) were found. Furthermore, significant improvements were demonstrated for all teacher-reported outcomes. Self-reported self-efficacy also significantly improved after receiving the intervention (see Table 4).

Table 4. Group 2 results of paired samples *t* tests of primary and secondary outcome measures at baseline, 10-week, and 20-week assessments.

Outcomes	Assessment, mean (SD)			T0 vs T1			T1 vs T2		
	Baseline (T0)	10 weeks (T1)	20 weeks (T2)	t_{81}	*P*	Cohen's *d*	t_{81}	*P*	Cohen's *d*
Parent-reported (n=82)									
Primary outcomes									
Time management	48.88 (15.25)	52.95 (18.17)	60.00 (14.71)	2.80	.006	0.24	4.36	<.001	0.43
BRIEF (subscale Plan/Organize)[a]	20.41 (4.61)	20.76 (4.54)	22.01 (4.27)	1.07	.29	0.08	3.29	.001	0.28
SSRS (Cooperation)	8.73 (3.68)	8.90 (3.46)	9.86 (3.16)	0.55	.58	0.05	2.85	.006	0.29
Secondary outcomes									
It's about time	30.88 (7.82)	31.61 (7.58)	33.89 (7.15)	1.05	.30	0.09	3.05	.003	0.31
BRIEF (subscale Working Memory)	14.23 (3.29)	14.42 (3.13)	16.39 (3.36)	0.63	.53	0.06	5.36	<.001	0.61
SSRS (subscale Assertiveness)	14.52 (3.81)	14.35 (3.73)	15.18 (2.65)	–0.67	.50	0.05	2.91	.005	0.26
SSRS (subscale Responsibility)	13.63 (3.16)	13.41 (2.92)	13.97 (2.61)	–0.95	.35	0.07	1.97	.05	0.20
SSRS (subscale Self-Control)	10.06 (3.78)	10.19 (3.95)	10.74 (3.15)	0.50	.62	0.03	1.50	.14	0.20
SSRS (subscale Total)	44.24 (10.50)	44.08 (10.67)	46.83 (8.84)	–0.23	.82	0.02	2.96	.004	0.28
Teacher-reported (n=82)									
Time management	65.04 (16.37)	64.68 (14.78)	70.20 (10.46)	–0.27	.79	0.02	4.09	<.001	0.43
BRIEF (subscale Plan/Organize)	20.17 (3.96)	20.16 (3.77)	20.92 (3.18)	–0.05	.96	0	2.40	.02	0.22
BRIEF (subscale Working Memory)	18.57 (3.73)	18.97 (3.87)	20.42 (3.18)	1.19	.24	0.11	4.11	<.001	0.41
SSRS (Total)	34.87 (7.62)	36.76 (7.21)	38.37 (6.33)	2.74	.01	0.25	2.52	.01	0.24
Self-reported (n=82)									
Self-efficacy	87.35 (23.63)	86.12 (25.55)	90.87 (22.32)	–0.48	.64	0.05	2.08	.04	0.20

[a] BRIEF: Behavior Rating Inventory of Executive Function; SSRS: Social Skills Rating Scale.

Group 1 Within-Group Effects and 10-Week (T2) Follow-Up Effects

Within-group differences for group 1 were then evaluated (see Table 5). While playing the serious game intervention in addition to treatment as usual for the first 10 weeks, significant improvements in outcomes of parent-reported time management, time perception, planning/organizing, and social (primarily cooperation and responsibility) skills were found. Furthermore, significant improvements were demonstrated for participants' time management, working memory, and social skills as reported by their teachers. Within-group effects showed significant improvement from 10 weeks to 10-week follow-up for parent-reported time management, working memory, time perception, and social skills (primarily cooperation, responsibility, and self-control). Furthermore, significant improvements were demonstrated for teacher-reported time management and working memory skills (see Table 5). This implies that most effects maintained or even further improved at 10-week follow-up.

Table 5. Group 1 results of paired samples *t* tests of primary and secondary outcome measures during baseline, 10-week, and 20-week assessments.

Outcomes	Assessment, mean (SD)			T0 vs T1			T1 vs T2		
	Baseline (T0)	10 weeks (T1)	20 weeks (T2)	t_{87}	*P*	Cohen's *d*	t_{87}	*P*	Cohen's *d*
Parent-reported (n=88)									
Primary outcomes									
Time management	49.73 (16.41)	59.45 (15.28)	64.70 (11.32)	5.82	<.001	0.61	4.66	<.001	0.39
BRIEF (subscale Plan/Organize)[a]	21.32 (4.21)	22.19 (3.70)	22.58 (3.63)	2.18	.03	0.22	1.25	.22	0.11
SSRS (Cooperation)	8.53 (2.71)	9.45 (3.24)	10.29 (2.27)	2.62	.01	0.31	3.12	<.01	0.30
Secondary outcomes									
It's about time	30.62 (7.21)	33.04 (6.55)	35.08 (6.36)	3.02	.003	0.35	3.48	.001	0.32
BRIEF (subscale Working Memory)	15.50 (3.52)	16.06 (3.32)	16.78 (3.48)	1.61	.11	0.16	2.29	.03	0.21
SSRS (subscale Assertiveness)	14.14 (3.33)	14.48 (2.69)	14.63 (3.04)	1.24	.22	0.11	0.62	.54	0.05
SSRS (subscale Responsibility)	12.83 (2.88)	13.53 (2.69)	14.06 (2.54)	2.83	.006	0.25	2.55	.01	0.20
SSRS (subscale Self-Control)	9.66 (3.51)	9.93 (3.03)	10.82 (3.05)	0.94	.35	0.08	3.58	.001	0.29
SSRS (subscale Total)	42.57 (8.81)	44.58 (8.50)	46.85 (8.69)	2.46	.02	0.23	3.93	<.001	0.26
Teacher-reported (n=88)									
Time management	65.31 (16.12)	70.31 (12.43)	73.92 (10.07)	3.45	.001	0.35	2.95	.004	0.32
BRIEF (subscale Plan/Organize)	20.30 (3.81)	20.87 (2.97)	21.38 (2.39)	1.54	.13	0.17	1.79	.08	0.19
BRIEF (subscale Working Memory)	18.49 (3.65)	19.75 (3.33)	20.62 (2.47)	3.87	<.001	0.36	2.55	.01	0.30
SSRS (Total)	33.73 (9.42)	36.75 (6.92)	36.38 (7.04)	4.03	<.001	0.37	–0.52	.60	–0.05
Self-reported (n=88)									
Self-efficacy	89.39 (25.03)	92.33 (22.01)	94.09 (20.66)	1.29	.20	0.12	1.62	.29	0.08

[a] BRIEF: Behavior Rating Inventory of Executive Function; SSRS: Social Skills Rating Scale.

Adverse Events

While playing the serious game, adverse events were registered by the researcher and checked by a health care professional. Overall, there were 10 adverse events that could be related to the intervention that were reported by parents, teachers, or participants themselves. All adverse events were of mild (n=5) or moderate (n=5) severity, but this was no reason to discontinue study participation. Examples of adverse events were pain in the fingers, irritability, and headache. An adverse event was a reason to discontinue the study for only one known participant. This participant did not want to play the game anymore because he could not concentrate during his school activities. Sounds reminded him of the game and this consequently distracted and frustrated him. No serious adverse events were reported.

Discussion

The findings of this 20-week multisite randomized controlled crossover open-label trial demonstrate the efficacy of an Internet-based serious game specifically developed for children with ADHD. Participants who played the serious game during the first 10 weeks significantly improved in their daily life functioning across domains of time management, social skills (eg, responsibility) and working memory compared to participants in group 2. These effects were small to medium and were maintained or even further improved at the 10-week follow-up for group 1. Children from group 2, who played the serious game during the second period of the study (weeks 10 to 20), improved on comparable domains of daily life functioning over time. In contrast to previous studies that typically demonstrate that computerized neurocognitive interventions for ADHD improve working memory skills but do not have a strong impact on daily life functioning ("far-transfer effects") [26-30,58], the findings of the current study provide clear evidence that a serious game for children with ADHD can improve the performance of these children in important daily life skills.

Of particular interest is the clear effect seen on time management skills because dysfunctional time management is one of the core problems in ADHD, affecting social and executive domains of

daily life functioning [4,37]. It should be noted that the improvements in time management and working memory were reported by parents at home and teachers at school supporting the claim that positive behavioral adaptations resulting from use of the serious game generalized across different settings. Although improvements in planning/organizing skills have been shown by other computerized neurocognitive training programs as well [39,59], this serious game is unique because it elicits its effects by promoting behavioral strategies instead of training executive functions by offering repeated cognitive exercises. As such, this approach provides sustainable therapeutic effects by improving behavioral strategies that can be applied in daily life.

Plan-It Commander demonstrated improvement of total social skills over time, but had nonsignificant between-group effects as reported by parents and teachers. Multiplayer and cooperative game play could be more explicitly integrated to improve social benefits of the current game format. Improvements in social responsibility among players was observed. This was expected given that game elements, such as a mentor figure or nonplayable characters and peers with ADHD with whom they could interact (eg, asking for help, being polite, and dealing with compliments in a good way), enabled players to practice socially responsible behaviors in the game that could be practiced in the "real world" as well. This finding is important given that well-developed social responsibility skills in children contribute to academic success and an optimal learning environment [52,53].

Another goal of Plan-It Commander was to improve children's self-efficacy. Children were more confident in self-control with regard to their time management and planning skills and engagement in positive social interactions. However, the between-group effect on self-efficacy did not meet statistical significance. It may be important that further development of serious gaming addresses aspects of the concept of self-efficacy (eg, modeling behavior) more thoroughly because increased self-efficacy has been shown to correlate significantly with self-esteem and adaptive behaviors such as persistence in reaching goals in daily life [60-62]. Overall, this study introduces serious gaming as an effective and attractive behavioral intervention for children with ADHD, especially for time management with evidence for effects on certain social skills and self-efficacy as well.

Clinical Implications

ADHD is a chronic health problem and previous studies have emphasized the need for efforts to treat impairments outside the therapy context and provide patients with greater autonomy [22,23,63]. The Internet-based serious game intervention in this study fulfills this need by addressing impairments associated with ADHD among school-aged children in the home and school context. Results demonstrated that parents as well as children were satisfied with their treatment. The current intervention was positioned as an adjunct to treatment as usual. No therapist or parent explicitly intervened during the game intervention. Furthermore, no additional rewards were given and no prompts to play the game regularly were explicitly provided outside the game. Given that young patients with ADHD have engagement and motivation issues in general, easy accessible interventions such as serious games can stimulate them to comanage their health care processes as part of the Chronic Care Model of Child Health and the World Health Organization Mental Health Action Plan 2013-2020 [22,23,64].

The current intervention is unique in its contribution to the adjunctive ADHD treatment repertoire because it differs from existing computerized neurocognitive training formats. Instead of requiring the repetition of executive function tasks normally presented in neurocognitive training format for children with ADHD, Plan-It Commander offers behavioral strategies (e.g., reinforcement, immediate performance feedback from a mentor, goal setting through missions, modeling, social support, and comparison) that increase functional outcomes within a relatively short period of time. Even more important is the fact that participants labeled as "clinically stable" by their clinicians still showed significant improvements in daily functioning. It is encouraging that significant results were obtained over and above medication effects. Future research could examine the effects of this serious game in a nonmedicated sample to disentangle its effects. Notably, participants with higher severity scores on ADHD symptoms were more likely to drop out from the study, which implies that we can only generalize our results to children with less severe ADHD symptoms, but this remains speculative because symptoms were within the normal range. Furthermore, future research should consider family factors (eg, social support network, socioeconomic status, parental ADHD) as well in contributing to study dropout.

Limitations

The results of this study must be considered in the light of several limitations. Group 2 followed treatment as usual and did not use a nontherapeutic "placebo game." Therefore, this study could be controlled for changes in time and effects of repeated measurements, but not for placebo effects. Further, parents were not rater-blinded and rater-blindness of teachers could not fully be guaranteed because children were free to report game experiences. Questionnaires to assess time management and self-efficacy were designed on theoretical basis and guidelines by Bandura [55]. Both instruments show good reliability. The time management questionnaire was developed because of a lack of instruments for this age group. This questionnaire was used previously in a randomized controlled pilot study (KCMB, unpublished data, 2016). Future research should evaluate the psychometric characteristics of these questionnaires in more detail.

Conclusions

The current randomized controlled study demonstrated that Plan-It Commander is an effective adjunctive Internet-based behavioral intervention for children with ADHD. It is a unique contribution to the literature on serious games because it showed that a serious game for ADHD, as an adjunct to treatment as usual, improves functional outcomes of time management as well as working memory and social responsibility. It fits the current interest in nonmedical treatment options for ADHD and stimulates young children to manage their impairments by offering an easy, accessible home treatment intervention. The findings contribute to scientific knowledge about the impact of

serious game interventions on behavioral outcomes, Internet-based interventions for mental health that are consistent with the Chronic Care Model of Health, and innovative approaches to treating people coping with chronic mental health conditions.

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Conflicts of Interest

Kim Bul has been paid by Janssen Pharmaceuticals for consultancy and lectures (fees were paid to the institution), but was not paid by Janssen Pharmaceuticals to perform the pilot study. Pamela Kato has been paid by Janssen Pharmaceuticals for consultancy during the development, but did not receive any fees for her work on this research evaluation. Leonie Vreeke, Ria van den Heuvel, Thérèse Van Amelsvoort, and Ingmar Franken declare no competing financial interests exist. Saskia Van der Oord has been involved in the development, implementation, and trialing of "Braingame Brian," an executive functioning game training for children with ADHD, and Zelf Plannen (Plan my Life) and Zelf Oplossingen bedenken (Solution focused treatment), 2 cognitive behavioral planning interventions for adolescents with ADHD. She has no financial interests in either of these interventions. She has been a paid consultant for designing a RCT of Plan-It Commander (Janssen Pharmaceuticals) and has received speaker's fees from MEDICE and Shire. Marina Danckaerts has received personal fees from Shire, MEDICE, Novartis, Janssen-Cilag, and Neurotech Solutions outside the submitted work. Helga van Oers and Annik Willems are employees of Janssen Pharmaceuticals. Athanasios Maras has been paid by Janssen Pharmaceuticals for consultancy and has been a consultant to, a member of an advisory board of, and/or speaker for Janssen Pharmaceuticals, Eli Lilly, Eurocept, and Neurim Pharmaceuticals in the past 2 years, but is not an employee or a stock shareholder of any of these companies.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [65].

[PDF File (Adobe PDF File), 3MB - jmir_v18i2e26_app1.pdf]

Multimedia Appendix 2

Time management questionnaire.

[PDF File (Adobe PDF File), 77KB - jmir_v18i2e26_app2.pdf]

Multimedia Appendix 3

Self-efficacy questionnaire.

[PDF File (Adobe PDF File), 149KB - jmir_v18i2e26_app3.pdf]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
BRIEF: Behavior Rating Inventory of Executive Functioning
DBDRS: Disruptive Behavior Disorders Rating Scale
IATQ: It's About Time Questionnaire
IQ: intelligence quotient
K-SADS: Kiddie Schedule for Affective Disorders and Schizophrenia-Lifetime
SSRS: Social Skills Rating System
WISC-III: Wechsler Intelligence Scale for Children III

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Original Paper

In Pursuit of Theoretical Ground in Behavior Change Support Systems: Analysis of Peer-to-Peer Communication in a Health-Related Online Community

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Abstract

Background: Research studies involving health-related online communities have focused on examining network structure to understand mechanisms underlying behavior change. Content analysis of the messages exchanged in these communities has been limited to the "social support" perspective. However, existing behavior change theories suggest that message content plays a prominent role reflecting several sociocognitive factors that affect an individual's efforts to make a lifestyle change. An understanding of these factors is imperative to identify and harness the mechanisms of behavior change in the Health 2.0 era.

Objective: The objective of this work is two-fold: (1) to harness digital communication data to capture essential meaning of communication and factors affecting a desired behavior change, and (2) to understand the applicability of existing behavior change theories to characterize peer-to-peer communication in online platforms.

Methods: In this paper, we describe grounded theory–based qualitative analysis of digital communication in QuitNet, an online community promoting smoking cessation. A database of 16,492 de-identified public messages from 1456 users from March 1-April 30, 2007, was used in our study. We analyzed 795 messages using grounded theory techniques to ensure thematic saturation. This analysis enabled identification of key concepts contained in the messages exchanged by QuitNet members, allowing us to understand the sociobehavioral intricacies underlying an individual's efforts to cease smoking in a group setting. We further ascertained the relevance of the identified themes to theoretical constructs in existing behavior change theories (eg, Health Belief Model) and theoretically linked techniques of behavior change taxonomy.

Results: We identified 43 different concepts, which were then grouped under 12 themes based on analysis of 795 messages. Examples of concepts include "sleepiness," "pledge," "patch," "spouse," and "slip." Examples of themes include "traditions," "social support," "obstacles," "relapse," and "cravings." Results indicate that themes consisting of member-generated strategies such as "virtual bonfires" and "pledges" were related to the highest number of theoretical constructs from the existing behavior change theories. In addition, results indicate that the member-generated communication content supports sociocognitive constructs from more than one behavior change model, unlike the majority of the existing theory-driven interventions.

Conclusions: With the onset of mobile phones and ubiquitous Internet connectivity, online social network data reflect the intricacies of human health behavior as experienced by health consumers in real time. This study offers methodological insights for qualitative investigations that examine the various kinds of behavioral constructs prevalent in the messages exchanged among users of online communities. Theoretically, this study establishes the manifestation of existing behavior change theories in QuitNet-like online health communities. Pragmatically, it sets the stage for real-time, data-driven sociobehavioral interventions promoting healthy lifestyle modifications by allowing us to understand the emergent user needs to sustain a desired behavior change.

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KEYWORDS

behavior change; online social media; web interventions; smoking cessation

Introduction

Unhealthy behaviors such as smoking, physical inactivity, poor diet, and alcohol consumption contribute to 835,000 deaths in the United States annually [1,2] and are associated with an increased risk of chronic diseases such as hypertension, diabetes, stroke, and cancer [3]. Behavior modification is an important component of chronic disease management and sustainable healthy living. Adherence to healthy behaviors (eg, abstinence from smoking) requires a significant support infrastructure for long time intervals [4,5]. Research suggests that social relationships play an important role in an individual's engagement in health issues [6-10]. While community-based social interventions harnessing the positive effects of social contacts exist [11-15], the mechanisms underlying the influence of social relationships on health behaviors are not fully understood. The ubiquity of online communities gives us invaluable datasets in the form of electronic traces of peer-to-peer communication, which may help us understand social influence and behavior. With the onset of mobility and connectivity in the communication sector, messages exchanged in health-related online communities reflect the intricacies of human health behavior as experienced in real time at individual, community, and societal levels.

Several studies on online social networks provide valuable insights into social influence, information spread, behavioral diffusion, and the structural aspects (who has ties to whom) [16-20]. Most prior research on social networks has made exclusive use of structure of social ties, where network structure is derived from the frequency of communication among members belonging to a network. Conversely, content analysis of online communities focused on specific behavior change mechanisms, social support [21-23], and emotional coping [24,25]. Prior qualitative studies on online community interactions have focused on (1) development and evaluation of network-based interventions [26,27], (2) user perceptions on utility of online communities for a specific health-related illness (eg, mental health [28]) and general conversational interests of specific population (eg, elderly [29,30]), (3) the role of online communities in identification of key quality indicators for patient-centered care [31], (4) effects of gamification features on overall technology acceptance [32], (5) users' privacy concerns [33], (6) the quality of communication content in the online platforms [34,35], and (7) user participation patterns in network-based interventions [36-38]. Other qualitative studies examining communication content in online communities adopt a passive approach where researchers attempt to understand information-seeking patterns on websites or interactions in discussion groups [39]. Such studies have examined the help mechanisms and social support-related content of online self-help groups for alcoholism [40], cancer [41], and other health disorders such as Huntington's disease [42]. Hwang et al conducted a network-based survey on the Sparkpeople forum, where members focus on a weight loss regimen [43]. The qualitative survey data were analyzed for social support themes using grounded theory techniques. Results indicated that the major social support themes were encouragement and motivation, information, and shared experiences [43]. The majority of research studies that have examined communication content in online communities have focused on assigning peer-to-peer communication events to various social support categories (eg, informational support, emotional support) [44]. However, social support is only one of numerous interpersonal mechanisms facilitated by the social ties established in online communities [45,46]. Existing theories of behavior change and patient engagement models suggest many different content-driven strategies to elicit specific sociobehavioral mechanisms beyond social support (eg, stimulus control, observational learning) to help users achieve a behavior change and self-manage an illness [47]. Different cognitive constructs in existing behavior change theories suggest different techniques [48]. Recent online survey research examined user perceptions of different social influence mechanisms to understand the relationship between network participation and smoking cessation self-efficacy [46]. Results of this survey have revealed that participation in health issue-specific social networking sites significantly influenced each social factor, which in turn resulted in greater smoking cessation self-efficacy. However, it is not known the extent to which any of the theoretically grounded strategies empirically manifest in the communication among network users [49]. Looking at the past and current trends of health-related online social networks, several research avenues can be pursued in order to strategize the use of the networks for improving health care. Advancing existing sociobehavioral theories, understanding fundamental mechanisms of behavior change, and formulating and evaluating novel interventional approaches are important avenues of research opened by these virtual platforms. Are theoretical models of sociobehavioral models of change applicable to both offline and online contexts? [49,50]. In-depth qualitative study of network interactions provides us with an unprecedented opportunity to refine existing theories and models of social networks, social support, and behavior-change that were formulated based on face-to-face communication.

In this paper, we describe the results of a grounded theory-based [51,52] content analysis of messages exchanged in an online social network for smoking cessation called QuitNet. We will use inductive coding techniques to (1) abstract and characterize the essence of peer-to-peer communication in online communities, and (2) understand how the identified themes relate to existing theoretical constructs and taxonomy of behavior change techniques. This approach will alter the current paradigm of studying behavior using online interactions from being hypothesis-driven [53] to being empirically grounded. Existing qualitative research conducted with a specific aspect of behavior change in mind is fundamentally different from our empirically driven, grounded theory approach. This analysis

enhances our understanding of the manifestation of multiple behavior change constructs, which were formulated in the context of face-to-face communication using laboratory-based social science approaches, in the context of online social relationships.

Theoretical Rationale

Several health behavior theories and models have been formulated to explain behavior change in general (see Table 1). These frameworks have served as guides for the development and evaluation of face-to-face and online interventions. Of the existing theoretical models, the Health Belief Model (HBM) [54,55], Theory of Reasoned Action (TRA) [56], the Transtheoretical Model (TTM) [57], and Social Cognitive Theory (SCT) [58] are found to be the most used in published smoking cessation intervention studies [59-62]. While each of these theoretical frameworks has its own merits and limitations, researchers have indicated concerns about the applicability of these models to consumers in the digital era [49,50]. The aforementioned four theories have been applied to the largest number of published studies on smoking cessation interventions.

The Transtheoretical Model of Change

TTM tries to explain the behavior change mechanisms by synthesizing several constructs drawn from other theories [57]. Stages and processes of change are the two main components of TTM. The former block explores the temporality of behavior change, while the latter encompasses cognitive and behavioral concepts such as decisional balance, self-efficacy, and rewards program. Precontemplation, contemplation, preparation, action, maintenance, and termination are the six stages of change, where each stage involves a process of progress.

The Theory of Reasoned Action

TRA suggests that the behavior of a person is determined by one's behavioral intention [56]. Intent of a behavior is a function of the person's attitude toward the behavior, their subjective norm associated with the behavior, and their perceived behavioral control.

Social Cognitive Theory

The SCT is a theory based on reciprocal determinism between a behavior, the environment, and a person [58]. This theory emphasizes self-efficacy, an important concept related to self-confidence. Self-efficacy is defined as "people's judgments of their capabilities to organize and execute courses of action required to attain designated types of performances" p. 391 [58]. Current literature agrees on a common definition that self-efficacy "refers to what a person believes he or she can do on a particular task" p. 506 [58]. Goal attainment and confidence building through self-monitoring and continuous feedback is often used to improve a person's self-efficacy. Other important constructs in SCT include behavioral capability, observational learning, reinforcement, outcome expectations and expectancies, emotional coping, and self-control. The construct of observational learning has been used by network scientists to provide an explanation for social influence and network clustering of people engaging in the same health behavior [58]. According to SCT, observational learning in behavior change occurs when an individual watches another person engage in a given behavior and receive reinforcements. Another component of SCT called reciprocal determinism takes into account the interactions among individuals, their environments, and behavior goals. The environment in SCT refers to a conglomeration of factors that are external to the individual including their social network (ie, family, friends, and peers) and physical objects that might affect behaviors. In the case of smoking, the physical objects can include availability of patches, access to smoking-designated areas in the work place, and so forth.

Health Belief Model

HBM is one of the most widely used conceptual frameworks for explaining and changing individual health behavior. HBM evolved from a cognitive theory perspective and is a value-expectancy theory, which attempts to explain and predict individual's attitudes toward objects and actions [54]. Major components in HBM include perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action, and self-efficacy. An individual's perceptions of a behavior can be used as predictors of behavior change outcomes under certain conditions that are dependent on demographic (eg, age, gender) sociopsychological (eg, personality, social class), and structural variables (eg, prior knowledge, experience).

Taxonomy of Behavior Change Techniques

Abraham et al defined a set of theory-linked behavior change techniques that can be used to characterize and differentiate between different types of intervention content [45]. Their taxonomy of 26 theory-linked techniques is the first step towards creating a model that provides a snapshot of intervention content in the context theory-driven behavior change constructs. A single behavior change technique can be related to similar behavior change processes from multiple theories. Consequently, the taxonomy integrates multiple behavioral theories [48] such as the theory of planned behavior [56], SCT [58], operant conditioning [63], and social support models on health-related behaviors [64]. As a result, the taxonomy provides a common vocabulary to understand the ways that sociobehavioral and cognitive constructs of the existing behavior change theories have been operationalized in a specific intervention.

Table 1. Theoretical constructs from behavior change theories (adapted from Revere & Dunbar [47]).

Theory	Concept	Definition
Health Belief Model	Perceived susceptibility	One's opinion of chances of getting a condition
	Perceived severity	One's opinion of how serious a condition and its consequences are
	Perceived benefits	One's opinion of the efficacy of the advised action to reduce risk or seriousness of impact
	Perceived barriers	One's opinion of the tangible and psychological costs of the action
	Cues to action	Strategies to activate readiness
	Self-efficacy	Confidence in ability to take action and persist in action
Stages of Change Model	Pre-contemplation	Unaware of problem, hasn't thought about changes
	Contemplation	Thinking about changes
	Preparation	Making a plan to change
	Action	Implementations of a specific action plan
	Maintenance	Continuation of desirable actions, or repeating periodic recommended step(s)
	Consciousness raising	Increasing awareness via information, education, and personal feedback about the healthy behavior
	Dramatic relief	Feeling fear, anxiety, or worry because of the unhealthy behavior, or feeling inspiration and hope when they hear about how people are able to change to healthy behaviors
	Self-reevaluation	Realizing that the healthy behavior is an important part of who they are and want to be
	Environmental reevaluation	Realizing how unhealthy behavior affects others
	Social liberation	Realizing that society is more supportive of the healthy behavior
	Self-liberation	Believing in one's ability to change and making commitments and recommitments
	Helping relationships	Finding people who are supportive of their change
	Counter-conditioning	Substituting healthy ways of acting and thinking for unhealthy ways
	Reinforcement management	Increasing the rewards that come from positive behavior and reducing those that come from negative behavior
	Stimulus control	Using reminders and cues that encourage healthy behavior as substitutes for those that encourage the unhealthy behavior
Theory of Planned Behavior and Theory of Reasoned Action	Behavioral intervention	Perceived likelihood of performing the behavior; prerequisites for action
	Attitude	One's favorable or unfavorable evaluation of the behavior
	Behavioral belief	Belief that the behavioral performance is associated with certain attributes or outcomes
	Normative belief	Subjective belief regarding approval or disapproval of the behavior
	Subjective norm	Influence of perceived social pressure weighted by one's motivation to comply with perceived expectations
	Perceived behavioral control	One's perception of how easy or difficult it will be to act
Social Cognitive Theory	Reciprocal determinism	Behavior change results from interaction between individuals and environment
	Behavioral capability	Knowledge and skills to influence behavior
	Expectations	Beliefs about likely results of action
	Self-efficacy	Confidence in ability to take action and persist in action
	Observational learning	Beliefs based on observing others
	Reinforcement	Responses to a person's behavior that increase or decrease chances of recurrence
	Emotional coping responses	Strategies or tactics that are used by a person to deal with emotional stimuli.

Methods

Materials

QuitNet is one of the first online social networks for health behavior change [65] and has been in continuous existence for the past 16 years. It is widely used with over 100,000 new registrants per year. QuitNet has members who are current and former smokers seeking to quit or stay abstinent. The members are globally distributed and come from over 160 countries including Canada, the United Kingdom, Australia, and South Africa. Previous studies on QuitNet indicated that participation in the online community was strongly correlated with abstinence [66]. The dataset studied in this paper was drawn from a previously studied quality improvement database and consists of de-identified messages in the public threaded forums, in which participants post messages and reply directly to each other. A database of 16,492 de-identified public messages from March 1-April 30, 2007, was used in our study. All messages were stripped of identifiers but re-coded for ego id (the individual posting) and alter id (the individual whose message is being replied to), self-reported abstinence status of sender and receiver, date, and position within the thread.

Methods

The objective of this qualitative analysis was to characterize the nature of communication content exchanged by QuitNet members, thus capturing essential meaning of communication and factors affecting smoking cessation. This sort of analysis ultimately enables the abstraction of communication themes as they emerge from the data itself. Such inductive analysis is the principle technique used in the grounded theory method generating themes, where themes emerge from data itself [51,52]. Open coding and constant comparison are the two main characteristics of the analysis that can be used to ensure the derivation of meaningful representative themes from social network data. Open coding describes data by means of conceptual (rather than descriptive) codes, which are derived directly from the data, and constant comparison enables creation of precise and consistent codes by comparing these codes to observed phenomena and their contexts many times.

Often the messages exchanged among network members reflect a local language that is ingrained in the network's unique culture. However, when it is interpreted out of context, they lose their context-specific meaning. Similarly, in a much more general sense, before the advent of Twitter (an online social networking and microblogging service), the word "tweeps" (defined as followers of a person/organization on Twitter) was never used. Interestingly, current trends suggest having a high number of "tweeps" as a metric to measure how well followed a person is. Emergence of local language is a commonly found feature of a community, and the same can be applied to online communities as well. Therefore, when analyzing online social network data to understand communication patterns underlying human behavior, understanding community-specific context is mandatory to derive meaningful inferences from the data.

A grounded theory approach was used to analyze QuitNet data to understand the core concepts, the interrelations among concepts, and the roles played by these concepts in an individual's smoking cessation activity. The first step in the coding process involved open coding, where a line-by-line analysis was performed on the messages to derive abstract concepts from the data. The messages considered for analysis were selected at random using a scripted random number generator [67]. Each selected message was then reviewed, noting pertinent smoking cessation-related concepts in terms of general open codes that were generated dynamically as the data were reviewed.

Examples of open codes included "statistics," "pregnancy," "boredom," "temper," "patch," and "pledge." This process was repeated until no new concepts were produced from the dataset. Appropriateness of code assignment was ascertained using constant comparison, where instances of codes were compared in an iterative manner to make sure they reflected the same concept. The second step was performed by re-organizing and re-grouping the open codes using axial coding. Axial coding allowed for the identification of unifying, repeated patterns underlying the concepts and their relationships, thereby revealing core themes relevant to smoking cessation. Examples of core themes include "Family and friends," "Obstacles," and "Traditions." Initial coding was performed manually, and later the NVivo software suite for qualitative analysis was used to analyze themes and their patterns of occurrence in the data. A total of 585 randomly selected messages were analyzed as described using grounded theory principles. Furthermore, the analysis was carried out for an additional 210 messages to ensure no new concepts emerged. Once themes were identified, a second coder conducted thematic analysis of a subset of 100 messages to ascertain the applicability of the derived themes to other QuitNet messages. This second round of coding was used to measure interrater reliability using Cohen's kappa measure. This qualitative analysis allowed for an in-depth evaluation of the interactions among people in the QuitNet virtual community and thereby a deeper understanding of the behavior change processes that QuitNet users undergo when attempting to cease smoking.

This thematic taxonomy derived from our grounded theory analysis was then mapped to theoretical constructs derived from SCT, TTM, HBM, and TRA, since these theories had been applied to several published studies on smoking-related behavior change. In addition, we also used the original behavior change taxonomy, developed by Abraham et al, with 26 theory-linked behavior change strategies [45]. As part of theme-theory mapping, the messages in each theme and corresponding thematic definitions were compared to descriptions of theoretical constructs and taxonomy techniques in order to ascertain whether a particular theme facilitates the transmission of a specific behavior change construct.

Results

QuitNet Themes

A total of 43 different concepts were identified, which were then grouped under 12 themes. Examples of the grouping strategy employed to arrive at the thematic level are shown in Figure 1, where the "Obstacles" theme is composed by subsuming multiple concepts: "sleepiness," "weight gain,"

"temper," "boredom," and "trouble sleeping." These concepts were cited as hurdles that members faced in their attempts to quit smoking. Similarly, "traditions," "playing games," "sharing weather details," "attending virtual bonfire events," and "taking part in daily online pledge" were the observed communal practices that are deeply rooted in the QuitNet community. Definitions of the themes and example messages for each theme are listed in Table 2.

Table 2. QuitNet themes, definitions, and example messages.

Theme	Definition	Example message
Quit Obstacles	Messages in which members talk about the hurdles they are dealing with or have dealt with to stay abstinent (eg, sleepiness, weight gain, temper)	I lost quits in the past because I was so mean and nasty that my family and friends told me to smoke.
Teachable Moments	Messages where the senders mention about the incentives one gets for not smoking in terms of quality of life	Food is wonderful...smell is wonderful...I smoked from 14-46...I never knew what I was missing.
Quit Readiness	Messages that attempt to provide inspiration and prompt readiness to quit and initiate a smoke-free life	You can do anything if you would want it bad enough...
Cravings	Messages that capture the real-time expressions of the users urge to smoke	I want a cigarette very much. I am trying to resist.
Conflict	Messages that reflect a rift between two group members	No one likes being called a liar, especially if they are NOT. Go sit
Relapse (confessions, reasons, retries)	Messages in which members explain why they relapsed and/or share their emotions after they suffered a relapse	I hate myself, I slipped again. I lighted the nicodemon
Traditions	Messages that focus exclusively on QuitNet-specific events such as bonfires, pledges, games, and so on	I've got over 5K unsmoked cigs which I'd be delighted to unload onto a raging bonfire.
Quit Progress	Messages in which members communicate their progress based on abstinence time and/or number of unsmoked cigarettes	Gratefully smoke free for 33 days, 17 hours, 1 minute and 6 seconds.
Family and Friends	Message in which members mention their spouses, children, or friends as motivators	My hubby...poor guy used to get to sleep when I smoked...now he is sleepless but smiling...
Virtual Rewards	Messages in which members mention the virtual gifts (such as bracelet, virtual pet, socks) received on QuitNet marking a milestone	awesome three days. I like the bracelet.
Social Support	Messages where the content reflects the elements of praise, advice, empathy, and guidance	Almost a year already.//// Congratulations to you, what a great accomplishment.
Pharmacotherapy	Messages where members explicitly discuss and evaluate various pharmacotherapy options and best practices for management of nitone withdrawal symptoms	I did not use any nrt though I recently went on welburtin after days ct

A detailed distribution of the themes across messages is shown in Figure 2. "Traditions," "Social support," and "Progress" were the most frequently found themes, followed by discussions related to "Teachable moments/Benefits," "Relapse," and "Cravings," "Conflict"-related messages were the least frequently found, only behind "Virtual Rewards," "Pharmacotherapy," "Family and friends," and "Obstacles."

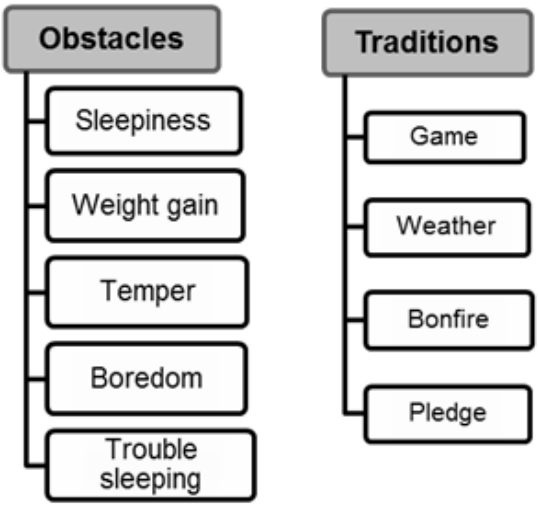
QuitNet members exchange messages pertaining to traditions that are specific to QuitNet. Examples of traditions are as follows: (1) bonfire: a virtual event hosted regularly where members bring their unsmoked cigarettes and throw them into a fire, and (2) pledge: a member virtually extends their hand to another member indicating their commitment towards staying abstinent. This represents the support the member offers to the next person in line to help them stay smoke-free, and as such is one example of the content of messages belonging to the social support category. These messages provide guidance, express empathy, convey admiration, and promote bonding. Expressions of empathy, love, trust, and caring, which form the basis of emotional support, were also communicated using phrases such as "hugs," "flowers," and "kisses." Members use measurable metrics such as the number of unsmoked days and cigarettes, the amount of money not spent on cigarettes, and the number of days of life saved by staying smoke-free to measure their "Progress." These metrics are automatically calculated by the website using a user's recorded quit date and displayed to the user and can be embedded in messages similar to an email signature. Members refer to these calculated metrics when providing positive feedback to others and utilize them for self-monitoring.

Analysis of the QuitNet data provided crucial insights into the relapse experiences of smokers and ex-smokers. Work-related stress, family tragedies, inability to ward off cravings, and a false notion of "just one puff" (denotes weak moments where members smoke a cigarette thinking that it would not affect their ability to stay abstinent from then on) were cited as common reasons for relapse. Relapse is a common problem encountered by smokers who are trying to quit and ex-smokers who successfully quit [68]. In addition to messages indicating risk factors for relapse, messages where members declare their relapse and communicate their emotions (eg, "tears rolling down," "cheating the loved ones," and "feeling like a loser")

after relapse were also included in this theme. Also, messages describing the "aha moments" where members recollect the reasons behind their decision to quit smoking occur in the dataset. Health-related issues such as the onset of smoking-related disease and pregnancy are cited as common drivers for these teachable moments/benefits, while quality of life concerns such as problems related to exercise, family time, physical appearance, and social awkwardness are also listed as reasons for quitting.

The day-to-day urges to smoke in QuitNet members' journeys towards smoke-free lives were defined by cravings for cigarettes. This theme ("Cravings") includes messages with content where successful quitters explained to fellow members how they dealt with cravings. Some messages even contained information about members' experiences and efforts as they dealt with cravings in real-time. Messages relevant to the quit readiness theme displayed an effort made by QuitNet members to encourage fellow members by making inspiring, engaging, and thought-provoking comments on the role played by personality traits such as attitude and willpower in a successful quit attempt. Messages also have content through which members mentioned the obstacles they were facing, or have faced, at some point of their abstinence phase. Weight gain, temper, problems with sleep, and boredom were among these hurdles. Family (eg, spouse, children) and friends are mentioned in some of the messages as support network or motivators or obstacles. For instance, members mentioned not being able to stay abstinent because of watching their spouses smoke. Pharmacotherapy options are also discussed in QuitNet messages. Usage of patches and gums and going "cold turkey" (ie, quitting without any pharmaceutical assistance) are discussed as facilitators of behavior change. The members requested information about withdrawal effects and side-effects associated with the use of nicotine replacement therapies. Also, successful quitters advised newer members to make use of a patch to fight cravings and avoid relapse. Another emergent behavior exhibited by QuitNet members involved the role of virtual rewards. Some of these rewards included bracelets, virtual pets, socks, and access to an "elder lodge" where successful quitters meet virtually. Rewards were given when members met milestones such as 3-day, 15-day quit, and 100-day quits, 1-year anniversaries, and so forth.

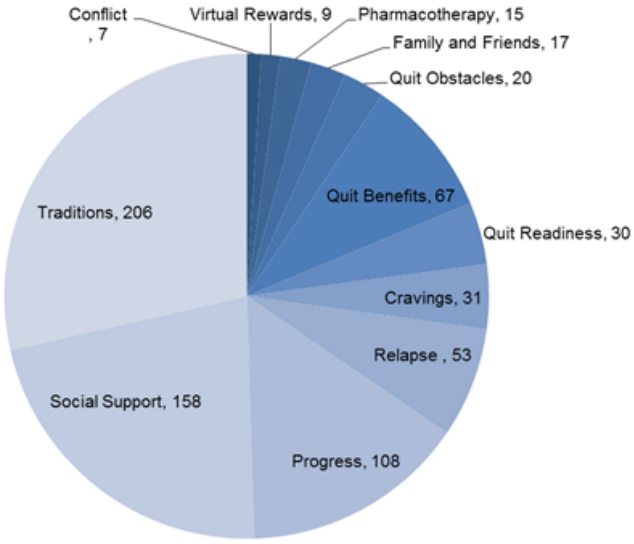
Figure 1. Themes in QuitNet.



Interrater Reliability

Two researchers independently coded another subset of 100 randomly selected messages using the thematic terminology developed using grounded theory techniques. The codes they assigned to the messages had a Cohen's kappa measure of 81.6%, where the 84 of the 100 messages had observed agreement. Disagreement was resolved using discussion, and the majority of the disagreement (12/16 discrepancies) was attributable to messages with "dual" content, where they could potentially be deemed as observing a community-specific tradition or measuring user progress in their smoking cessation efforts.

Figure 2. Grounded theory-based qualitative analysis of 795 messages.



Thematic Interrelationships: Comparison With Existing Behavior Change Theories

The themes identified in QuitNet communication relate to the sociobehavioral and cognitive constructs of the existing behavior change theories. Tables 3 and 4 show how QuitNet themes can facilitate a driver of behavior change that relates to one of the theoretical constructs. A comparison matrix for inductively derived themes (seen in columns) and theoretically derived constructs (seen in rows) is provided based on the analysis of their definitions and the concepts they represent. An "X"-marked cell (see Tables 3 and 4) indicates that a given theme relates to a particular construct. For example, consider the concept of stimulus control, which involves using reminders and cues that encourage healthy behavior as substitutes for those that encourage the unhealthy behavior. For individuals who are accustomed to smoking early in the morning, there exists a QuitNet-specific tradition where members post messages describing early morning weather and reaffirm their commitment to stay abstinent. Themes such as virtual rewards, traditions, and progress have components that attempt to improve self-efficacy of an individual. An individual's self-efficacy can affect their motivation to achieve a goal, such as adhering to a healthy behavior [17,18]. Persons with high self-efficacy are more likely to persist longer in efforts to achieve the desired goal [19,20]. In the case of smoking cessation, ability to ward off cravings and stay abstinent can be improved by enhancing a person's self-efficacy [69-72], which can be achieved by setting and achieving short-term goals. Organizing such goals in a group environment also induces observational learning. For instance, virtual rewards such as bracelets and virtual pets accomplish the task of short-term goal setting. Watching other members receive these rewards often motivated QuitNet members to stay abstinent as evidenced by the following quote: "So proud of you, I won't light my cigarette, want that lovely bracelet on my hand". Bonfires (a component of the "Traditions" theme) are related to observational learning, where a QuitNet member is motivated by the praise another member received at the event on account of the number of unsmoked cigarettes they brought. Similarly, themes such as cravings and relapse address the aspect of dramatic relief described by the TTM. Teachable moments/benefits and obstacles relate to the decisional balance component of behavior change. Environmental reevaluation is also provided by these two themes. The social support theme includes several important constructs such as consciousness raising, cue to action, emotional coping, and helping relationships. For example, when a member was attempting to overcome a craving, other QuitNet members often post messages that attempt to help the peer member realize how far they have come, the reasons for their quitting, and provide them with a supporting shoulder.

As described above, several constructs from the existing intra- and inter-individual behavior change theories are put together and compared with the themes derived from QuitNet content. The graphs in Figure 3 present the prevalence of the constructs in QuitNet themes. Self-efficacy and observational learning are the most relevant theoretical constructs, followed by observational learning and helping relationships (see Figure 3). On the other hand, traditions-related messages were highly aligned with theoretical constructs, followed by relapse, virtual rewards, and teachable moments/ benefits (Figure 3). Results indicate that community-based activities such as traditions organized in virtual communities such as QuitNet might play an important role in operationalizing theoretical constructs in the virtual settings. In addition, member-generated strategies such as bonfires and pledges facilitated the highest number of theoretical constructs from a variety of theories. Therefore, it is important to note that no single theory from behavioral science provides a basis for all of the themes emerging from QuitNet messages.

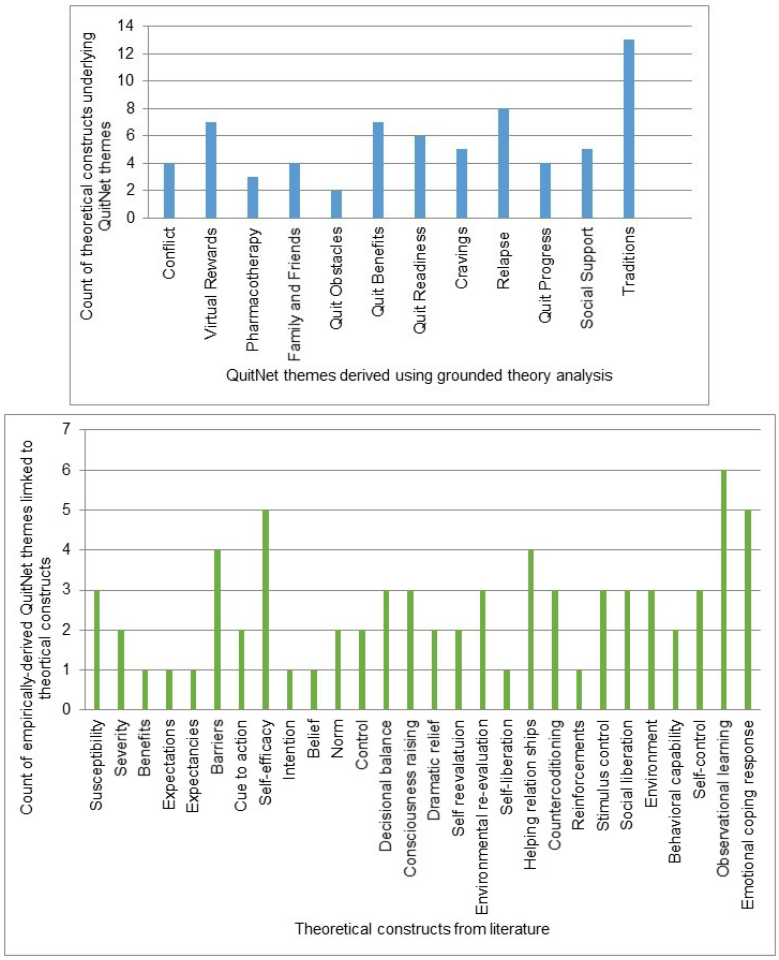
Table 3. Theme-theory matrix: conflict, virtual rewards, pharmacotherapy, family and friends, quit obstacles, and quit benefits.

Themes/Theoretical constructs	Conflict	Virtual rewards	Pharmacotherapy	Family and friends	Quit obstacles	Quit benefits
Susceptibility						X
Severity						X
Benefits						X
Expectations						
Expectancies						X
Barriers					X	
Cue to action			X			
Self-efficacy	X	X				
Intention						X
Belief						
Norm	X					
Control						
Decisional balance					X	X
Consciousness raising	X		X			
Dramatic relief						
Self-reevaluation						X
Environmental re-evaluation	X			X		X
Self-liberation						
Helping relationships	X			X		
Counterconditioning		X	X			
Reinforcements		X				
Stimulus control		X				
Social liberation	X			X		
Environment		X		X		
Behavioral capability						
Self-control		X				
Observational learning		X		X		
Emotional coping response				X		

Table 4. Theme-theory matrix: quit readiness, cravings, relapse, quit progress, social support, and traditions.

Themes/Theoretical constructs	Quit readiness	Cravings	Relapse	Quit progress	Social support	Traditions
Susceptibility	X		X			
Severity	X					
Benefits						
Expectations			X			
Expectancies						
Barriers		X	X		X	
Cue to action					X	
Self-efficacy	X		X	X		X
Intention						
Belief	X					
Norm						X
Control	X					X
Decisional balance		X				
Consciousness raising					X	
Dramatic relief		X	X			
Self-reevaluation						X
Environmental re-evaluation						
Self-liberation						X
Helping relationships			X		X	X
Counterconditioning						X
Reinforcements						
Stimulus control				X		X
Social liberation	X					
Environment						X
Behavioral capability			X			X
Self-control				X		X
Observational learning		X	X	X		X
Emotional coping response		X	X		X	X

Figure 3. Thematic and theoretical prevalence in QuitNet content.



Mapping to Taxonomy of Behavior Change Techniques

The themes identified in QuitNet communication relate to the 21 standardized theory-linked behavior change techniques put together by Abraham et al. Tables 5-7 show the manifestation of the behavior change techniques in QuitNet themes. A binary matrix for inductively derived themes (seen in columns) and theoretically linked constructs (seen in rows) is provided based on the comparative analysis of their definitions and the concepts they represent. A tick mark (see Tables 5-7) indicates that a given theme operationalized a specific behavior change technique. For example, quit obstacles, cravings, and relapse are the three themes that embedded content to prompt barrier identification among QuitNet users. Similarly, providing general information about the risks associated with smoking cessation (eg, mortality-related information) has been facilitated through exchange of messages that belong to quit obstacles, quit benefits, and quit readiness. As shown in Figure 4, almost all (25/26, 96%) the behavior change techniques are found to be operationalized through messages exchanged by QuitNet users. Follow-up prompting, which is implicitly embedded in peer communication in QuitNet, was found to be the only technique where a specific QuitNet theme cannot be matched. Of the remaining 25 techniques in the taxonomy, we found that proving social approval, social support, prompting self-talk, providing instructions, and general encouragement were most commonly facilitated in QuitNet communication. Conversely, messages categorized under traditions were transmitting content that can operationalize many (18/26, 69%) behavior change techniques. Interestingly, from our analysis on theme-theory-comparison, we found that traditions-related messages were aligned with the highest number of theoretical constructs. All QuitNet themes derived using grounded theory techniques were found to be facilitating at least one behavior change technique.

Table 5. Theme-taxonomy matrix: conflict, virtual rewards, pharmacotherapy, and family and friends.

Behavior change techniques	Conflict	Virtual rewards	Pharmaco-therapy	Family and friends
Provide information about behavior health link	–	–	–	–
Provide information on consequences	–	–	–	–
Provide information about others' approval	–	✓	–	✓
Prompt intention formation	–	–	–	✓
Prompt barrier identification	–	–	–	–
Provide general encouragement	–	✓	–	✓
Set graded tasks	–	✓	–	–
Provide instruction	–	–	✓	–
Model or demonstrate the behavior	–	✓	–	✓
Prompt specific goal setting	–	✓	–	–
Prompt review of behavioral goals	–	✓	–	–
Prompt self monitoring of behavior	–	–	✓	–
Provide feedback on performance	–	–	–	–
Provide contingent rewards	–	✓	–	–
Teach to use prompts or cues	–	–	✓	–
Agree on behavioral contract	–	✓	–	–
Prompt practice	–	–	–	–
Use follow-up prompts	–	–	–	–
Provide opportunities for social comparison	–	✓	–	✓
Plan social support or social change	–	✓	–	✓
Prompt identification as a role model	–	✓	–	–
Prompt self-talk	✓	✓	–	–
Relapse prevention	–	–	✓	–
Stress management	–	–	✓	–
Motivational interviewing	–	–	–	–
Time management	–	–	–	–

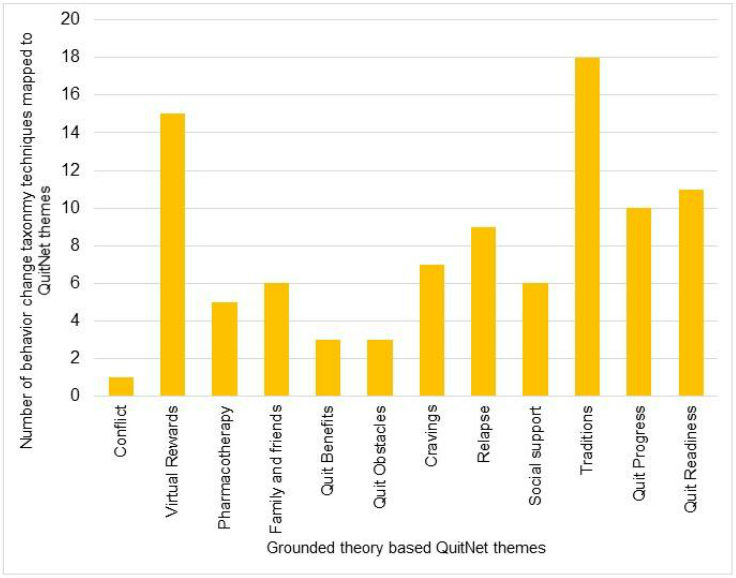
Table 6. Theme-taxonomy matrix: quit obstacles, quit benefits, cravings, and relapse.

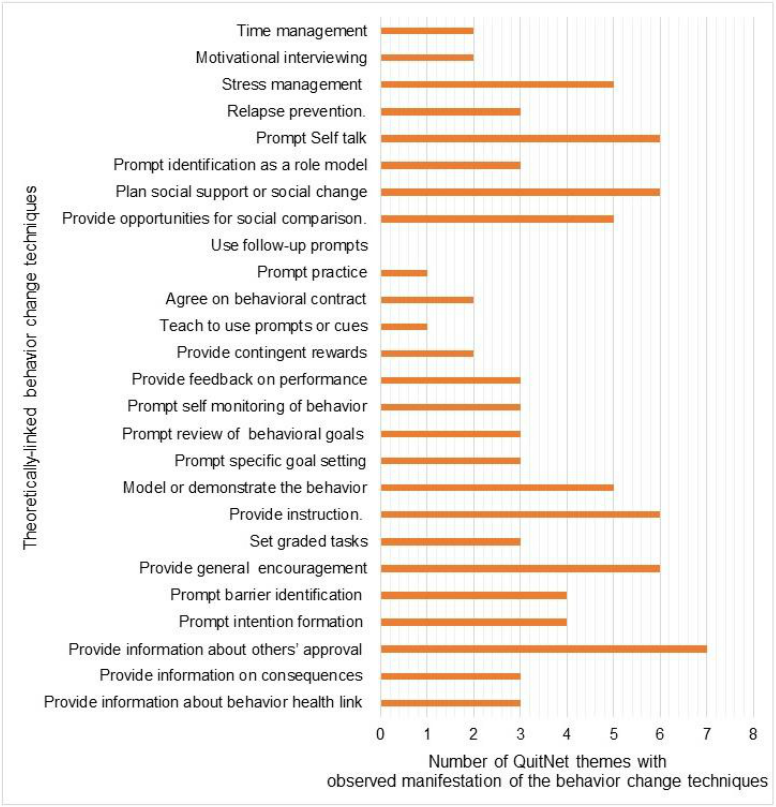
Behavior change techniques	Quit obstacles	Quit benefits	Cravings	Relapse
Provide information about behavior health link	✓	✓	–	–
Provide information on consequences	✓	✓	–	–
Provide information about others' approval	–	–	✓	✓
Prompt intention formation	–	✓	–	–
Prompt barrier identification	✓	–	✓	✓
Provide general encouragement	–	–	–	–
Set graded tasks	–	–	–	–
Provide instruction	–	–	✓	✓
Model or demonstrate the behavior	–	–	✓	–
Prompt specific goal setting	–	–	–	–
Prompt review of behavioral goals	–	–	–	–
Prompt self monitoring of behavior	–	–	–	–
Provide feedback on performance	–	–	–	✓
Provide contingent rewards	–	–	–	–
Teach to use prompts or cues	–	–	–	–
Agree on behavioral contract	–	–	–	–
Prompt practice	–	–	–	–
Use follow-up prompts	–	–	–	–
Provide opportunities for social comparison	–	–	–	✓
Plan social support or social change	–	–	✓	✓
Prompt identification as a role model	–	–	–	–
Prompt self-talk	–	–	–	✓
Relapse prevention	–	–	✓	✓
Stress management	–	–	✓	✓
Motivational interviewing	–	–	–	–
Time management	–	–	–	–

Table 7. Theme-taxonomy matrix: quit progress, social support, traditions, and quit readiness.

Behavior change techniques	Quit progress	Social support	Traditions	Quit readiness
Provide information about behavior health link	–	–	–	✓
Provide information on consequences	–	–	–	✓
Provide information about others' approval	–	✓	✓	✓
Prompt intention formation	–	–	✓	✓
Prompt barrier identification	–	–	–	✓
Provide general encouragement	✓	✓	✓	✓
Set graded tasks	✓	–	✓	–
Provide instruction	–	✓	✓	✓
Model or demonstrate the behavior	✓	–	✓	–
Prompt specific goal setting	✓	–	✓	–
Prompt review of behavioral goals	✓	–	✓	–
Prompt self monitoring of behavior	✓	–	✓	–
Provide feedback on performance	✓	–	✓	–
Provide contingent rewards	–	–	✓	–
Teach to use prompts or cues	–	–	–	–
Agree on behavioral contract	–	–	✓	–
Prompt practice	–	–	✓	–
Use follow-up prompts	–	–	–	–
Provide opportunities for social comparison	✓	–	✓	–
Plan social support or social change	–	✓	✓	–
Prompt identification as a role model	✓	–	✓	–
Prompt self-talk	✓	–	✓	✓
Relapse prevention	–	–	–	–
Stress management	–	✓	–	✓
Motivational interviewing	–	✓	–	✓
Time management	–	–	✓	✓

Figure 4. Taxonomy-based analysis of QuitNet themes.





Discussion

Study Implications

In the case of QuitNet, activities such as pledges and bonfires emerged from within the community and each of those events marks a specific aspect of the smoking-cessation process. With the evolution of communication channels from being traditional face-to-face conversations to virtual social networks powered by Web-based mHealth systems, the validity of existing behavior change theories in the digital era has been questioned [49,50]. This qualitative analysis establishes the validity of behavior change theories in the context of 21st-century technologies. In addition, the inductive evaluation of social network content revealed new sociocognitive constructs, which have not been considered by existing behavior change theories. For instance, the conflict theme, which deals with the conflicts that arise between QuitNet members, is not found in any existing sociobehavioral theories because the foundation for these theories is group cooperation and not group competition. This finding highlights the need to incorporate mechanisms that build trust among members who communicate with one another using virtual channels. In addition to emphasizing progress and positive aspects of smoking cessation, focus on community-building and social togetherness (eg, bonfires) have helped members adhere to their quit attempts. As another example, none of the messages mentioned the role of a physician

in their efforts to cease smoking, suggesting the behavior change effort in this community is primarily self-propelled. Like any other virtual community, most content embeds aspects of social support. In addition to support, several other sociobehavioral elements related to behavior change theories were found in QuitNet messages. Our analysis revealed that most QuitNet themes (1) relate to important behavior change constructs belonging to multiple theories and (2) operationalize several techniques outlined in the behavior change taxonomy.

Qualitative methods form a very important toolkit to conduct nuanced analysis of health-related communications in online platforms. As we have shown, inductive analytic techniques that are data-driven enabled us to characterize peer interactions in QuitNet. Further, use of grounded theory analysis allowed us to develop thematic representations of QuitNet messages that are empirically driven and not theoretically biased. Subsequently, comparison analysis consisting of (1) sociobehavioral constructs from existing behavior change theories and (2) theoretically linked taxonomy of behavior change techniques allowed us to understand the theoretical roots and operational features of consumer-driven QuitNet communication. The methodological process itself is immensely informative, comprehensive, and generalizable, while being empirically grounded and theoretically aligned simultaneously. The applicability of the methods discussed in this paper can be taken well beyond the analysis of a small scale sample through use of automated text analysis methods. Communication exchanges in online communities are time-stamped and digitized and therefore are amenable to machine learning [73-75]. Classification of conversational and informational postings on social media websites has been attempted using a combination of human coding, statistical analysis, and machine learning [76]. Methods of distributional semantics have also been combined with machine learning algorithms to classify consumer health webpages based on language use patterns [77]. Semantic space models, methods of distributional semantics where both terms and larger units of text are represented in a high-dimensional vector space [78], have been applied to peer-to-peer interactions in online communities [79-83]. While much of this work is at an early stage, the adaptation of such methods of distributional semantics to represent communication between members of online communities shows considerable promise. As part of our ongoing and future studies, we have adapted methods of distributional semantics in conjunction with machine learning algorithms to enable high-throughput analysis of online social network data [82,83]. Such methods facilitating resource-optimized extension of qualitative analysis to large-scale digital health data can extend the research and application frontiers of social media, thereby further enhancing their positive impact on health-related behaviors.

Limitations

This paper provides insights into the ways that consumer interactions in online communities can be conducted using methods that are empirically motivated and theoretically driven. Such qualitative analysis provided useful insights into prominent themes in QuitNet communication. Although we have ensured the study of coding and reliability was conducted before we formulated theme-theory linking as a potential next step in order to minimize the influence of predispositional knowledge on theme identification, the analysis may be amenable to subjective knowledge. In addition, manual coding is highly labor-intensive and time-consuming. Consequently, the analysis is limited to a small sample size, potentially limiting the generalizability of these results. It is possible that given the low fraction of messages thematically coded, the distribution of the themes might not have been accurately represented. To attempt to address this, 210 messages were coded to reach thematic saturation. However, it may be possible that the remainder of the dataset contains additional themes that were not captured. The rapid growth of digital technologies will further complicate this issue, as it will generate a data deluge of millions of messages transmitted over the Web and mobile media. Therefore, for large datasets, one needs to complement the qualitative method with an automated technique that can optimize resource utilization. The QuitNet dataset considered in our analysis was recorded in 2007. For future studies, we will attempt to obtain further data drawn from recent datasets. However, we strongly believe that the findings from the reported data on human behavior still hold, since the basic tenet of forum-based communication (structure and logistics) remains the same. Even emerging health-related network platforms (eg, PatientsLikeMe) also embed online forums to facilitate peer-to-peer communication. Threaded discussions in the form of comments in contemporary platforms also provide forum-like environments to facilitate text-based communication among users in online platforms. In addition, this analysis does not take into account seasonal patterns that might affect an individual's behavior change (eg, New Year's resolutions) because of the limited size and time period of our QuitNet dataset. We will attempt to address these issues through use of larger longitudinal datasets. Similarly, there have been some novel developments with respect to modes of nicotine intake (eg, e-cigarettes) [84] that were not observed in our dataset. However, we do not believe the mechanisms of social influence in a forum-based context have changed substantially over the past decade. Proliferation of daily use social networks like Facebook and Twitter engage users in peer communication through modes other than text-based messaging. These open domain social networks facilitate study of online behavior through "likes" and "shares," which may have provided additional insights [85,86] but were not a feature of our dataset. Consequently, our analysis is limited to text-based user communication among users of an online community.

Conclusions

This paper describes a qualitative analysis of online social network communication using a grounded theory approach. The key contributions of this study are as follows:

1. The study describes the first grounded theory–based qualitative analysis of the communication in an online social network developed to promote behavior change. Contrary to prior qualitative studies that focused on a specific behavior change mechanism (either social support or emotional coping), our paper presents an empirically driven perspective on manifestations of theoretical behavior change constructs in online platforms.

2. The methodological process allows investigation of consumer-driven behavior change attempts in online communities from the perspective of existing behavior change theories.
3. The study attempts to understand the applicability of hypothesis-driven behavior change constructs to organically evolving user communication in online platforms.
4. This is the first reported attempt of analyzing online user interactions using the taxonomy of behavior change techniques, subsequently imposing the structure of common vocabulary to understand the ways that consumer interactions implicitly operationalize sociobehavioral and cognitive constructs of existing behavior change theories.

Capturing the essence of the meaning underlying the messages exchanged during different situations and contexts in this manner provides important information to guide further investigations. Qualitative analysis of communication between members of an online social network can provide valuable insights into the mechanisms underlying human behavior change. With the onset of mobile phones and ubiquitous Internet connectivity, online social network data reflect the intricacies of human health behavior as experienced by real people in real time. Therefore, analysis of these data can also provide us with the much needed theoretical and empirical foundations for the design of effective intervention strategies. This study offers insights into the various kinds of behavioral constructs prevalent in the messages exchanged among QuitNet users. In addition, it underlines the need for the use of inductive approaches for the analysis of online social network data to capture community-specific culture. As such, these findings suggest the need for an aggregation of multiple theoretical constructs from more than one inter- and intra-individual theory. Given the context-rich nature of the messages, they yield empirical understanding of human behavior change. This understanding has important implications for both theory and practice. Theoretically, inductive analysis of virtual communities provides us with a basic understanding of human behavior in the digital era. In terms of practical implications, the study sets the stage for (1) modeling supervised machine learning algorithms that can scale the theoretically valid findings to large datasets [82] and (2) simulating social network models where the relations between members were inductively derived [82,83]. The study thus facilitates the development of data-driven digital health interventions that promote healthy lifestyle modifications by harnessing social influence mechanisms. Such transdisciplinary, theoretically validated, empirically grounded solutions may hold the key to a healthier future.

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Conflicts of Interest

None declared.

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Abbreviations

HBM: Health Belief Model
TRA: Theory of Reasoned Action
TTM: Transtheoretical Model
SCT: Social Cognitive Theory

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Original Paper

Association Between Media Dose, Ad Tagging, and Changes in Web Traffic for a National Tobacco Education Campaign: A Market-Level Longitudinal Study

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Abstract

Background: In 2012, the US Centers for Disease Control and Prevention (CDC) launched *Tips From Former Smokers (Tips)*, the first federally funded national tobacco education campaign. In 2013, a follow-up *Tips* campaign aired on national cable television networks, radio, and other channels, with supporting digital advertising to drive traffic to the *Tips* campaign website.

Objective: The objective of this study was to use geographic and temporal variability in 2013 *Tips* campaign television media doses and ad tagging to evaluate changes in traffic to the campaign website in response to specific doses of campaign media.

Methods: Linear regression models were used to estimate the dose-response relationship between weekly market-level television gross rating points (GRPs) and weekly Web traffic to the *Tips* campaign website. This relationship was measured using unique visitors, total visits, and page views as outcomes. Ad GRP effects were estimated separately for ads tagged with the *Tips* campaign website URL and 1-800-QUIT-NOW.

Results: In the average media market, an increase of 100 television GRPs per week for ads tagged with the *Tips* campaign website URL was associated with an increase of 650 unique visitors ($P<.001$), 769 total visits ($P<.001$), and 1255 total page views ($P<.001$) per week. The associations between GRPs for ads tagged with 1-800-QUIT-NOW and each Web traffic measure were also statistically significant ($P<.001$), but smaller in magnitude.

Conclusions: Based on these findings, we estimate that the 16-week 2013 *Tips* television campaign generated approximately 660,000 unique visitors, 900,000 total visits, and 1,390,000 page views for the *Tips* campaign website. These findings can help campaign planners forecast the likely impact of targeted advertising efforts on consumers' use of campaign-specific websites.

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KEYWORDS

Internet; advertising; health communication; smoking cessation; public health; tobacco control

Introduction

As websites and social media have evolved into powerful channels for tobacco advertising [1], they have also become a vital component of health education campaigns. Daily Internet use is high among US adults (82%) and most Internet users (80%) report searching for health-related information online [2]. State tobacco control programs have accelerated their creation of state-sponsored websites and social media accounts [2], offering multiple platforms to tobacco users for outreach and cessation interventions. Furthermore, Web analytics have

evolved to allow organizations to assess the effectiveness of campaigns on increasing traffic to websites [3].

In 2012, the US Centers for Disease Control and Prevention (CDC) launched *Tips From Former Smokers* (*Tips*), the first federally funded national tobacco education campaign, resulting in an estimated additional 1.6 million quit attempts nationally [4]. A second wave of *Tips* aired from March 4 to June 21, 2013, using similar creative content—graphic, emotional advertisements portraying the health consequences of smoking. Approximately one-third of all television ads were tagged with the *Tips* campaign website URL [5], while two-thirds promoted the national 1-800-QUIT-NOW telephone quitline. The 2013 campaign was also supported by digital advertising, including online video, display, mobile, and paid search ads.

Previous research has shown that weekly traffic to the *Tips* website increased dramatically during the 2013 *Tips* campaign compared with the 4 weeks before and after the campaign [6]. However, a limitation of this analysis was the use of a pre-post analysis that assesses changes in Web traffic purely as a function of campaign airdates. This approach fails to account for variation in media dose during the campaign (ie, temporal variation) and across media markets (ie, geographic variation), in addition to the differences in population and sociodemographic characteristics of each market. To our knowledge, no studies have examined the relationship between varying doses of advertising for a national health education campaign and the magnitude of changes in Web traffic over time. To address this gap in the literature, we used geographic and temporal variation in 2013 *Tips* gross rating points (GRPs) to quantify market-level changes in use of the *Tips* website in response to specific unit increases in weekly dose of GRPs. These results were used to estimate the additional traffic to the *Tips* website attributable to the 2013 *Tips* television ads tagged with the *Tips* campaign website URL or 1-800-QUIT-NOW.

Methods

Outcome Variables

We assessed three primary outcomes of Web traffic to the *Tips* website: (1) total unique visitors, (2) total visits, and (3) total page views. These metrics were derived from Adobe SiteCatalyst, a tool that provides utilization and engagement metrics for websites.

Unique visitors included the total number of unique individuals who visited the site during a given period, regardless of number of repeat visits by each individual. Visits are defined as the total number of visits made to the website during a given time period. A visit occurs when an individual arrives at and navigates the website, even if the individual has previously visited the site. A visit may consist of multiple page views, and each individual visit continues until there are 30 minutes of browser inactivity or 12 hours of continuous activity. Page views are the total number of times that individual website pages are viewed. For example, if one user views five pages on the site, this represents five total page views for that period. For these three aforementioned outcomes, metrics for each of the 210 US media markets were aggregated for each of the 16 weeks of the 2013 *Tips* campaign and for the 4 weeks before and after the campaign—24 weeks total.

Control Variables

The primary measure of 2013 *Tips* exposure was weekly media market-level GRPs for television ads. GRPs measure the relative "dose" of advertising delivered to a target audience in a given media market and time period. They are defined as the product of the proportion of an audience that is potentially exposed (ie, audience reach) and the frequency of that exposure (ie, number of times an ad was aired). For example, if a television ad reaches 50% of an audience twice in one week, the GRP for this ad during that week is 100 (50 x 2) [7].

During 2013 *Tips*, CDC also delivered a significantly higher dose of digital video advertising to three media markets—Cleveland, Ohio; Sacramento, California; and Tampa, Florida. This additional digital video advertising used the same creative content as the television ads, all of which were linked to the *Tips* website. To account for the impact of this higher dose of digital video advertising on Web traffic in these three markets, separately from the main effect of *Tips* television GRPs, our analysis included an indicator (fixed effect) for the higher-dose markets that is equal to 1 for those three markets and 0 otherwise.

Statistical Analysis

We used linear regression models to estimate each outcome variable at the media market level as a function of market-level weekly television GRPs (in 100s) tagged with the *Tips* website URL and GRPs tagged with 1-800-QUIT-NOW. We estimated separate models to assess the impact of each type of ad tagging. We also controlled for week of the campaign; additional state-funded airings of *Tips* ads, measured with GRPs (in 100s); and market-level sociodemographic characteristics, including total population (in 10,000s), cigarette smoking prevalence (0-100), percentage African American (0-100), percentage Hispanic (0-100), percentage with a bachelor's degree (0-100), and median income (in US dollars). Linear predictions were made using the observed *Tips* GRP effect and effect of higher-dose digital advertising (actual) and an alternate scenario that assumed zero television GRPs and no higher-dose digital advertising (counterfactual). The differences between the actual and counterfactual predictions for each outcome are reported as the campaign-attributable effects. All analyses were conducted using Stata 13.2 (StataCorp LP) [8].

Results

An increase of 100 television GRPs per week for ads tagged with the *Tips* website URL was associated with increases of 650 unique visitors ($P<.001$), 769 total visits ($P<.001$), and 1255 total page views ($P<.001$) per week in each media market (see Table 1). An increase of 100 television GRPs per week for ads tagged with 1-800-QUIT-NOW was associated with increases of 280 unique visitors ($P<.001$), 334 total visits ($P<.001$), and 547 page views ($P<.001$) per week in each media market. State-funded *Tips* campaign GRPs were not associated with measures of Web traffic. Media markets that received higher-dose digital advertising had approximately 2950 more

unique visitors (*P*<.001), 6050 more visits (*P*<.001), and nearly 8150 more page views (*P*<.001) at the *Tips* website per week than markets that did not receive higher-dose digital advertising. Increases in market-level smoking prevalence were significantly associated with lower weekly Web traffic. Specifically, a 1% increase in smoking prevalence was associated with a decrease of approximately 19 unique visitors, 21 visits, and 28 page views per week.

Based on these findings, we estimate that 2013 *Tips* was responsible for approximately 660,000 additional unique visitors, 900,000 additional visits, and 1,390,000 additional page views to the *Tips* website over the course of the 16-week campaign (see Table 2).

Table 1. Multivariate regressions for Web traffic as a function of 2013 *Tips* campaign dose.

Independent variable	*Tips* website URL, ad model coefficient (SE), *P*			1-800-QUIT-NOW, ad model coefficient (SE), *P*		
	Unique visitors	Visits	Page views	Unique visitors	Visits	Page views
Weekly GRPs[a] for ads tagged with *Tips* campaign website URL (in 100s)	650.2 (59.8), <.001	768.5 (77.3), <.001	1254.6 (116.7), <.001	N/A[b]	N/A	N/A
Weekly GRPs for ads tagged with 1-800-QUIT-NOW (in 100s)	N/A	N/A	N/A	279.6 (27.3), <.001	333.8 (35.3), <.001	546.7 (53.3), <.001
Weekly state-funded GRPs (in 100s)	11.5 (6.0), .06	12.2 (7.8), .12	19.3 (11.8), .10	11.6 (6.0), .05	12.4 (7.8), .11	19.6 (11.8), .10
Digital advertising higher-dose markets	2951.8 (98.2), <.001	6051.3 (126.9), <.001	8173.3 (191.6), <.001	2956.1 (98.3), <.001	6056.6 (127.0), <.001	8182.0 (191.8), <.001
Population of market (in 10,000s)	-330.8 (33.3), <.001	-358.6 (43.0), <.001	-602.8 (64.9), <.001	-331.7 (33.3), <.001	-359.5 (43.0), <.001	-546.7 (53.3), <.001
Smoking prevalence of market	-19.6 (5.8), .001	-22.0 (7.5), .003	-28.7 (11.3), .01	-19.0 (5.8), .001	-21.4 (7.5), .005	-27.7 (11.3), .02
Percentage of market population that is African American	11.9 (0.9), <.001	12.8 (1.2), <.001	20.7 (1.8), <.001	12.0 (0.9), <.001	12.9 (1.2), <.001	20.8 (1.8), <.001
Percentage of market population that is Hispanic	8.9 (1.1), <.001	9.7 (1.4), <.001	15.8 (2.1), <.001	9.0 (1.1), <.001	9.7 (1.4), <.001	15.9 (2.1), <.001
Percentage of market population that has a bachelor's degree or higher	-11.3 (3.4), .001	-12.4 (4.4), .005	-15.7 (6.7), .02	-11.1 (3.4), .001	-12.2 (4.4), .006	-15.5 (6.7), .02
Median income in market	0 (0), <.001	0.1 (0), <.001	0.1 (0), <.001	0 (0), <.001	0.1 (0), <.001	0.1 (0) <.001
Week of the campaign	-1.0 (1.7), .57	-0.2 (2.2), .91	1.1 (3.3), .74	0.2 (1.7), .92	1.1 (2.2), .61	3.3 (3.3), .31
Number of observations, n	5040	5040	5040	5040	5040	5040

[a]GRP: gross rating point.

[b]N/A: not applicable.

Table 2. Linear predictions of 2013 *Tips* campaign-attributable effects on unique visitors, visits, and page views for *Tips* campaign website.

Prediction scenario[a]	Unique visitors[b], n	Visits[c], n	Page views[d], n
Actual (observed campaign)	1,560,000	1,850,000	2,950,000
Counterfactual (no campaign)	900,000	950,000	1,560,000
Difference (campaign-attributable effect)	660,000	900,000	1,390,000

[a]All predictions are rounded to the nearest 10,000.

[b]Unique visitors represents the number of unique users of the website over a given time period.

[c]Visits represents total number of visits (including multiples by the same individual) to the website over a given period.

[d]Page views represents the total number of pages viewed on the website [5] across all visits in a given period.

Discussion

Principal Findings

This is the first study to quantify specific dosing levels for television advertising that are associated with weekly traffic to the *Tips* website. Although the estimated campaign-attributable increase in visits is substantial, the increase estimated in this study—660,000 additional unique visitors—is lower than the estimated 2.8 million additional unique visitors reported in earlier aggregate results [6]. Our estimates are likely more conservative because this analysis specifically quantifies the response of website use to specific unit increases in media doses while controlling for potential confounders, as opposed to a more crude approach of comparing Web traffic during the campaign period to time periods before and after the campaign.

As expected, the impact on Web traffic of ads tagged with 1-800-QUIT-NOW was smaller than the effect of ads tagged with the *Tips* website URL. The existence of an association with 1-800-QUIT-NOW tagging suggests that *Tips* ads, regardless of tagging, may generate measurable traffic to the *Tips* website. We also found that after adjusting for market-level sociodemographic characteristics, the higher-dose digital video advertising was associated with substantial increases in Web traffic. These findings demonstrate that a targeted digital strategy can help drive consumers to online resources offered by campaigns.

Our study is limited by the relatively short period of pre- and postcampaign Web traffic data available at the media market level (4 weeks before and after) compared to the length of the campaign (16 weeks). Our estimates may also be understated because traffic from users whose market location could not be established were excluded from the analysis. We also cannot establish that visitors to the campaign website were looking for cessation information, though with data on specific pages viewed, such an analysis would be possible and could establish an important link between increases in traffic to campaign websites and information-seeking for health education.

Conclusions

In conclusion, this analysis demonstrates a significant relationship between specific doses of television advertising and the magnitude of changes in campaign Web traffic over time. This is important given that one of the primary functions of the *Tips* campaign website is to provide smokers with information and resources to help quit; it is likely that many of the additional visitors are smokers seeking help in quitting. This study shows that direct tagging of traditional television ads with campaign website addresses and/or targeted digital advertising strategies can play a direct role in increasing the use of health-related online resources, independently of the dose-response effect of campaign intensity on Web traffic. These findings may help campaign planners forecast the likely impact of advertising efforts on consumers' use of campaign-specific websites and optimize their campaigns to increase use of online resources.

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Authors' Contributions

PS led drafting of the manuscript and conducted the analysis. KD assisted with study design and drafting of the manuscript. DP assisted in the drafting of the manuscript. RR and DB assisted in the implementation of the media buy and provided feedback on the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CDC: Centers for Disease Control and Prevention
GRP: gross rating point
N/A: not applicable

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Original Paper

What Predicts Patients' Willingness to Undergo Online Treatment and Pay for Online Treatment? Results from a Web-Based Survey to Investigate the Changing Patient-Physician Relationship

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Abstract

Background: Substantial research has focused on patients' health information–seeking behavior on the Internet, but little is known about the variables that may predict patients' willingness to undergo online treatment and willingness to pay additionally for online treatment.

Objective: This study analyzed sociodemographic variables, psychosocial variables, and variables of Internet usage to predict willingness to undergo online treatment and willingness to pay additionally for online treatment offered by the general practitioner (GP).

Methods: An online survey of 1006 randomly selected German patients was conducted. The sample was drawn from an e-panel maintained by GfK HealthCare. Missing values were imputed; 958 usable questionnaires were analyzed. Variables with multi-item measurement were factor analyzed. Willingness to undergo online treatment and willingness to pay additionally for online treatment offered by the GP were predicted using 2 multiple regression models.

Results: Exploratory factor analyses revealed that the disposition of patients' personality to engage in information-searching behavior on the Internet was unidimensional. Exploratory factor analysis with the variables measuring the motives for Internet usage led to 2 separate factors: perceived usefulness (PU) of the Internet for health-related information searching and social motives for information searching on the Internet. Sociodemographic variables did not serve as significant predictors for willingness to undergo online treatment offered by the GP, whereas PU (B=.092, *P*=.08), willingness to communicate with the GP more often in the future (B=.495, *P*<.001), health-related information–seeking personality (B=.369, *P*<.001), actual use of online communication with the GP (B=.198, *P*<.001), and social motive (B=.178, *P*=.002) were significant predictors. Age, gender, satisfaction with the GP, social motive, and trust in the GP had no significant impact on the willingness to pay additionally for online treatment, but it was predicted by health-related information–seeking personality (B=.127, *P*=.07), PU (B=–.098, *P*=.09), willingness to undergo online treatment (B=.391, *P*<.001), actual use of online communication with the GP (B=.192, *P*=.001), highest education level (B=.178, *P*<.001), monthly household net income (B=.115, *P*=.01), and willingness to communicate with the GP online more often in the future (B=.076, *P*=.03).

Conclusions: Age, gender, and trust in the GP were not significant predictors for either willingness to undergo online treatment or to pay additionally for online treatment. Willingness to undergo online treatment was partly determined by the actual use of online communication with the GP, willingness to communicate online with the GP, health information–seeking personality, and social motivation for such behavior. Willingness to pay extra for online treatment was influenced by the monthly household net income category and education level. The results of this study are useful for online health care providers and physicians who are considering offering online treatments as a viable number of patients would appreciate the possibility of undergoing an online treatment offered by their GP.

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KEYWORDS

physician-patient relationship, online treatment; general practitioners; willingness to pay

Introduction

The Changing Patient-Physician Relationship

The relationship between a physician and a patient is a very delicate conjunction. When selecting a general practitioner (GP), patients take multiple factors into consideration in addition to their location or office hours. Other factors, such as the ability to communicate, to develop trust, and the engagement of the physician regarding the patient's care, are also important factors in the selection process [1]. When patients feel well informed, they are more likely to follow the medication and treatment plan prescribed by a physician [2]. Within the last few years, there has been an enormous increase in demand for physicians' time (eg, for consultations and treatments). This can be explained by the increasing need for primary health care management of chronic diseases and preventive medicine [3]. The patient's role in the medical decision-making process has also shifted over the past few years. The relationship is changing from one in which patients follow the physicians' orders to one in which decisions are made together, between the physician and the patient, and this consensual decision-making process requires more time than a top-down process. Patients are empowered to change their behavior to achieve better health care results [1,4-6]. Emanuel and Emanuel [5] outline 4 models to describe the increasingly complex patient-physician relationship, which is often characterized by conflicts between health and autonomy and conflicts between differing values held by the physician and patient. The models emphasize differing opinions about the goals of the interaction of physician and patient, of the physician's obligations in the relationship, of the role that the patient's values play, as well as of the level of patient autonomy.

According to the paternalistic model, shared objective criteria exist regarding what is best for the patient's well-being. These criteria are known to the physician and the physician decides which interventions would be appropriate. These interventions might even sometimes be contradictory to the patient's own opinion. The physician has the role of a guardian and provides the patient with little information. Possible scenarios where paternalistic care proves necessary might include, for example, cases involving acute or trauma care when treatment is needed immediately. The second model is the informative model, which assumes that the physician provides relevant factual information about available treatment possibilities to the patient, but it is the patient who selects the medical treatments based on his/her values. The physician then implements the patient's selection of intervention. This model comprises increased involvement and high autonomy of the patient, with the decision making being a shared effort. The physician's role is that of a competent technical expert. The third model is the interpretive model, where the physician's obligation is not only to provide the patient with factual information, but the physician also explains and interprets the patient's values. This model assumes that the patient's values are often not fixed and that they sometimes might even be unknown to the patient. The physician elucidates the patient in understanding the values and informs the patient about possible interventions, but the patient makes the ultimate decision. The physician behaves as an adviser or counselor to the patient. The fourth model is the deliberative model, which assumes that the physician should help the patient to reflect his/her preferences and health-related values before making a decision. The patient's autonomy is high and the patient's values are open to development and revision through moral discussion. The physician's obligation is to articulate and persuade the patient of the most admirable values as well as to inform the patient and implement the patient's selected intervention. The physician's role is characterized as that of a friend or a teacher [5].

The Internet is gaining increasing importance in the patient-physician relationship and is relevant to each of the 4 models. The patient-physician relationship via the Internet can range from simple information provision and searching (eg, the physician puts office hours and addresses on the website and the patient looks them up) to more sufficient interactions (eg, they both exchange documents via email or the patient rates a physician on a physician-rating website) to very complex interactions, such as the substitution of a personal face-to-face meeting in the physician's office by a virtual meeting on the Internet. For instance, advice from a physician to a patient regarding possible medication options via a simple email might be found in the paternalistic or informative model, whereas a more intensive online video meeting might be found in the interpretive or deliberative model. Patients and physicians have to adapt to this new form of health care [7,8].

With regard to Europe, empirical evidence regarding the application of the 4 models developed by Emanuel and Emanuel is scarce. However, the study by Falkum and Førde [9] conducted among physicians in Norway found similar dimensions as those described by Emanuel and Emanuel [5]. Falkum and Førde detected 3 dimensions of the patient-physician relationship: paternalism, patient autonomy, and moral deliberation. Based on a survey conducted with 990 physicians, the results indicated that the physicians' gender, country of graduation, practice type, personal illness experience, or workplace were not statistically significant in association with any of the 3 dimensions, whereas the age of the physicians and their specialty were related to paternalism. All respondents agreed that patient information and patient consent should be the central focus in modern medical treatments. More than 80% of the respondents reported that the patient is a "customer," who should be informed about different treatment alternatives by their physician. Almost half of the physicians stated that the physician is an expert and, therefore, should decide what he/she thinks would be the best for the patient under most medical circumstances. And 40% of the respondents indicated that it is a burden for the doctor most of the time when the patient is

involved in the treatment decision because the patient often lacks relevant medical knowledge. In addition, almost 80% of the respondents agreed the patients should have the right to choose the treatment that matches his or her own values most closely. From this study, it can be argued that the physicians' attitudes toward paternalism, the patients' autonomy, and the moral deliberation is quite ambiguous. The doctor's empathetic understanding of each single patient should be at the very center of the patient-physician communication [9].

Patients' Use of the Internet for Health-Related Information Seeking

The use of the Internet as a source of health information by patients has increased rapidly in many Western societies within the last few years [10,11]. An increasing number of people want to gain a more collaborative view of their own health and use the Internet as an aid to self-diagnosis and self-medication, which leads to the "empowered patient" [2]. In the past, the physician typically held the majority of the information and power and provided the patient with selected information. Now, because patients have access to an enormous quantity of health-related information through the Internet [11], the asymmetry of information in the patient-physician relationship is decreasing. A national survey conducted by the Pew Internet & American Life Project in 2013 showed that 72% of US adults who use the Internet have searched online for health-related information (representing 59% of all US adults). More than one-quarter (28%) base their decision about whether or not to visit a physician on online health-related information. Most US adults (70%) use the Internet primarily to obtain health-related information to inform themselves and/or to change their decision about a treatment for their illness, whereas half of US adults (50%) use the Internet to find answers to specific health-related questions or to get different opinions from other physicians or Internet users. From a demographic point of view, women are more prone to searching for health-related information than men, and younger people use the Internet to obtain health-related information more often than older individuals do. In the United States, Internet users between the ages of 30 and 64 years are the most likely group to consult or post online reviews and rankings of health treatments and services. Furthermore, Internet users with a higher level of education are more likely to consult or post online health-related reviews and rankings in comparison to those with a lower level of education. The same is true for people with a higher annual household income compared to those with a lower annual household income [12].

Online Treatments

Online treatments are gaining popularity with more and more patients using online health care providers for personal health care issues and GPs consulting and advising the patients by telephone, email, videoconferences (eg, Skype), or online [10,13]. The treatments can be differentiated into online treatments offered by the patients' local and personally known GPs, and online treatments offered by unknown GPs associated with an already existing online health care provider (eg, DoctorSpring.com, MeMD, or Teladoc) in countries where the health care system offers this possibility by law. In place of personal face-to-face appointments, patients can be treated online by GPs, which means that a consultation or a treatment can be offered to patients without requiring their physical presence in the physician's office [3,14]. The patients can communicate about nonemergency health care issues online with the GPs from home, work, or any place equipped with Internet access [15]. For face-to-face treatments, the patients only need a computer or mobile device (eg, mobile phone or tablet) with Internet access, a video camera, and a microphone, which are integrated in most modern devices anyway [3,15,16]. If the patients wish to undergo an online treatment with an unknown GP of an online service provider, an account has to be created. Afterwards, data specification is often needed about the patients' health record, lifestyle, family history, as well as information about their usual GP and pharmacy. Payment information should also be determined; in a next step, individual appointments can be made (eg, during the lunch break, late at night after work, or on weekends) to discuss personal health-related issues at the earliest opportunity [14,17-19].

Many different types of online consultation exist, some for acute conditions, such as minor infections, and others for the management of chronic conditions or for consulting with patients with nonurgent acute health care concerns, such as a needed prescription (ie, for colds, flu, allergies, urinary tract infections, or acne), which should be sent to the patient's pharmacy, or for laboratory tests which should be ordered [3,14,20].

In an established online medical treatment, the patient reports his or her symptoms in a standardized way. The GP reviews the symptoms and diagnosis or treatment plans are made. This can include prescriptions for medicines or advice regarding follow-up care [15]. Online treatments might be relevant for each of the 4 models of the physician-patient relationship developed by Emanuel and Emanuel [5]. Communication between the patient and the physician about factual information can be easily conducted via email. For instance, if the physician knows the patient personally and the patient needs medical treatment or advice (eg, needs a prescription for medicine for a chronic disease), information through email communication can be shared. This could be the case in the paternalistic or in the informative model. Or when deciding about different treatment options (eg, different possible therapies), an online video consultation might be used. The online video meeting of physician and patient offers similar possibilities to discuss treatments and options or to reflect on the patient's values and preferences. Interventions can also be discussed and selected jointly in an online video meeting, as would be the case in the interpretive model or in the deliberative model.

Advantages of Online Treatments

From the patients' point of view, online treatments may offer several advantages when requiring an online consultation from a GP, such as no waiting time for an appointment, no waiting time in the doctor's waiting room, and no traveling to the physicians' office, which saves money and time in the long run [3,15,16]. Furthermore, if patients are timid or easily intimidated when communicating face-to-face with their physician, online interactions may make them feel more at ease, given that the interaction is mediated by technology. They may even elect to

remain anonymous. It might well be that patients who undergo online treatments may sometimes be less shamefaced and may talk more openly, which might be especially relevant in the context of personal health care issues that are embarrassing for patients [21-23]. Additionally, many physicians working for online health care providers cooperate with online pharmacies, where the prescribed medicine can be ordered directly and is subsequently sent by post without delay to the patient's private address (eg, DrEd.com) [24]. Another advantage of using an online treatment offered by a GP from an online health care provider is that the patients can contact the GPs 24/7. For physicians, online treatments offer the possibility to optimize their productivity, improve chronic disease management, and control their time schedule better, such as by filling a patient's cancelation with an e-visit or by working more flexibly in the evenings, on the weekends, or from home [7,25-27]. In addition to the already mentioned positive aspects of online treatments, lower costs compared to traditional office settings of GPs are also advantageous [13,20].

Disadvantages of Online Treatments

Despite the clear advantages of online treatments, adverse aspects also exist, including concerns about the quality of online treatments; for example, whether GPs can make a precise diagnosis without seeing the patient face-to-face and performing a medical assessment in form of a real physical examination. Additionally, there are also concerns about appropriate follow-up visits and accurate prescriptions of medication [3,14,28]. Other obstacles regarding online treatments are concerns about the patients' privacy and sensitivity of information. The adoption of online treatments has been slow because of the complexity of effective electronic communication, difficulties in reimbursement, and privacy concerns [15,29]. From the patients' point of view, establishing contact with an unknown GP through a service provider bears the risk of being unable to judge the trustworthiness and expertise of the GP. On the other hand, physicians often fear being inundated with online messages from the patients, which they cannot answer in detail in a timely manner [30,31].

Willingness to Undergo Online Treatments

As far as we know, European studies until now have only examined health-related patient-physician communication and the willingness to undergo an online consultation by email, whereas recently conducted studies in the United States have already investigated patients' willingness to undergo online treatments through video.

In 2007, 7.4% of 1021 Danish respondents of a national survey conducted in 7 European countries (N=7022) reported having contacted a family doctor, specialist, or other health professionals via email or the Internet to request or renew a prescription. In all, 9.9% of respondents reported having scheduled an appointment and 6.7% had asked specific health-related questions via email or the Internet. In comparison, respondents from Portugal indicated no email usage for health communication. In general, Danes reported the highest willingness to undergo an online consultation with their GP (26.2%) [8]. Another survey canvassing 14,000 citizens across 14 European countries in 2011 found that more than a quarter of all participants reported sending or receiving emails from their doctors, nurses, or health care organizations. Statistically significant differences among countries were found; Denmark reported the highest level of sending/receiving emails (50.7%) and participants from France reported the lowest level (18.7%). Respondents from Denmark, Estonia, Italy, and Sweden were more willing to use email for health-related communication in comparison to those from France, Belgium, Slovakia, Slovenia, and the United Kingdom [32]. The high reported level of email communication in Denmark is in accordance with the Danish compulsory primary care services for physicians to offer email contact and online services to their patients [33,34]. Furthermore, more men than women, younger respondents aged between 16 and 24 years, and people with higher education used email for health care communication [32].

According to a December 2014 online survey by The Harris Poll of 2019 US adults aged 18 years and older, almost 64% of respondents were willing to see a doctor online using video. Of those who were willing to consult their doctor over video, 61% listed convenience as the main determinant for their willingness. The survey also showed that 11% of patients aged 18 to 34 years, 8% of patients aged 35 to 44 years, 5% of patients aged 45 to 64 years, and 4% of patients aged 65 years and older would switch to an online visit with a GP, indicating that willingness decreases with age. Furthermore, a majority of the respondents (70%) would prefer to receive a prescription after an online video visit with the physician if medication is necessary [35]. Another survey revealed that only 11% of US households with broadband Internet access prefer an online video consultation with their physician compared to almost 70% who prefer in-person visits conducted at their physician's office. The most likely patient segments to use online health care communication tools have a mean household income of US $50,000 or more, which is approximately the median household income in the United States [36]. According to a report by Parks Associates [37], it is expected that by 2018 more than 65% of US households with an Internet connection will use virtual health care video consultations with a GP.

Willingness to Pay for Online Treatments

According to a 2006 study in the United States by Adler [30], who endeavored to evaluate current patient readiness and willingness to pay for online services, more than three-quarters (n=185) of all interviewed patients with Internet access were willing to pay a small annual fee for online services, including appointment requests, billing inquiries, medication prescription refills, having email contact with their GP, and viewing parts of their medical record. Willingness to pay did not significantly vary by age. Furthermore, the study showed that the most important online services for patients with Internet access (n=248) were conducting email correspondence with their physician (34%), viewing parts of their medical record online (22%), and refilling prescriptions for medication (11%) [30]. In comparison, a more current study from 2013, conducted by the Pew Internet & American Life Project, showed that 26% of US Internet users who have searched online for health-related information have already been asked to pay a certain amount to gain access to health-related information. However, only 2% of those asked to pay actually did so [12]. According to the

results of the previously mentioned study, conducted by American Well, 62% of respondents were of the opinion that online treatments should cost less than in-person visits [35].

Technology Acceptance Model in the Patient-Physician Relationship

The Technology Acceptance Model (TAM) is a model that describes and predicts the acceptance and use of new information technologies and is applied in different contexts of online consumer behavior and online health information [38,39]. According to the model, different attributes influence the users' decisions about their acceptance of the technology. The model comprises 2 central beliefs about a new technology—the perceived usefulness (PU) and the perceived ease-of-use (PEOU)—which influence the behavioral intention to adopt a certain technology [40-46]. By definition, PU is "the degree to which a person believes that using a particular system would improve his/her performance" [47]. The PEOU is defined as "the degree to which a person believes that using a particular system would be free of effort" [47]. In our study, we define PU as "the usefulness of the Internet to gain health-related information" and PEOU as "the perceived ease-of-use of the Internet to gain health-related information" [38].

Although studies have shown that PU and PEOU influence the behavioral intention to use health information technologies (eg, the Internet) positively [48-51], and given the expanding role of the Internet regarding health-related information in the patient-physician relationship, there has been little discussion about what kind of variables may predict willingness to undergo online treatment and willingness to pay additionally for online treatment offered by the GP. Therefore, this study analyzes several variables to predict willingness to undergo online treatment and willingness to pay for online treatment offered by the GP.

This study's purpose is to address the following objectives:

1. Identify sociodemographic and psychosocial variables as well as variables of Internet usage that predict willingness to undergo online treatment.
2. Identify sociodemographic and psychosocial variables as well as variables of Internet usage that predict willingness to pay additionally for online treatment offered by the GP.

Sociodemographic variables include age, gender, highest education level, and monthly household income. Psychosocial variables contain the constructs of health-related information–seeking personality, social motive, and trust in the GP. Variables of Internet usage refers to a set of variables, which are termed as actual use of online communication with the GP, perceived usefulness of the Internet for health-related information (PU), willingness to communicate online with the GP more often in the future, and willingness to undergo online treatment offered by the GP.

Methods

Participant Recruitment

An online survey of 1006 randomly selected German patients was conducted in September 2012. The sample was drawn from an e-panel maintained by GfK HealthCare (Gesellschaft für Konsumforschung), a leading survey research company in Nuremberg, Germany. The term "patients" in this study refers to individuals who have visited a physician at least once in the previous 3 months before the beginning of the study. In total, 20 respondents were excluded from the analysis because of inconsistent answer patterns (eg, flatliners or contradictions) or an extremely short answer time. Another 28 participants were excluded from the study because their number of missing values exceeded the limit of 30% [52]. Missing values were imputed with SPSS version 22 (IBM Corporation, Armonk, NY, USA). In total, 958 usable questionnaires were analyzed by using 2 multiple regression models. Small amounts of money were offered as incentives to participate in the survey and fill out the questionnaire.

Questionnaire

The questionnaire was designed by the researchers based on the existing literature. Originally, the online questionnaire was in German. Available scales from the literature were used where applicable. The literature used for the scales is quoted in square brackets within the text as well as in Multimedia Appendix 1, where an excerpt of the questionnaire can be perused. Items for which no literature are quoted were developed by the researchers. All items were measured by 7-point rating scales, except the categorical variables. As an alternative, all items had a "no answer" category. The denotation of the items (D1 to D8, F11_1 to F34) in parentheses refers to Multimedia Appendix 1.

Measurement of Sociodemographic Variables

Age (D2_1) was measured by asking the patient's year of birth. Gender (D1) was measured by single items (1=male, 2=female). The highest education level was measured through the inquiry about the participant's highest completed level of education (D4). An indication of the monthly household income was also requested (D8).

Measurement of Psychosocial Variables

Health-Related Information–Seeking Personality

Health-related information-seeking personality refers to the phenomenon that some patients have a higher need for cognition and information than others when making decisions as a patient. The need for cognition is a tendency of engagement as well as enjoyment in cognitive efforts, which means that people with a high need for cognition are more willing to engage in information-seeking activities in comparison to people with a lower need for cognition, who are less willing to do so. Furthermore, people who are more prone to seeking information are more likely to evaluate the information thoroughly, use more information sources, and rely more on the information [53,54]. Hence, patients with high levels of health-related information-seeking personality tend to inform themselves extensively when visiting a physician by searching for health-related information [55]. The health-related information-seeking personality scale (F20) consists of 9 items, developed by the researchers, partially adapted from the health information orientation scale derived by Dutta-Bergman [56] as well as by Simon et al [57] and Wilson and Lankton [58].

Social Motive

Patients' motives for using the Internet for health-related information searches were measured based on 18 items partly derived from literature; some items were added by the researchers. The possibility to access different Web portals (eg, social networks, podcasts, or health forums) (F11_9) [7,59,60], the social component of establishing contact with someone easily (F11_11) [7,61], the need to be up-to-date (F11_12) [7], the preference for gathering information anonymously (F11_13) [7,60], and the possibility of sharing knowledge with others (F11_15) [7] were measured by multi-item scales. Items measuring fun (F11_17) and entertainment (F11_18) were adapted from Shih [62], Davis et al [63], and Venkatesh et al [44,64].

Trust in the General Practitioner

The respondents' trust in their GP (F34) was examined by asking the following question: "How much do you trust your GP?" (1=no trust at all, 7=very high trust).

Measurement of Variables of Internet Usage

Actual Use of Online Communication With the General Practitioner

To assess the respondents' actual use of online communication with their GP (F13), respondents were asked to indicate how often they use the Internet to communicate with their GP. The answer scale ranged from daily, weekly, less frequently than once per week, monthly, less frequently than once per month, to never. The item was measured on a 6-point ordinal scale, reverse-coded, with a lower frequency revealing a higher score of actual use. This item was recoded for analyses for better readability.

Perceived Usefulness of the Internet for Health-Related Information

Perceived usefulness of the Internet to gain health-related information (F11_1 to F11_5, F11_14) was measured by existing multi-item scales partly derived and adapted from Venkatesh and Davis [40,44,47] as well as from other relevant literature [7,45,59,60].

Willingness to Communicate Online With the General Practitioner More Often in the Future

The willingness to communicate online with the GP more often in the future (F15) was measured by asking the respondents the following question: "Can you imagine using the Internet more often in the future for communication with your GP?" (1=highly unlikely, 7=very likely).

Measurement of Willingness to Undergo Online Treatment Offered by the General Practitioner

To measure the willingness to undergo an online treatment offered by the GP (F18), respondents were asked to indicate the importance of being able to undergo online treatment by the GP (1=not important at all, 7=very important).

Measurement of Willingness to Pay Additionally for Online Treatment Offered by the General Practitioner

Willingness to pay additionally for an online treatment offered by the GP was measured by asking the following question: "Indicate how willing you would be to pay a certain amount additionally for online treatment." Participants could indicate their agreement on a scale ranging from 1 ("I would not be willing at all") to 7 ("I would be willing") (F19).

Results

Sample Characteristics

In total, 54.0% (517/958) of the participants were male and 46.0% (441/958) were female. The mean age was 43.73 (SD 13.00) years and 57.0% (546/958) of the respondents had a higher level of education (high school diploma or higher).

Regarding the variable gender, the data for this sample represent the German online population quite well compared to German Internet users in 2012 [65] (Table 1). With reference to the variable age, participants in our study were slightly older than the German Internet population. However, participants in our study had a minimum age of 18 years and the minimum age in the dataset used by the German Internet users was 10 years. With regard to the variable education, participants in our study were more highly educated than the German online population [65]. No comparable data could be found referring to the variable monthly household net income because the Federal Statistical Office (Statistisches Bundesamt) does not provide this information in their German Internet population dataset.

Table 1. Sociodemographic data of the sample in comparison with the German Internet population (2012).

Variable and categories	Total N=958	German Internet users[a] N=58,556,000
Gender, n (%)		
Male	517 (54.0)	29,553,000 (51.81)
Female	441 (46.0)	27,492,000 (48.20)
Age (years; range 18-70 years), mean (SD)	43.73 (13.0)	>10
Age categories (years), n (%)		
<44 years	471 (49.2)	32,896,000 (57.60)
45-70 years	487 (50.8)	24,147,000 (42.34)
Education, n (%) [b]		52,589,000[b]
Without school qualification	4 (0.4)	
Secondary general school	13 (1.4)	9,487,000 (18.04)[c]
Polytechnic secondary school	120 (12.5)	
Intermediate secondary school	269 (28.1)	29,467,000 (56.03)[d]
Matura examination or higher	545 (57.0)	13,635,000 (25.93)[e]
Monthly household net income (€), n (%)	347 (100)	
<1500	77 (22.2)	
1500-2500	97 (28.0)	
2501-3500	94 (27.1)	
3501-4500	53 (15.3)	
>4500	26 (7.5)	

[a] Rounded to 1000 people. Projected number of Germans who used the Internet in the last 3 months. Age limit for questions concerning education and occupation: 16 years.

[b] For the German Internet users, low education corresponded with levels 0, 1, and 2 of the ISCED classification system (up to secondary general school), medium education corresponded with levels 3 and 4 of the ISCED classification system (up to university entrance qualification), and high education corresponded with levels 5 and 6 of the ISCED classification system (higher than matura examination respectively university entrance qualification).

[c] Low education.

[d] Medium education.

[e] High education.

Exploratory Factor Analyses

The facets of patients' personalities to engage in information-searching behavior on the Internet (9 items) were analyzed by an exploratory factor analysis (EFA) leading to a single-factor solution explaining 52.64% of variance, reflecting the personal tendency of information-searching behavior on the Internet. The factor was labeled "health-related information–seeking personality" and the factor scores were saved and used for the multiple regressions. The second EFA was executed with the variables measuring the motives for Internet usage (18 items), leading to 2 separate factors: PU of the Internet for health-related information searching and social motives for information searching on the Internet, explaining 63.74% of variance. Items with loadings below 0.45 or with loadings on both of the factors were eliminated. The construct of PEOU did not turn out to be a distinct factor according to the EFA for the remaining motivational items. Thus, in reference to the Eigenwert criterion, only 2 factor scores (PU and social motive) reflecting the contents of the remaining motivational items were saved for each respondent as variables for the following multiple regressions.

Multiple Regression Analyses

Before performing the multiple regression analyses, we calculated the means and standard deviations of the dependent variables "willingness to undergo online treatment offered by the GP" and "willingness to pay additionally for online treatment offered by the GP" to estimate the overall willingness to undergo online treatments and pay for them. The frequency distribution of the 2 dependent variables is shown in Multimedia Appendix 2. The mean of the variable "willingness to undergo online treatment offered by the GP" was 3.60 (SD 2.02) on a 7-point scale; hence, it was slightly below the midpoint of the scale. By adding the percentages of those who marked the highest and lowest 2 points of the willingness to undergo online treatment answer scale, we found out that 19.9% (191/958) of the respondents indicated a high willingness to undergo online treatment in comparison to 36.5% (350/958) who reported a low willingness. The mean of the variable "willingness to pay

additionally for online treatment offered by the GP" was a low 2.30 (SD 1.81) on a 7-point scale. Among those who marked one of the 2 highest points of the willingness to pay additionally answer scale, less than 10% (8.7%, 83/958) were willing to pay for an online treatment additionally.

Multiple Regression Analysis to Predict Willingness to Undergo Online Treatment Offered by the General Practitioner

Sociodemographic variables did not serve as significant predictors for willingness to undergo online treatment offered by the GP, but health-related information–seeking personality, social motive, existing experience with online communication with the GP, and willingness to undertake online communication with the GP significantly affected willingness to undergo online treatment offered by the GP. In terms of sociodemographic variables, the wealthier and more highly educated people were more willing to pay additionally for online treatment. Existing experience with online communication with a GP, willingness to undertake online communication with a GP, and willingness to undergo online treatment also significantly affected willingness to pay additionally for online treatment. The details of the multiple regression were gender, age, monthly household net income, and trust in the GP did not serve as significant predictors for willingness to undergo online treatment offered by the GP. PU had a positive influence on willingness to undergo online treatment offered by the GP (B=.092, *P*=.08), but the impact did not meet statistical significance. Furthermore, willingness to undergo online treatment offered by the GP could be predicted by the following variables on a 5% significance level, arranged in descending order: willingness to communicate online with the GP more often in the future (B=.495, *P*<.001), health-related information–seeking personality (B=.369, *P*<.001), actual use of online communication with the GP (B=.198, *P*<.001), and social motive (B=.178, *P*=.002). The adjusted R^2 was .546 ($F_{10,765}$=94.191, *P*<.001), indicating that the dependent variable was explained quite well through the explanatory variables in the regression (Table 2).

Table 2. Explanatory variables to predict willingness to undergo online treatment offered by the GP.

Explanatory variables	B	*P*
Intercept	2.697	<.001
Sociodemographic variables		
Gender	.025	.81
Age	.004	.28
Education	-.013	.78
Monthly household net income	.008	.85
Psychosocial variables		
Health-related information–seeking personality (factor score EFA1)	.369	<.001
Social motive (factor score EFA2)	.178	.002
Trust in the GP	-.061	.16
Internet usage		
Actual use of online communication with the GP	.198	<.001
Perceived usefulness of the Internet for health-related information (PU) (factor score EFA2)	.092	.08
Willingness to communicate online with the GP more often in the future	.495	<.001

Multiple Regression Analysis to Predict Willingness to Pay Additionally for Online Treatment Offered by the General Practitioner

A second multiple regression was calculated with the same predictors as described previously and additionally with the variable "willingness to undergo online treatment offered by the GP" for the dependent variable "willingness to pay additionally for online treatment offered by the GP" (Table 3). With respect to sociodemographic variables, the wealthier and more highly educated people were more willing to pay additionally for online treatment. Existing experience with online communication with the GP, willingness to undertake online communication with the GP, and willingness to undergo online treatment also significantly affected willingness to pay additionally for online treatment offered by the GP. The details of this multiple regression analysis were gender, age, trust in the GP, and social motive did not serve as significant predictors. Health-related information–seeking personality (B=.127, *P*=.07) and PU (B=–.098, *P*=.09) both had a significant impact on willingness to pay additionally for online treatment offered by the GP, but these impacts did not meet statistical significance. The variables willingness to undergo online treatment offered by the GP (B=.391, *P*<.001), actual use of online communication with the GP (B=.192, *P*=.001), highest education level (B=.178, *P*<.001), monthly household net income category (B=.115, *P*=.01), and the willingness to communicate with the GP more often in the future (B=.076, *P*=.03) were significant predictors on a 5% level. The resulting adjusted R^2 was .361 ($F_{11,764}$=39.308, *P*<.001).

Table 3. Explanatory variables to predict willingness to pay additionally for online treatment offered by GP.

Explanatory variables	B	*P*
Intercept	2.298	.62
Sociodemographic variables		
Gender	–.013	.91
Age	.001	.91
Education	.178	<.001
Monthly household net income	.115	.01
Psychosocial variables		
Health-related information–seeking personality (factor score EFA1)	.127	.07
Social motive (factor score EFA2)	.066	.30
Trust in the GP	.032	.51
Internet usage		
Actual use of online communication with the GP	.192	.001
Perceived usefulness of the Internet for health-related information (PU) (factor score EFA2)	–.098	.09
Willingness to communicate online with the GP more often in the future	.076	.03
Willingness to undergo online treatment offered by the GP	.391	<.001

Discussion

Principal Findings

The sociodemographic variables age and gender and the psychosocial variable trust in the GP did not serve as significant predictors for either the willingness to undergo online treatment or the willingness to pay additionally for online treatment. Younger people were described as being more prone to switching to an online visit with a GP in another study [35], but the nonsignificant influence of age in our study deserves further consideration. One reason might be that participants in our study were selected via an online panel, so that participants (younger and older) in our sample are probably more open to online-related issues than the general public. Gender was not significant either. Hence, males and females did not differ in their general willingness to undergo online treatments and in their willingness to pay additionally for online treatments. More detailed analyses of other aspects of the online patient-physician relationship (eg, online correspondence, appointments) may allow additional insights into possible gender differences (eg, see Bidmon and Terlutter [66]). Trust in the GP also failed to be a significant predictor. This may be because patients do not perceive any differences in having to communicate with their GP face-to-face or online as long as they can contact their own GP, in whom they place their trust. Trust might play a more important role if online consultations are analyzed in which patient and physicians are less well-acquainted with each other (eg, if the patient contacts an unfamiliar online health care provider for advice). Other important findings of this study are that willingness to undergo online treatment is partly determined by the level of existing experience, willingness to communicate online with the GP, and health information-seeking personality and social motivation for such behavior. These findings are in line with Roger's diffusion of innovation theory. This theory explains how and why new ideas and technologies are spread through different cultures. According to our results, early adopters are willing to undergo online treatments offered by the GP and pay for online treatment. Early adopters are characterized by a high social status and are more socially forward than late adopters, and they are characterized by higher available financial resources and a higher level of education. Early adopters are also opinion leaders for the other adopter categories, which implies that they may spread their opinion about and experiences with online treatments among others [67]. Furthermore, as mentioned previously, some patients inform themselves more extensively before visiting a physician and are more involved in the patient-physician interaction compared to others who do this to a lesser extent [53,55], which is in line with the interpretive and deliberative models of Emanuel and Emanuel [5]. This may imply that those people who are more involved in the patient-physician interaction (eg, the physician is responsible for explaining and interpreting the patient's values, informing the patient, and implementing the patient's selected interventions; the physician helps to reflect the patient's preferences and values before making a decision) [5], have a higher need for information searching and are also more prone to looking online for health-related information, which can also satisfy their need for PU. Ascribing higher PU, which regards the Internet as a source for gaining health-related information easily, might lead to a higher adoption of undergoing an online treatment and paying extra for the online consultation [38]. Patients who already communicate with their GP online (eg, through email) might be more willing to undergo an online treatment and are more prone to pay for it [30]. Furthermore, it can be accentuated that people with a higher social motive (eg, people who use the Internet in order to be up-to-date, to establish contact with someone easily, to gather information anonymously, and/or people who like to share their knowledge with others) are more willing to try new technologies

and new techniques, and are more willing to replace a face-to-face treatment with an online consultation.

The frequency distribution (see Multimedia Appendix 2) clearly shows that respondents are not willing to pay additionally for this service. Instead, they may even expect online treatments to be available at a lower price (ie, to be less expensive) [13,35]. The factor willingness to pay extra for online treatment is influenced additionally by the monthly household net income category and education level, which can be explained by the fact that more highly educated people usually have a higher monthly net income (ie, earn more) and may be more willing to pay for an online treatment.

Limitations

There are some limitations within this study. The study was based on a patient online panel sample. Therefore, only patients with Internet access who visited a GP within the last 3 months before the survey were able to participate in the survey. As a consequence, participants of the survey may be more familiar with online health-related issues and are, therefore, more willing to undergo and pay for online treatments compared to patients without Internet access. However, the research question is especially relevant to those patients with some Internet affinity.

Furthermore, there are different legal backgrounds and restrictions in different European countries. For instance, online medical treatments offered by German physicians are not legally allowed at present [68,69]. Similar restricted regulations are found in Austria [70-73]. In other European countries, such as Switzerland or Great Britain, online medical treatments are already permitted and more established [24,74-76]. For this reason, we classify our study as exploratory in nature.

Practical Implications and Directions of Future Research

In general, patients only show a medium willingness to undergo online treatments with a GP. However, 19.9% in our study indicated a very high willingness to undergo an online treatment, whereas another third (36.5%) clearly rejected the idea. These results of our study could be useful for the patients' GPs and for online health care providers. GPs could offer online treatments to reduce waiting hours, to acquire new segments of patients, and to work in a manner that is more time-flexible; there is a viable portion of patients who would clearly appreciate such offers. Furthermore, GPs could offer predetermined time slots for in-person and online treatments and patients could be segmented according to their willingness to undergo an online treatment. This could be advantageous, especially for GPs who offer on-call services and have to be time-flexible and geographically independent. In a next step, the legal restrictions should be clarified and remuneration models should be discussed. Additionally, considerations must follow for which realms of physician-patient relationships are suitable for online treatments and which are not.

Furthermore, the results of this study could be useful for physicians who are considering offering online treatments for specified patient segments (eg, women or men, people with special chronic diseases, or employed people). If physicians know sociodemographic and psychosocial details about their patients who are willing to undergo online treatments, specific and time-flexible treatments may be tailored more easily. According to some surveys (eg, American Well [35]), younger people aged between 18 and 34 years, who may be more Internet literate and have a higher social motive, are more willing to undergo an online treatment. This may indicate that physicians should incorporate online treatments more into their practice and promote it through different online media channels (eg, social media channels such as Facebook or Twitter or on online physician-rating websites). In addition, online treatments should be affordable and are expected to cost less than personal face-to-face treatments.

The reputation of the GP associated with an online health care provider (eg, DoctorSpring.com [17]) might also have a significant influence on patient's trust and on the patient's willingness to use an online consultation with a physician whom the patient has not previously seen. Patients wish to select their physician on their own and want to know which medical school the GP has attended, their specialties, and their certifications. People will be more satisfied with an online treatment if they can see a picture of the physician, have the possibility to review the physician's credentials, and can verify their board certification [35]. Therefore, to increase the patient's trust in their physicians, GPs should satisfactorily show which school and additional educational programs they have attended by publishing verified certificates on the website. Moreover, physicians should offer patients the option to leave a review and/or a rating after an online consultation. One of the most important factors to ensure compliance is empathetic communication with the patient, while demonstrating competence [11]. Further studies should analyze the impact of online treatments on the information asymmetry between physicians and doctors, concordance, and compliance. Based on this study, results may also be useful for the improvement of online treatments by tailoring the websites of online health care providers to more accurately reflect the needs and requirements of the patients. The usability, accessibility, and design (eg, convenient handling, clear design, and easy access without an inconvenient log-in process) of the website [39,77,78] should match the patients' needs to enhance the willingness to undergo an online treatment in the future. Furthermore, detailed information about the offered online treatments (eg, information about the different kinds of treatments, costs, and how to arrange an appointment) should be revealed on the website. When talking about the websites of online health care providers, the privacy of the patients should always be protected and this should be imparted in such a way that the users feel secure and enjoy undergoing an online treatment without fearing a lack of privacy. Although the legal and ethical aspects for offering and using online treatments are almost unknown in the public opinion, it would be interesting to ascertain how legal regulations influence the willingness to undergo online treatments and the willingness to pay additionally for online treatments. Future research should consider these important aspects. Other possible future research questions which arise based on the results of this study are if there are any differences between patients who are willing to undergo an online treatment and patients who are willing to pay for it, how the willingness to engage in online treatments can

be influenced to match the requirements of the patients, or how the willingness to pay additionally for online treatments offered by the GP can be influenced to match the requirements of the patients. Other research topics could include issues such as which tariff model is appropriate for policymakers and what are the likely social and Internet usage factors that might shift the balance in favor of the willingness to undergo and pay for online treatments, how the requirements of patients who are not willing to undergo an online treatment and are not willing to pay for it could be matched, or how communication concepts appeal to patients. Last but not least, patients' willingness to undergo online treatment and GPs' willingness to offer online treatment may be conceptualized as a kind of concordance [79-82], referring to the usage of the Internet in the patient-physician relationship. This perceived concordance may lead to higher patient compliance and higher patient satisfaction similar to the results of studies dealing with age or gender concordance [80,83,84].

Conclusion

Online treatments offer many opportunities for the health care sector and the future patient-physician relationship. Online treatments will certainly not replace face-to face treatments for acute or severe illnesses, for which a confirmed diagnosis is always mandatory, in the near future. As our study has demonstrated, willingness to undergo online treatment is limited and older people or people with complex health problems will probably avoid online treatments and prefer a face-to-face appointment with their GP [85,86]. There are also concerns regarding danger for those patients who use the Internet to search for health-related information (eg, misdiagnosis and exploitation) [87,88]. Online treatments will probably only be used by patients with common health issues (eg, headaches, sore throats, coughs, or chronic diseases) [85]. Telediagnosis using a combination of traditional face-to-face treatment and online treatment is on the rise [2] and will represent a strong future trend, which has already commenced now. Nevertheless, the physicians' quality in the patient-physician relationship will remain the most important element, independent of the medium of communication [11].

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questions and justification of items (original language and translation for the paper).

[PDF File (Adobe PDF File), 437KB - jmir_v18i2e32_app1.pdf]

Multimedia Appendix 2

Frequency distribution of willingness to undergo online treatment offered by the GP and willingness to pay additionally for online treatment offered by the GP.

[PDF File (Adobe PDF File), 166KB - jmir_v18i2e32_app2.pdf]

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Abbreviations

EFA: exploratory factor analysis
GfK: Gesellschaft für Konsumforschung
GP: general practitioner
PEOU: perceived ease-of-use
PU: perceived usefulness

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